

To: Congressman Earl Blumenauer, Congressman Jason Smith, Congresswoman Cathy McMorris Rodgers, and Congressman Tony Cardenas
Cc: Kristen Donheffner, Andrew Gradison, Megan Perez, Jacqueline Usyk, Nick Uehlecke, Melanie Egorin, J.P. Paluskiewicz, and Tiffany Guarascio
From: American Society of Nephrology
Re: Recommendations regarding the Dialysis PATIENTS Demonstration Act
Date: May 23, 2017

On behalf of the American Society of Nephrology, thank you for your commitment to improving the lives of the hundreds of thousands of Americans with End-Stage Renal Disease (ESRD). ASN represents nearly 17,000 physicians, scientists, nurses, and other health professionals dedicated to improving the lives of people with kidney diseases through treatment and research, including approximately 90 percent of the nephrologists in the United States. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. Foremost among the society's concerns is the preservation of equitable patient access to optimal quality care for chronic kidney disease (CKD) and ESRD and the integrity of the patient-physician relationship.

The society commends you for your dedication to improving the lives of the millions of Americans affected by kidney diseases, and we thank you for your engagement with the kidney community to identify and refine policies to improve their lives. We appreciated the opportunity to provide input and suggestions for improvement related to the Dialysis PATIENTS Demonstration Act (DPDA) during the stakeholder meeting in March 2017, and in comments at this time, prior to its reintroduction in the 115th United States Congress.

In this memorandum, ASN offers 19 specific recommendations we believe will strengthen the proposed legislation in order ensure this demonstration project will achieve the goals of delivering better outcomes and experiences of care for patients, at lower cost. We also include for your consideration some general comments regarding opportunities to improve care.

ASN believes that optimal care for people with kidney diseases needs a nephrologist-led team that cares for patients with CKD across transitions such as dialysis initiation and transplantation, and provides comprehensive integrated care. Many of these transitions are seminal, life-changing events for patients and their families. Ensuring that patients who have a longstanding relationship with their nephrologist can maintain that trusted bond and continuity of care, whether in an open or preferred network, is of paramount importance. The society greatly appreciates your interest in hearing from us and other stakeholders about the role of the nephrologist in this program. Several of our recommendations below address that interest, focusing on maintaining the integrity of the patient-nephrologist relationship throughout the course of the patient's disease.

ASN also believes that incentives should be aligned across transitions of care, particularly the transition from dialysis to transplantation, as well as across providers (such as transplant centers and dialysis providers). Ideally, a new kidney care delivery model would distinguish itself from the ESRD Seamless Care Organization (ESCO) program by fully encompassing all ESRD patients, including those who have received a kidney transplant. However, we understand that

ASN Recommendations: Dialysis PATIENTS Demonstration Act

this is a dialysis-focused model and have included several strategies to strengthen the transitions of care surrounding transplantation and limit potential disincentives in its structure.

The society strongly supports the transition of health care delivery towards value-based care, including the enactment of the Medicare Access and CHIP Reauthorization Act of 2015. Reflecting ASN's support for shifting from payment for volume to payment for value based on quality of care, the society believes that DPDA should include a clear link between payment and outcomes. We appreciate that the version of this bill in the 114th United States Congress applied the same criteria for expansion of the Program as was applied to Accountable Care Organizations (increased quality at no increased cost or reduced cost with no changes in quality), but we believe that success throughout the course of the demonstration project should be quantified by performance on meaningful quality measures that *are* linked to payment. Tying payment to quality measures that are evidence-based, reliable, and valid would also bring this program into alignment with other Advanced Alternative Payment Models.

Lastly, we note that the legislation as currently written does not define what an Organization "is" in terms of structure or scope, and we would request that the bill be updated to provide details along these lines.

Summary of recommendations

A. *Role of the Nephrologist and Supporting the Patient-Physician Relationship*

1. Formalizing the role of nephrologists and patients in the Organization's governance
2. Clarifying the ability to maintain patient-physician relationships in units owned by Organizations
3. Clarifying payment rates for nephrologists and other health professionals
4. Establishing a mechanism for patients to determine physicians' participation status in open or preferred networks

B. *Transplantation and Other Patient Services*

5. Clarifying the eligibility of individuals who have a failed kidney transplant and return to dialysis are eligible to participate in the program.
6. Excluding kidney acquisition costs from an Organization's capitated payments and assigning coverage for kidney acquisition costs to Medicare Fee-for-Service
7. Developing quality metrics on beneficiary education related to transplantation
8. Adding a study regarding a payment adjustor regarding transplant evaluations
9. Improving transitions for pediatric patients into adult care
10. Providing access to palliative care services
11. Clarifying benefits (including education) for transition into hospice care

C. *Program Design and Operation*

12. Removing the term "medical home"
13. Expanding the Secretary's discretion in setting quality measures for the demonstration
14. Ensuring patients can opt for the open network during the annual open enrollment
15. Removing specifications regarding timeline for implementation and strengthening stakeholder engagement in development of the demonstration program
16. Clarifying patient eligibility
17. Remaining consistent with the concept of a demonstration project
18. Adding a study to examine the effect of the program on the dialysis marketplace and patient care options prior to program expansion
19. Linking payment to performance on quality metrics

A. Specific recommendations: Role of the Nephrologist and Supporting the Patient-Physician Relationship

1. Formalizing the role of nephrologists and patients in the Organization's governance
Page 19, lines 17-25 and Page 20, lines 1-10: Regarding required elements of the ESRD Integrated Care Strategy in order for the Secretary to approve.

Original text: “The Secretary may not approve an ESRD Integrated Care Strategy of an Organization unless under such Strategy the Organization— (I) provides services to Program-eligible beneficiaries enrolled in the Organization through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services pursuant to regulations; and (II) specifies the covered items and services that will not be provided directly by the Organization, and to arrange for delivery of those items and services through contracts meeting the requirements of regulations.”

Comment 1: In order to clarify the structure and management of participating Organizations, and to guarantee the influence of nephrologist and patients, we recommend that description of a governing body be included as a required element of the ESRD Integrated Care Strategy.

Revised text: Insert at Page 20, line 10: “(III) establishes a governing body that consists of representation from each eligible participating provider, as defined in subsection (a)(2)(A), includes at least one nephrologist who may be affiliated with a participating provider in the preferred network, at least one nephrologist in the open network, and includes at least one beneficiary advocate. The governing body shall have responsibility for the oversight of the Organization in its activities described herein.”

2. Clarifying the ability to maintain patient-physician relationships in units owned by Organizations.

Comment 1: We would request clarification that nephrologists who are not part of preferred networks will still be able to see patients in units owned by Organizations, maintaining continuity of the patient-physician relationship. This clarification would prevent introducing conflict between plan benefits and longstanding pre-existing patient-physician relationships. Ensuring a continuous relationship with a nephrologist, regardless of whether he or she is in the open or preferred network, would also prevent the inadvertent creation of siloes by stages of kidney disease, such that advanced kidney disease, ESRD, and transplant may be treated as continuous phases of disease along a continuum by the same nephrologist or group of nephrologists.

Revised text: Page 14 line 11 add a new “(v)”: “(v) Promoting access to nephrologists – An Organization offering an ESRD Integrated Care Model shall permit qualified nephrologists who are both participating in the Organization (preferred network) and not participating in the Organization (open network) to treat program-eligible beneficiaries in dialysis units owned by the Organization.

We believe report language clarifying this intent would be an acceptable alternative as well.

3. Clarifying payment rates for nephrologists and other health professionals, and patient co-payment responsibility

Page 11, line 13

Comment 1: Nephrologists and other health professionals who are treating patients who are enrolled in the Organization should have (at least) parity between their payments and the payments that they would have received under the Part B physician fee schedule had their patients not enrolled in the Organization. We recognize that physicians who join the preferred network may in fact receive greater payments than in Part B, but request a floor of at least the Part B payment. For nephrologists and other health professionals who are not part of the preferred network, we recommend that they continue to receive Medicare Part B physician fee schedule rates.

Revised text: Page 11, line 13: add “subject to subclause (III)” “(II) **subject to subclause (III)**, shall provide for payment for items and services furnished by providers of services and suppliers within such network to Program-eligible beneficiaries enrolled in such Organization in accordance with payment rates determined pursuant to an agreement entered into between the Organization and such providers of services and suppliers”

“(III) shall, in the case of an Organization that pursuant to an agreement described in subclause (II) reimburses providers and suppliers according to the Medicare fee-schedules under Part A and Part B, establish payment rates not less than the amount the provider or supplier would otherwise receive under this title”

4. Establishing a mechanism for patients to determine physicians’ participation status in open or preferred networks

Page 21, line 6 (4): Beneficiary Protections

Comment 1: Creating a way for patients to determine which physicians and other health professionals are participating in the open or preferred networks before making enrollment decisions would help patients select the network that best suits their care needs.

Revised text: Insert on page 32, line 22 “(iv)”: (iv): develop a mechanism for patients to determine the participation status of physicians and other health care providers in the open and preferred networks prior to patient selection of a network.

B. Specific recommendations: Transplantation and Other Patient Services

5. Clarifying the eligibility of individuals who do not currently have a functioning kidney transplant

Page 4, lines 14-24: *Regarding the exclusion of individuals who have received a successful kidney transplant.*

Original Text: “(ii) is identified by the Secretary or the Organization as receiving renal dialysis services under the original Medicare fee-for-service program under parts A and B; “(iii) resides in the service area of such Organization; “(iv) receives renal dialysis services primarily from a facility that participates in such Organization; and “(v) has not received a successful kidney transplant.

Comment 1: We recommend clarifying that people who have received a successful transplant but who eventually return to dialysis for some reason are eligible for the program.

Revised Text: Page 4, line 23-24: “(v) does not currently have a functioning kidney transplant.”

6. Excluding kidney acquisition costs from an Organization’s capitated payments and assigning coverage for kidney acquisition costs to Medicare Fee-for-Service
Page 34, lines 9-14: Payment by the Secretary to Organizations.

Original text: “(1) IN GENERAL.—For each Program-eligible beneficiary receiving care through an Organization, the Secretary shall make a monthly capitated payment in accordance with payment rates that would be determined under section 1853(a)(1)(H), as adjusted pursuant to paragraph (2).”

Comment 1: Paragraph (1) requires the Secretary to make a monthly capitated payment to Organizations that is risk-adjusted pursuant to paragraph (2), and made under the same manner as described in section 1853(a)(1)(H) of the Social Security Act. The suggested revision below would further adjust the monthly capitated payment by excluding kidney acquisition costs from the Fee-for-Service (FFS) benchmarks used to set capitation rates. Kidney acquisition costs would instead be paid through Medicare FFS directly. These revisions mirror the Medicare Advantage ESRD reforms included in Section 17006 of the *21st Century Cures Act* (Public Law 114-255) and were included to avoid disincentives for kidney transplantation evaluation-

Revised text: “For each Program-eligible beneficiary receiving care through an Organization, the Secretary shall make a monthly capitated payment in accordance with payment rates that would be determined under section 1853(a)(1)(H), as adjusted pursuant to paragraph (2) and paragraph (3).”

Revised text: Insert at Page 34, after line 20: “(3) TREATMENT OF KIDNEY ACQUISITION COSTS.— (A) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS FROM MA BENCHMARK.—The Secretary shall adjust the payment amount 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 for the year. (B) FFS COVERAGE OF KIDNEY ACQUISITIONS.— An Organization shall provide all benefits described in subclause (I) of subsection (b)(2)(A)(i), except for kidney acquisition costs. Payment for kidney acquisition costs covered under this title furnished to such Program-eligible beneficiary shall be made in accordance with this title and in such amounts as would otherwise be determined for such items and services provided to such a beneficiary not enrolled under the Program.”

Conforming revisions: Starting on Page 34, line 21 and ending on Page 35, line 16: Update paragraph numbers to reflect the newly inserted paragraph (3).

7. Developing quality metrics on beneficiary education related to transplantation
Pages 14 and 15 Quality and Reporting Requirements

Comment 1: We recommend adding a provision that would require the Secretary to develop quality metrics on beneficiary education related to transplantation. In developing the quality metrics, the Secretary would receive input from stakeholders.

Revised Text: Page 15, line 8: “(IV) Quality Metrics related to Transplantation – To ensure that dialysis patients in the integrated care model have equitable access to transplantation education and referral, in developing quality metrics under subclauses (II) and (III) of clause (i) the Secretary, with input from the stakeholder board as described under clause (ii), shall develop quality metrics on the provision of beneficiary education related to transplantation.”

8. Adding a study regarding a payment adjustor for transplant evaluations

Page 28, line 3 *Regarding program expansion*

Comment 1: In order to protect against financial disincentives for organizations to refer patients for transplant evaluations and to facilitate kidney transplantation among potential kidney transplant candidates, a study assessing a payment adjustor to ensure there are no disincentives should be conducted.

Revised text: Add a new (7): “(7) The Secretary shall conduct a study on an appropriate payment adjustor to ensure there are not disincentives in a capped reimbursement model from providing proper transplant evaluations.”

9. Improving transitions for pediatric patients into adult care.

Page 4, line 13: Program eligible beneficiaries are defined as being “18 years of age or older”

Page 19, line 17: *Regarding elements the Secretary must consider when assessing an organizations ESRD Integrated Care Strategy.*

Comment 1: In order to support the successful transition of pediatric and young adult patients into care provided at adult facilities participating in the demonstration, we recommend the inclusion of an additional element to be considered in the ESRD Integrated Care Strategy.

Revised text: Insert at Page 19, line 17: “(XVI) Defined protocols to facilitate the transition of pediatric patients into adult ESRD care allowing patients to opt in at the discretion of the patient, their caregivers, and their pediatric nephrologist.”

10. Providing access to palliative care services

Page 16, lines 13-18 and Page 17, lines 20-21: *Regarding required elements of the ESRD Integrated Care Strategy in order for the Secretary to approve.*

Original text: “The Secretary may not approve an ESRD Integrated Care Strategy of an Organization unless under such Strategy the Organization— (I) provides services to Program-eligible beneficiaries enrolled in the Organization through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services pursuant to regulations; and (II) specifies the covered items and services that will not be provided directly by the Organization, and to arrange for delivery of those items and services through contracts meeting the requirements of regulations.”

Comment 1: Palliative care encompasses care provided through the life cycle treatment to improve the quality of life of those with ESRD, using approaches such as pain and symptom management. We would recommend that palliative care be added to the elements of Organizations’ proposed integrated care strategies.

Revised text: Insert at Page 17, at line 20-21, the phrase “palliative care”: “(V) Services, such as transplant evaluation, **palliative care**, and vascular access care.”

11. Clarifying benefits (including education) for transition into hospice care

Page 6, lines 6-10 Benefits requirements

Original text: “(I) shall cover all benefits under parts A and B (other than hospice care) and include benefits for transition (including education) into palliative care...”

Comment 1: Palliative care is not limited to end of life hospice care but can encompass care provided through the life cycle treatment to improve the quality of life of those with ESRD. We would recommend deleting “palliative” and replacing with “hospice.”

Revised text: Substitute on page 6 lines 9-10 the word “hospice,” for the current word (“palliative”): “(I) shall cover all benefits underparts A and B (other than hospice care) and include benefits for transition (including education) into hospice care; and”

C. Specific recommendations: Program Design and Operation

12. Removing the term “medical home.”

Page 2, lines 24-26: Regarding terminology applied to organizations participating in the demonstration.

Original text: “An Organization shall integrate care and serve as the *medical home* for Program-eligible beneficiaries.”

Comment 1: The term medical home, italicized in the original text for emphasis, has a specific meaning in the context of a Medicare Shared Savings Program. In order to minimize confusion and maintain distinction between the two programs, this term should not be used. Additionally, the term is not used to imply any specific meaning under this program.

Revised text: Change at Page 2 line 25: “An Organization shall integrate care for Program-eligible beneficiaries.”

13. Expanding the Secretary’s discretion in setting quality measures for the demonstration.

Page 14, lines 15-24: Regarding the clinical quality measures to be reported to the Secretary by participating Organizations.

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

Comment 1: In developing clinical quality measures to assess the care provided by participating Organizations, similar models such as the Comprehensive ESRD Care (CEC) Initiative should be reviewed as a point of reference. However, the Secretary should have flexibility in defining quality measures for a new demonstration like the PATIENTS Act/DPDA. Furthermore, the Secretary should not be restricted to a fixed set of quality measures that were employed at a specific point in time by the CEC Initiative. The revision

offered below ensures that the CEC Initiative will remain as a point of reference for PATIENTS Act quality measures, while allowing for increased flexibility.

Comment 2: To eliminate any potential incentive for participating Organizations to deter Program-eligible beneficiaries from pursuing kidney transplantation, we recommend adding a clinical quality metric that will monitor the transplantation education efforts of participating Organizations.

Revised text: “(I) require each participating Organization to submit to the Secretary data on clinical measures, which may include those measures submitted by organizations participating in the Comprehensive ESRD Care Initiative operated by the Center for Medicare and Medicaid Innovation, and must include a measure concerning the annual education of Program-eligible beneficiaries on transplantation options, to assess the quality of care provided.”

14. Ensuring patients can opt for the Open Network during the annual open enrollment

Page 31, line 8-10: *Additional opportunity to opt out or elect a different model or Organization*

Comment 1: Page 31 of the bill allows enrollees to opt out or elect a different model or Organization. The language is not clear that an individual could elect to move from an Organization’s preferred network model to its open network. We would recommend the language be clarified in this regard, allowing patients who wish to remain in the Organization but switch from preferred network to open network to do so.

Revised text: Page 31, add a new (iv): “(iv) elect the open network model offered by the same Organization.”

Comment 2: Because dialysis initiation is an overwhelming experience for many of these vulnerable patients and their families, it may be difficult to make an informed decision regarding provider networks or fully understand the implications of these options. Accordingly, we recommend an additional, one-time opportunity for a patient to opt out, select an open or preferred network within the Organization, or elect a different model or Organization, approximately six months after program enrollment.

Revised text: Page 29, line 14 add: “—and a one-time opportunity six months after that date—”: “The Secretary shall provide for a 75-day period beginning on the date on which the assignment of a Program-eligible beneficiary into an open network model offered by an Organization becomes effective—and a one-time opportunity six months after that date—during which a program-eligible beneficiary may—”

15. Removing specifications regarding timeline for implementation and strengthening stakeholder engagement in development of the demonstration program.

Page 24, lines 1 – 6 *Program Operation and Scope*

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

Comment 1: Given the complexity of the program and the number of details the Secretary is tasked with addressing, we believe the timeline to open the process for application submission should be left to the discretion of the Secretary, ensuring the strongest launch of the demonstration project and that as many providers can participate as possible. Smaller providers in particular will need time to arrange contractual agreements with adequately capitalized partners in order to potentially be able to participate. Further, allowing the Secretary discretion in setting the timeline will ensure ample time for stakeholder feedback, through a formal rulemaking process with opportunity for public comment.

Revised text: “(1) In general – The Secretary shall establish a process through which an Organization can apply to offer one or more ESRD Integrated Care Models. Such an application shall include information on at least the following:”

16. Clarifying patient eligibility

Page 29 line 24 – page 30, lines 1-12 Additional Opt-In Population

Comment 1: We would recommend that only patients who are currently receiving dialysis in a unit owned by an Organization should qualify as program-eligible beneficiaries.

Revised text: Strike lines 24-25 on page 29 and lines 1-12 on page 30.

17. Remaining consistent with the concept of a demonstration project

Page 23, line 25 and Page 24, lines 1-20: Program Operation and Scope

Comment 1: Given that this model is a demonstration program, we suggest that the Secretary determine limits to the total number of patient participants and the geographic scope of an Organization, in order to remain consistent with the concept of a demonstration. This will also facilitate comparison of the performance of Organizations to those in other demonstration models such as the ESCO, other payment models such Medicare Advantage and Special Needs Plans, and other potential models that may emerge in the next several years.

Revised text: Add on the bottom of page 24, in a new subsection (F), “the Organization shall include information on the geography encompassed and number of Program-eligible beneficiaries included in the model.”

18. Adding a study regarding the effect of the program on the dialysis marketplace and patient care options prior to program expansion.

Page 27 line 7 – page 28, line 2 Regarding program expansion

Original text: “(6) Program Expansion – 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—”

Comment 1: We believe that a defined geographic scope of the program is needed in order to facilitate comparisons between it and similar ESRD demonstrations prior to program expansion. When expansion is considered by the Secretary, we recommend that the Secretary conduct a study on effects of potential expansion of the Organization on market diversity and patient choice and consider its findings this data in the decision.

Revised text: Add a new (D): “(D) The Secretary shall conduct a study on the anticipated effects of program expansion on market diversity and patient choice and determine that such expansion would not limit patient choice of dialysis providers in the service area of an Organization.”

19. Linking payment to performance on quality metrics

Page 14, line 11 and Page 16, line 3: *Quality and Reporting Requirements*

Original text: “(iii): establish quality performance standards on such measures to assess the quality of care”

Comment 1: The proposed Organizations are simply required to submit clinical measures data and the Secretary is required to “establish quality performance standards.” However, there is nothing that imposes consequences for failure to meet the standards, nor is there any clear linkage with payment (e.g., changes in the capitation rate). This omission is incongruous with other ongoing demonstration plans, criteria for advanced alternative payment models, and the Quality Payment Program. We recommend that financial incentive(s) based on quality metric performance be established.

Revised text: Add to page 15, line 8: “and to be used in determining adjustments to payments (increases or decreases)”: (III): establish quality performance standards on such measures to assess the quality of care and to be used in determining adjustments to payments (increases or decreases).”

Comment 2: If the change described in comment 1 above (payments to Organization could be adjusted up or down) were instituted, we would also recommend applying a multiplier to savings related to transplantation. For example: If transplantation increased from expected transplantation rates, use a multiplier greater than one; and if transplantation decreased, use a multiplier less than one.

Conclusion

Again, the society greatly appreciates your work to identify policies to help the millions of Americans with kidney diseases and looks forward to continuing to work with you to achieve that shared mission. ASN would be pleased to discuss these comments and stands ready to assist in any way; please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely,



Eleanor D. Lederer, MD, FASN
President