

Comprehensive End-Stage Renal Disease Care Model and Future Payment Models

In our opinion, the single most important change that can occur for patients with kidney disease is to change the focus of the current reimbursement system from care for patients on dialysis to care for patients with kidney disease, at whatever stage of their journey they may be. To provide optimal care, interventions should focus on the patient where that person currently “sits,” instead of seeing the patient as someone who may need dialysis care in the future.

When we heard about the possibility of a kidney care demonstration with CMMI five years ago, we started building a model to improve the overall care for patients with kidney disease.

Although we started with patients on dialysis, we quickly realized that if we wanted to truly improve care for patients on dialysis, we needed to go “upstream” and provide better care

Our primary goal in this program is to keep patients off dialysis; if we are unable to avoid dialysis, we do everything we can to safely delay the transition to dialysis.

earlier so that fewer start dialysis, more benefit from transplant, and those who do start dialysis are better prepared and more likely to choose home dialysis. In short, if we only focus on patients and dialysis care, we are missing an incredible opportunity to improve care and reduce costs for this medically complex and costly group of patients.

To address this opportunity, DCI created the REACH Kidney Care program, and today we provide care to more than 3,500 patients with CKD in 29 communities

in 16 states across the United States. Our primary goal in this program is to keep patients off dialysis; if we are unable to avoid dialysis, we do everything we can to safely delay the transition to dialysis.

Until April of this year, all of this care was provided free of charge. We now have agreements with two regional commercial payers, and are negotiating with other payers to establish a model to provide better care for their patients with CKD. As our partnership with payers grows, we look forward to sharing more granular data on the benefits of better CKD care.

Our comments to the ten questions below are based on our experience in caring for these patients. Our outcomes are not theoretical outcomes. And, they also are not just from a few locations. We anticipate that in the near future we will care for more patients with CKD than patients on dialysis, and we see this as a wonderful transformation in care for patients with kidney disease.

How could participants in alternative payment models (APMs) and advanced alternative payment models (AAPMs) coordinate care for beneficiaries with chronic kidney disease and to improve their transition into dialysis?

As will be noted in the answer to Question 2, patients with CKD have high clinical needs and their care is very costly for Medicare. Although multiple APMs, including accountable care organizations, are responsible for the care for patients with CKD, to our knowledge no APM has developed a systematic approach to care for patients with CKD.

We strongly believe that a separate CMMI demonstration project is needed to directly address only patients with CKD. Until this demonstration model exists, we are concerned that either a systematic approach to care for patients with CKD will not be implemented, or the approach to care for patients with CKD will only narrowly address patients as “pre-ESRD” in preparation for dialysis.

We strongly believe that a separate CMMI demonstration project is needed to directly address only patients with CKD.

We also strongly recommend that the demonstration project focus on the population served and be agnostic as to what type of provider takes the lead in implementing the program. There are numerous different models that could be implemented to improve care for patients with CKD, including models led by nephrologists, other physicians, health systems, and other providers. By allowing multiple providers to lead these programs, CMMI would allow a broader diversity of models to be implemented.

We are thus explicitly suggesting that a provider organization treating patients with end-stage renal disease by dialysis might also treat CKD patients using other methods, and might even lead the treatment program. We recognize that this proposal might arouse concern about potential conflicts of interest. We actually think that providing a financial incentive to improve CKD management without dialysis will reduce conflicts of interest for nephrologists, and will enlist dialysis providers in working to keep patients off dialysis, by promoting treatments to slow the progression of kidney disease, pre-emptive transplantation and medical management without dialysis. Under the existing structure of care, all of these treatments are under-utilized.

DCI has cared for patients using dialysis for more than 45 years. Participating in the care of patients who have not yet begun dialysis treatment has transformed our understanding of the treatment of kidney disease. We hope that if other dialysis providers have the opportunity to explore this model of care, their understanding of their role will change similarly.

We recommend the following basic parameters for a demonstration project addressing CKD:

1. As in the ESCO, each program should be required to have at least one owner nephrologist.
2. Because of the critical role of a primary care physician in managing a patient with stage 3b CKD, each program should be required to have at least one owner primary care physician.
3. We recommend that the demonstration project include patients with a GFR ≤ 45 through stage 5 CKD not receiving RRT. If the demonstration project does not go as far upstream as a GFR of 45, we are concerned that opportunities to slow progression of kidney disease will be missed, and that the model will overemphasize “pre-ESRD” care above proactive comprehensive CKD management.
4. The model should provide financial incentives for slowing progression of CKD, and starting beneficiaries on dialysis later in the progression of their CKD.
5. It is critical that patients who will transition to transplant, dialysis or medical management without dialysis are prepared for that transition. However, in a model that only focuses on CKD care, the interventions that improve the transition could be seen as an additional cost of care for these patients. We recommend that the model be established to provide a financial incentive that leads to improved transition to transplant, dialysis or medical management without dialysis.

How could participants in APMs and AAPMs target key interventions for beneficiaries at different stages of chronic kidney disease?

We recommend that a program focused on improving care for patients with CKD begin with patients with a GFR \leq 45. Although optimally we would like to provide care for all patients with CKD, the number of patients with GFR $>$ 45 is so large that it would potentially overwhelm the program. We recommend going back to at least a GFR \leq 45 so that there is adequate opportunity to slow progression of CKD and ideally avoid dialysis.

Based on NHANES data provided in the 2014 USRDS report¹, we estimate that a program managing patients with CKD will have a population distribution matching the following distribution of patients (and number of patients per 1,000,000) in the following stages:

- Stage 3b (GFR 30 – 45): 69.2% (14,750 patients per 1 million patients)
- Stage 4a (GFR 20-30): 15.0% (3,200 patients per 1 million patients)
- Stage 4b (GFR 15-20): 7.5% (1,600 patients per 1 million patients)
- Stage 5, not on dialysis (GFR $<$ 15): 6.6% (1,450 patients per 1 million patients)
- Transitioning to renal replacement therapy each year: 1.7% (359 patients per 1 million patients)

The cost of care for these patients is significant. And as the patient's kidney disease progresses, the cost of care increases. The following is an estimate of cost of care by stage; based on an analysis of 2013 Medicare 5% claims data:

- Stage 3: \$23,680 per year (2.2 times the cost of care for typical patient with Medicare coverage)
- Stage 4: \$33,374 per year (3.1 times the cost of care for typical patient with Medicare coverage)
- Stage 5 not on dialysis: \$36,147 per year (3.3 times the cost of care for typical patient with Medicare coverage)
- Stage 5, on dialysis: \$84,645 per year (7.8 times the cost of care for typical patient with Medicare coverage)

¹ 2014 USRDS ADR Vol, 1. Table 1.2, assuming that 66% of patients with stage 4 CKD have early stage 4 CKD

We note the change in cost of care for a patient with stage 5 CKD not on dialysis and a patient on dialysis. ***For every month that we can delay the start of dialysis, we will decrease the cost of care for Medicare by more than \$4,000 per patient.***

In addition, certain patients with CKD are more expensive than other patients. The two primary causes of CKD are diabetes and hypertension, and patients with these additional comorbidities are more expensive than patients without these comorbidities.

- CKD with CHF: \$34,715 per year (3.2 times the cost of care for typical patient with Medicare coverage)
- CKD with CHF and DM: \$38,230 per year (3.5 times the cost of care for typical patient with Medicare coverage)²

For every month that we can delay the start of dialysis, we will decrease the cost of care for Medicare by more than \$4,000 per patient.

There is also a great opportunity to improve care for these patients, since most of these patients are not receiving comprehensive care related to their kidney disease, and many do not even know that they have kidney disease. According to the USRDS, only 8.4% of patients with stage 3 CKD even know that they have kidney disease. For patients with stage 4 CKD, only 44.2% of the patients know that they have kidney disease.³

Our answer to this question is based on our experience with care for patients with chronic kidney disease, and on what we see as opportunities to improve care for patients with kidney disease. We have developed a program in which we change our focus of care for patients based on CKD stage with two primary goals:

1. Decrease the likelihood that a patient will need to be on dialysis,
2. Individualize the care by patient and by stage to make sure that the patient gets the best care possible for his current state, treating the patient as someone with CKD, not someone who is pre-ESRD.

² 2015 USRDS ADR. Vol. 1. Table 6.1

³ 2015 USRDS ADR. Vol. 1. Figure 1.16

We currently care for more than 3,500 patients with CKD in 29 different communities, in 16 states. Our most developed program is in Spartanburg, SC. We will use results from Spartanburg, SC, as a goal for how well we think a fully developed CKD program can perform. Our other 28 programs are in various levels of development. We will use the results from these programs to establish that these opportunities to improve care are scalable.

Below is the distribution among stages for the CKD population that we currently manage:

- Stage 1 or 2 (GFR > 60): 5% (190 patients)
- Stage 3a (GFR 45-60): 10% (363 patients)
- Stage 3b (GFR 30 – 45): 24% (843 patients)
- Stage 4a (GFR 20-30): 23% (796 patients)
- Stage 4b (GFR 15-20): 22% (778 patients)
- Stage 5, not on dialysis (GFR < 15): 16% (577 patients)

Stage 3b (GFR 30-45)

We start our formal interventions at stage 3b. We agree with Elizabeth Montgomery, Senior Project Director for CKDintercept at the National Kidney Foundation, who often points out that “CKD is a canary in a coal mine.” The fact that a patient has lost more than 50% of kidney function is often an indicator that this patient has some condition that has not been adequately controlled, and therefore has damaged their kidney function. We strongly believe that in-person, one-on-one, care coordination is essential to providing optimal care. Our care coordinator typically spends more than an hour with a patient during the initial meeting. Most of this meeting does not focus on kidney disease, but instead on the patient’s life goals. We then make sure that the patient understands three key things:

1. You have kidney disease.
2. If your comorbid conditions are appropriately managed, you likely will not need to be on dialysis.
3. Working together, we can make it more likely that you can have the life you want to live, without your kidney disease getting in the way.

For patients with a GFR 30 – 45, our intervention is primarily focused on:

- Improved blood pressure control
- Improved blood sugar control

- Cardiovascular risk factor control
- Increased exercise
- Smoking cessation
- Weight loss

Although these interventions may seem very similar to other programs addressing population health, we see one key difference – these patients have already lost more than 50% of their kidney function. *They are already half-way to the dialysis clinic.* Time and time again we see patients with uncontrolled hypertension or diabetes become more engaged in their care, and improve their clinical outcomes, once they learn that their hypertension or diabetes have caused their kidney disease and learn that they can avoid dialysis.

In addition, we also work with patients to protect their kidney health and educate them on kidney disease, with topics including:

- Avoidance of NSAIDS and other medications that could harm kidney function
- Avoidance of interventions that could harm kidney function
- Protecting their potential access arm
- Diet
- Sodium
- Anemia
- Phosphorous

We continue to see these patients in partnership with the patient's primary care physician and other physicians. If the physician sees the patient once every six months, we also see the patient once every six months, with the net effect that the patient is seen every three months. After every visit, we send a progress note to the patient's physicians covering the topics discussed in our visit and providing a clinical update for the patient.

We also ensure that adequate kidney screening has been performed for these patients. If the patient has not been checked for urine proteinuria, we recommend that this is checked. In addition, if the patient's kidney disease is rapidly progressing, we recommend that the patient is seen by a nephrologist, and we flag this patient for the nephrologist so that the patient can be prioritized for a visit.

We have recently signed an agreement to manage patients with CKD for two regional payers. We look forward to collecting clinical and financial outcomes for the interventions at stage 3b and sharing our results with CMS and others.

Stage 4a (GFR 20 – 30)

If a patient's kidney disease does progress to stage 4a, we intensify our efforts to improve the care for this patient. Most importantly, we recommend to the patient's primary care physician that the patient be referred to see a nephrologist. In addition, we check the patient's medications to make sure that s/he is on the correct medications, at the correct dose for the stage of kidney disease. We also continue to provide population health management for these patients, working with them to improve their management of comorbid conditions, and improve their current health so that they can have the best quality of life possible. After each visit we send a progress note to the patient's primary care physician and nephrologist.

Stage 4b (GFR 15 – 20)

If a patient's kidney disease does progress to stage 4b, we further intensify our efforts and continue to focus on population health for these patients. We also carefully manage those patients who will progress to needing renal replacement therapy so that we can start them as late as possible in the progression of their CKD. If the nephrologist sees the patient once a month, we also see the patient once a month, with the net result that the patient is seen once every two weeks. We have seen that with this close care, we can safely start a patient later in the progression of their CKD.

Nationwide, 12.6% of patients start dialysis each year with a GFR > 15.⁴ In our most developed program in Spartanburg, SC, we will not start a patient on dialysis until their GFR has dropped to 15. Since January 1, 2014, for the 101 patients who have started dialysis in Spartanburg from our CKD program, *none* had a GFR > 15 (we do note that 4 patients had a GFR of 15.)

In addition, we start preparing the patient for their next step in care. We educate the patient on the following four options:

- Transplant
- Home Dialysis

⁴ 2015 USRDS ADR. Vol. 2. Figure 1.18.

- In Center Dialysis, preferably with a fistula
- Medical Management Without Dialysis

We do not stop at education but include navigation services to ensure that the patient is able to implement his/her choice. For example, it is not an easy process to get on a kidney transplant list and stay active on the list. We work with the patient to make sure that all the necessary steps are followed.

We note that based on the NHANES estimation of the prevalence of CKD, patients with stage 4b and stage 5 not on dialysis only comprise about 16% of the population that we are recommending be the focus of this initiative. Although these patients are critical, if CMS were to implement a program that only addressed these patients, it would exclude 84% of the population that we believe can benefit from improved care. And it would greatly increase the risk that CKD programs would only treat patients as “pre-ESRD” who eventually may need dialysis, instead of focusing on their current clinical challenges and arresting—or at least slowing—their progression into ESRD.

Stage 5, not on dialysis (GFR < 15)

We continue to intensively manage our patients with stage 5 CKD, not on dialysis. For some of these patients, our care coordinator sees them on a weekly basis so that we can make sure that we are managing their symptoms as effectively as possible and are pushing back the start of dialysis as far as possible.

We evaluate each patient clinically, and do not simply rely on their GFR when deciding whether to start a patient on dialysis. Overall, we are seeing that a GFR of 5-10 is optimal for many patients to allow for a smooth transition to dialysis. In Spartanburg, 53.2% of patients started with a GFR of 5-10 from January 1, 2014, to September 2015.

Transition in Care *Transplant*

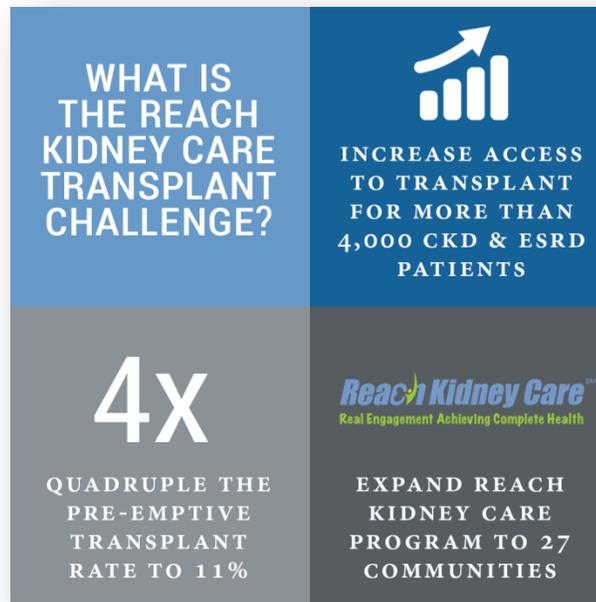
We see transplant as the optimal therapy for patients with kidney failure. We currently operate DCI Donor Services, which is responsible for the operation of three organ procurement organizations (OPOs) – in Tennessee, New Mexico and in Northern California. Our founder Keith Johnson started DCI to keep patients alive so that they could receive a kidney transplant.

He was the original president of the Southeast Organ Procurement Foundation (SEOPF, the precursor to UNOS) and is a past president of the United Network of Organ Sharing.

Because of the hard work of the staff at DCI Donor Services, 546 people received a kidney transplant in 2015. In 2015, our largest OPO, Tennessee Donor Services, had the largest number of donors per million and the largest number of organs per donor of all OPOs in the country with more than 200 donors.

Unfortunately, only 2.6% of individuals transitioning to RRT receive a pre-emptive transplant.⁵ We know that we can do much better. In June 2016 we made the following commitment as part of the White House summit on transplant:

Dialysis Clinic, Inc. (DCI) will increase access to pre-emptive transplant by expanding the REACH Kidney Care program to 27 communities in 17 states, offering this service to 2,500 patients with less than 30 percent kidney function. DCI's goal is that by next year, 11 percent of its patients who need a transplant will receive one preemptively—quadruple the current national number.



⁵ 2015 USRDS ADR. Vol. 2. Figure 1.1.

Although this goal may seem unattainable, we know it can be reached. In fact, under the “Healthy Transitions in Late Stage Kidney Disease” CMMI Challenge Grant program led by Dr. Steven Fishbane, more than 11% of patients have received a pre-emptive transplant. The Rogosin Institute, a nonprofit kidney care provider in New York City, currently has a 25% pre-emptive transplant rate for its CKD program.

Our transplant outcomes for our Spartanburg CKD program are limited by the fact that the closest transplant center is 100 miles away. Despite this barrier, we have coordinated 4 pre-emptive transplants for patients in the Spartanburg program.

Medical Management Without Dialysis

When we talk with our patients about the option of dialysis care, we strongly believe that we should first ask the patient “do you want dialysis?” instead of only asking “would you like to dialyze at home or in center?”

For most patients starting dialysis, they are making a commitment to start a therapy that will require them to receive three four-hour treatments per week. After including the time for travel to and from dialysis, and the recovery from dialysis care, many patients essentially “lose” three out of seven days a week because of the obligations of dialysis care. Especially for patients over 80 years old with multiple comorbidities, ethically we believe we have an obligation to talk openly with patients about medical management without dialysis and allow them to make their best decision in care. When we talk with a patient about medical management without dialysis, we make it clear that the patient can change his/her decision at any time. In addition, we make it clear that we will not abandon the patient. We will continue to intensively manage his/her care and will coordinate with the patient and family to identify appropriate community resources such as palliative care and hospice, based on the patient’s wishes. The only difference in our care is that we will not include dialysis care as treatment (unless the patient changes his/ her mind and decides to start dialysis).

Based on recent published literature, we know that patients who are older than 80 with multiple comorbidities who start dialysis have similar survival outcomes compared to those who choose medical management without dialysis. For those who live longer, most of those extra days were spent in a dialysis clinic or in a hospital.

If a patient chooses medical management without dialysis, we meet with the family and help them understand the patient's options and decision regarding care. According to published literature, about twice as many patients would choose medical management compared to their families. It is critical that we sit down with the patient and his/her family and discuss medical management without dialysis as an option in care.

In our most developed program in Spartanburg, SC, we are seeing that more than 15 percent of patients choose medical management without dialysis. In Spartanburg, we currently care for 100 patients with a GFR < 20. Of these patients, 24 have selected medical management without dialysis.

In our Spartanburg program, for those who have selected medical management without dialysis, less than 6% have changed their mind and have started dialysis. You may hear from other programs that have a larger number of patients change their mind and start dialysis. We note that most of these programs provide telephonic care coordination. We strongly believe that in-person, face to face care coordination is critical to providing optimal care and that this different type of care coordination allows for different, improved outcomes.

Home Dialysis

A person dialyzing at home has more independence, is more likely to be able to continue to work, and has much higher satisfaction in their dialysis care. In addition, the cost of care for a patient dialyzing at home is lower than the cost of care for a patient dialyzing in center.

According to the 2015 USRDS ADR, the average annual cost of care for a patient dialyzing with peritoneal dialysis (the primary home modality) is \$14,631 less than the annual cost of care for a patient dialyzing with hemodialysis (the primary in center modality)⁶.

Our experience is that if we educate patients early about the option of home dialysis, they are more likely to start dialysis at home. Nationwide, 9.3% of patients start dialysis at home.⁷ In our Spartanburg program in 2015, 37% of patients started dialysis at home. Nationwide, in our 29 CKD programs, 27% of patients started dialysis at home.

⁶ – 2015 USRDS ADR. Vol. 2. Figure 11.7. We were unable to find a cost comparison of home dialysis to in center dialysis in the 2015 USRDS.

⁷ 2015 USRDS ADR. Vol. 2. Figure 1.1.

In Center Dialysis

Even with an optimal CKD program, we anticipate that about half of the patients starting RRT will start dialysis in center (versus 88% of patients starting in center dialysis currently). For these patients, the best clinical improvement that we can make is for them to start dialysis with a permanent access and not a hemodialysis catheter. These patients are less likely to have an infection, and less likely to have a hospitalization. Although a fistula is the ideal access for some patients, other patients (especially elderly patients) will receive most effective care with a graft. ***Our primary goal is to avoid the use of a catheter.***

In addition, the cost of care for a patient with a fistula is less than the cost of care for a patient with a catheter. According to the USRDS, the annual cost of care to Medicare for a patient with a fistula is \$20,098 less than a patient with a catheter, and the annual cost of care for a patient with a graft is \$6,809 less than a patient with a catheter.⁸

By educating patients early about the importance of a permanent access, more patients are starting dialysis with a permanent access and never had a catheter. Nationwide, only 20% of patients start dialysis with a permanent access.⁹ In contrast, in our Spartanburg REACH site 68% of patients starting dialysis in 2015 started with a permanent access. Of those who started with a catheter, 50% had a maturing fistula or graft in place, and we removed the catheter as soon as the permanent access had matured. Nationwide, in our 29 CKD programs, 41.6% of patients started dialysis with a permanent access.

Avoiding Hospitalization Before First Dialysis Treatment

We also work to decrease the likelihood that a patient will receive his/her first dialysis treatment in a hospital. We see this as an important improvement in care since patients avoiding hospitalization will also be able to avoid the complications from hospitalization. In addition, we have seen that patients can have a smoother transition to dialysis if their first treatment is in the outpatient setting instead of the hospital. We do, however, recognize that certain patients should receive their first treatment in the hospital to ensure that they receive safe care and therefore err towards starting a patient in the hospital if there is a clinical indication to do this.

⁸ USRDS 2010. Vol 2. Figure 11.19. We are unable to find a more recent edition of the USRDS report that compares the cost of care for patients with different types of hemodialysis access.

⁹ 2015 USRDS ADR. Vol. 2. Figure 4.7.

Still, we expect that Medicare will see significant savings if we can increase the number of patients avoiding the first hospitalization before a dialysis treatment. We estimate that the cost of hospitalization and follow-up care is \$25,000 for a patient on dialysis.

Nearly 2/3 of patients receive their first dialysis in the hospital.¹⁰ In Spartanburg, on the other hand, 67% of our patients starting dialysis received their first treatment in the clinic and avoided that initial hospitalization. ***Nationwide, in our 29 REACH locations 58% of patients start dialysis as an outpatient and avoid the initial hospitalization.***

Delaying Start of Dialysis

Anyone with kidney disease would want to do everything possible to push back the start of dialysis. It is much easier to have the quality of life that we want, and continue to work, if we could avoid going to the dialysis clinic for a four hour treatment, three times a week. The cost of care for a patient with Stage 5 CKD, *not on dialysis*, is substantially lower. For every month that we delay the start of dialysis, Medicare saves more than \$4,000 per patient.

As has been noted before, nationwide 12.6% of patients starting dialysis had a GFR > 15. Based on the results from our Spartanburg program, we know that we can safely push back the start of dialysis. As noted previously, since January 1, 2014, for the 101 patients who have started dialysis in Spartanburg from our CKD program, *none* had a GFR > 15 (we do note that 4 patients had a GFR of 15.)

From a clinical perspective and financial perspective, we see efforts to delay the start of dialysis as low-hanging fruit. In our opinion, a model that addresses CKD care that does not financially incentivize a safe, later transition to dialysis is an incomplete model. Our patients deserve better.

Some may be concerned with financially incentivizing a later start of dialysis. However, by following the patient closely, we can quickly identify when they need to start dialysis and can arrange for a smooth transition to the start of dialysis. In addition, because the patient is starting dialysis later in the progression of CKD, the patient has more time to make the decision to start dialysis at home and has more time for his or her permanent hemodialysis access to

¹⁰ Wong SPY, Kreuter W, O'Hare AM: Healthcare intensity at initiation of chronic dialysis among older adults. J Am Soc Nephrol 25:143–149, 2014.

mature if s/he chooses to start dialysis in center. For patients transitioning to dialysis in Spartanburg, SC:

- **37% of patients start dialysis at home** (more than three times the national average)
- **68% of patients start hemodialysis with a permanent access** (more than three times the national average)
- **67% of patients avoid hospitalization before first dialysis** (compared to only 33% nationwide)

As a person with CKD, if you could start dialysis later in the progression of your CKD, wouldn't you want to do this? And as providers of care for patients covered by Medicare, as good financial stewards don't we owe it to the Medicare system to strive for these savings?

How could participants in APMs and AAPMs better promote increased rates of renal transplantation?

As we note above, we see transplant as the optimal therapy for a patient with kidney failure. A patient with a transplant is more likely to stay employed, does not need to go to the dialysis clinic three times a week for a four-hour treatment, and is less likely to have kidney disease keep him/her from having the life s/he wants to have. In addition, over time, a patient with a transplant is much less expensive than a patient on dialysis. After the first to second year of the transplant, the annual cost of care for a patient with a transplant is \$54,630 less than a patient on hemodialysis.¹¹

We strongly recommend that CMMI establish a demonstration project that solely focuses on improved care for patients with CKD so that patients starting RRT will be more likely to receive a kidney transplant. Unless a separate demonstration project to address patients with CKD is implemented, we are concerned that patients will not have the optimal opportunity to receive a kidney transplant and avoid dialysis.

If a patient does start dialysis, there are still opportunities to increase renal transplantation. We should continue to educate patients on dialysis about the opportunity to receive a kidney transplant and work with them to get on the transplant list. Our patients on dialysis need hope for a better life. Knowing about the possibility of a transplant can give them that hope.

We also believe that more patients on dialysis would receive a transplant if more cadaveric kidneys were transplanted. Over the last few years, we have seen OPOs discarding kidneys that were previously used for kidney transplant. In Tennessee Donor Services, we discarded three times more kidneys in 2015 than in 2002. Nationwide, more than 3,000 kidneys were discarded in 2015.

We would like to use the ESCO to test use of kidneys that would otherwise be discarded for high risk donor recipients. Transplant centers associated with ESCOs could be allowed to use these kidneys for high risk recipients, including patients in their first year on dialysis, and patients who are older than 70. CMS should closely follow the outcomes for these transplants,

¹¹2015 USRDS ADR. figure 11.7

but we would recommend that CMS not penalize the transplant centers in an ESCO for using these kidneys. If these interventions are successful, CMS could potentially expand the practice to other locations.

We would suggest that CMMI test a program in which ESCOs with the best transplant outcomes compared to their benchmark receive a higher percentage of shared savings than programs with lesser transplant outcomes.

In addition, we recommend the models include provisions to improve care for patients after they receive a kidney transplant to make it less likely that they will lose their transplant. We will be working on an improved approach to care for patients with a kidney transplant and look forward to sharing our results in the future.

How could CMS build on the CEC Model or develop alternative approaches for improving the quality of care and reducing costs for ESRD beneficiaries?

DCI strongly supports the CEC Model. We have operated three ESCOs since the inception of the CEC model and have applied to operate three more ESCOs starting in 2018. We have seen that our patients in the ESCOs receive better, more individualized care. We are also encouraged by our initial financial outcomes.

We recommend that the CEC model include transplantation. A patient with a kidney transplant is more likely to continue to work, does not need to go to the dialysis clinic four hours per day, three times a week, and is less likely to have his or her kidney disease keep him or her from having the life s/he wants to have. In addition, beyond the first few years, a patient with a transplant is \$54,630 less expensive to Medicare than a patient on hemodialysis.

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We would like for CMMI to put our shared savings at risk, based on our transplant outcomes.

We propose a budget neutral program in which ESCOs with higher transplant performance relative to their benchmark receive a higher percent of shared savings and ESCOs with lower transplant performance relative

to their benchmark receive a lower percent of shared savings. We note that we are willing to put our shared savings at risk despite the fact that one of our ESCOs, the Palmetto Kidney Care Alliance, is more than 100 miles away from the closest transplant center.

We would recommend that CMMI allow transplant programs in ESCOs to use kidneys with a KDPI score > 80 for high risk recipients, including patients in their first year on dialysis and patients 70 years or older. We recommend that CMS closely follow the outcomes for these transplants, but not penalize the transplant centers for the outcomes for these high risk transplants. If this pilot is successful, we recommend that the practice be implemented more broadly.

Are there specific innovations that are most appropriate for smaller dialysis organizations?

All health care is local. We strongly believe that the best way to care for patients with kidney disease is to develop local partnerships, and implement programs that are uniquely beneficial in each community. Although DCI does now care for more than 15,000 patients on dialysis in 28 states, we do not see DCI as one large corporation providing standard care across the country. We intentionally grant a great deal of autonomy to each of our Medical Directors and to the other clinical leaders in each community in which we have dialysis clinics. We see ourselves as a partnership of a multitude of many small organizations, instead of one large organization.

We have learned that if we allow each community to innovate, we have the opportunity to test more models of care and have a better opportunity to learn how to improve care. Our CKD program, which now cares for more than 3,500 patients in 29 communities, was not started at the DCI Corporate Office. Instead, it was started as a small, independent program in Spartanburg, SC.

Many smaller dialysis organizations, and in particular nonprofit dialysis organizations, have deep roots in their community. As small, local organizations, they have the opportunity to be more nimble and quickly respond to changes in care. However, as small organizations, they also do not have the corporate capabilities of larger organizations.

One mid-sized provider that applied to start an ESCO in 2017 described their interventions in the ESCO as “high touch, low technology.” We believe that this is an excellent description of the different type of care that would be provided by smaller providers of dialysis care. In our current three ESCOs, we are seeing that high touch, individualized care can effectively improve outcomes for our patients and decrease their cost of care. By including more small providers in the ESCO and other demonstration programs, we will have a greater opportunity to learn about the effectiveness of different “high touch” models.

It is critical that smaller providers to be able to continue to care for patients on dialysis so that patients can have more choices for care, and so that there will be more models of care from which we can learn. A CMS launches demonstration projects it is critical that smaller providers be able to continue to care for their patients.

We greatly appreciate that CMMI has been sensitive to the needs for smaller providers, allowing multiple payment tracks in the ESCO and allowing smaller providers to aggregate. We do note one area in which CMMI could improve the ESCO experience for small providers. We strongly recommend that CMMI provide claims data in a format that can more easily be analyzed by smaller providers.

How could primary-care based models better integrate with APMs or AAPMs focused on kidney care to help prevent development of chronic kidney disease in patients and progression to ESRD? Primary-care based models may include patient-centered medical homes or other APMs.

We strongly believe that a new model of care for patients with chronic kidney disease will not be created without a separate demonstration project addressing patients with CKD. ACOs have been responsible for managing patients with CKD for several years and, to our knowledge, no ACO has implemented a new systematic approach to care for patients with CKD.

As you know, many ACOs have reported that they have been unable to decrease the cost of care for patients on dialysis. We currently operate three ESCOs, and are very encouraged by our initial clinical *and* financial results for our ESCOs. We anticipate that a demonstration project targeted only on patients with CKD could have the same clinical and financial impact for patients with CKD.

How could APMs and AAPMs help reduce disparities in rates of CKD/ESRD and adverse outcomes among racial/ethnic minorities?

We are learning from The Rogosin Institute (Rogosin) about opportunities to help reduce disparities in rates of CKD/ESRD and adverse outcomes among racial and ethnic minorities. In our three ESCOs, dual eligible patients are most likely to have the highest representation of racial and ethnic minorities. Based on data provided to us by CMMI for our ESCOs, these individuals are the most expensive beneficiaries in our ESCOs. There clearly is a need to develop a new and better approach to care for racial and ethnic minorities with kidney disease.

We borrow heavily from our colleagues at Rogosin in this area and greatly appreciate their leadership in this area and their willingness to openly share their plan to improve care for racial and ethnic minorities. We support the comments outlined in the Nonprofit Kidney Care Alliance letter addressing this question.

We also understand the challenges of the disproportionate manner of how kidney disease impacts certain ethnic groups. In order to understand the Native American population better, DCI is engaging a business that is owned by a Federally recognized tribe and covers some Native Americans and other ethnic minorities, who are covered by the businesses' health plan. In this program DCI goes upstream to identify, educate, coordinate care and treat patients in all stages of CKD and ESRD. This program went live June 1 2016. We look forward to reporting the results of this program.

Are there innovative ways APMs and AAPMs can facilitate changes in care delivery to improve the quality of life for CKD and ESRD patients?

We believe there are three areas that can be addressed by new and existing models to improve the quality of life for patients with CKD and ESRD:

1. Employment assistance,
2. A focus on mental health, and
3. End of life care.

These three areas are common roadblocks for patients with CKD and ESRD that, with proper assistance, could increase quality of life and general health.

First, there is a large decrease in employment between a patient learning that s/he has CKD to the patient's first dialysis visit. This is largely due to the progression of their disease, with difficulty managing symptoms, and eventually, the struggle to dialyze numerous times a week while working. We believe that by slowing the progression of the disease and educating patients early on their treatment options through CKD education, not only can patients delay the start of dialysis, but also mitigate its impact by preparing for home dialysis or even

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a transplant. Having options and managing the disease and its symptoms is important to maintain employment, adequate standard of living and quality of life. In addition, if we work with patients and their employers early in the progression of CKD, before starting dialysis, we believe we can make it more likely that these patients remain employed. DCI is a Stakeholder in KidneyWorks, the coalition started by AAKP and MEI to increase employment for people with kidney disease. We look forward to including initiatives proposed by KidneyWorks in our care for patients with CKD.

Additionally, for patients going through progression of the disease, mental health may become a struggle that should not go unaddressed. Nephrologists and other care providers may see the signs of mental illness, particularly depression, and in many cases diagnose and refer the patient to an appropriate mental health professional. Providing greater focus for providers to

engage with patients to catch the signs for mental health needs is an important part of care for patients with CKD or ESRD.

Finally, end of life care is an important part of the care continuum, particularly for our patients in order to educate them on their options and plan early based on their wishes. We applaud CMS for including an Advance Care Planning quality performance measure in the ESCO and encourage it to be utilized in other models as well. We also note that nationwide, few patients with CKD are educated about the option of medical management without dialysis. We have seen that more than 10% of patients will choose this option and strongly believe that this option should be fully discussed. The provider should serve as an advocate for patients who choose medical management without dialysis.

Are there specific innovations that are most appropriate for evaluating patients for suitability for home dialysis and promoting its use in appropriate populations?

We see home dialysis as optimal dialysis care. A person dialyzing at home has more independence, is more likely to be able to continue to work, and has much higher satisfaction in their dialysis care. In addition, the cost of care for a patient dialyzing at home is lower than the cost of care for a patient dialyzing in center. According to the 2015 USRDS ADR, the average annual cost of care for a patient dialyzing with peritoneal dialysis (the primary home modality) is \$14,631 less than the annual cost of care for a patient dialyzing with hemodialysis (the primary in center modality)¹².

As part of early discussions on treatment option, we believe that the earlier patients are educated on this option, the more likely they are to start dialysis at home. Nationwide, 9.3% of patients start dialysis at home.¹³ We believe there are policy changes that could be made to increase home dialysis such as increased screening and suitability, availability of staff assisted care partners, the use of telemedicine, remote monitoring, and respite care. These changes, when packaged together as a service of home dialysis, would promote sustainable growth in home dialysis.

There is substantial variability across nephrologists and dialysis programs in the criteria applied to identify appropriate candidates for home dialysis. In particular, lack of training in peritoneal dialysis in most nephrology training programs is a major impediment to the use of this treatment modality. We suggest that CMS undertake a program like that underway in the Canadian Province of Ontario to increase the utilization of peritoneal dialysis in this country.

The use of staff assisted care partners has been a helpful tool for patients and their families to dialyze at home by having assistance connecting and disconnecting from the dialysis machine. By providing this option to patients, and providing payment for these services, patients who may not otherwise have help to achieve this care option would be able to take advantages of the positive impact of home dialysis while still receiving trained care and assistance. We

¹² 2015 USRDS ADR. Vol. 2. Figure 11.7. We were unable to find a cost comparison of home dialysis to in center dialysis in the 2015 USRDS.

¹³ 2015 USRDS ADR. Vol. 2. Figure 1.1.

recommend that CMS consider the addition of these services to assist in the promotion of home dialysis.

Another innovative way that patients can increasingly utilize home dialysis is through telemedicine and remote patient monitoring. For patients and their families this can be an extension of staff assistance and in many cases can provide a feeling of safety when a family member or caregiver cannot be around. Many patients must travel long distances for their monthly physician visit. If a patient were able to complete a portion of those visits through telehealth, this would substantially decrease the burden on some patients who would otherwise need to travel a long distance or traverse a congested urban area. We recommend that a dialysis clinic as well as the home should be an originating site for this purpose. For healthier patients who have to drive twice a month (once for clinic visit and once for physician visit), allowing a telehealth option from the patient's home could offer much needed convenience. Subject to their physician's concurrence, this could be helpful to patients whose doctor may be at a distance, whether rural or within a large urban metro area and/or during periods of winter weather. We believe there is an opportunity to test a telemedicine model in the ESCO under a technology waiver. We also believe that telemedicine be used for a CKD demonstration program to communicate to patients between their in person, face-to-face visits. Telemedicine has increasingly been used by CMS and in particular, has expanded under the Medicare Access and CHIP Reauthorization Act (MACRA). Results could provide needed data and relief to expand for all home dialysis patients.

Finally, we recommend the use of respite care at home to assist patients and provide family members a break from care-giving. Access to respite care would make it easier for patients to remain at home safely. In our opinion, optimal respite care is a continuation of the current care that is provided at home, and not merely treating a patient as an in center hemodialysis patient. A patient receiving peritoneal dialysis at home should have the opportunity to receive peritoneal dialysis in center for a limited period of time; a patient receiving more than three treatments per week with home hemodialysis should have the opportunity to receive the same frequency of care during the respite period.

Are there specific innovations that could most effectively be tested in a potential mandatory model?

We do not recommend a mandatory payment model for CKD or ESRD at this time. We believe that there is enough interest in the community that a requirement isn't needed, that it would not provide any additional value to the program, and it could potentially get in the way of the substance and policy that continues to grow in the ESCO based on engaged participation.

We have been very active in the creation and evolution of the ESCO and hope to expand our participation in the ESCO. Currently about 10% of our patients on dialysis are cared for under the CEC model. If our three additional applications are approved, we hope to care for 20% of our patients under the CEC model in 2017. We also plan to expand our ESCOs to care for 30% of our patients under the CEC model in 2018. We hope that the CEC will be approved as a permanent model so that we can further increase the number of DCI patients under the CEC model.

From our experience, there are already a limited number of providers, and a mandatory model could prove overly difficult. Additionally, we remain concerned that for small dialysis providers a mandatory model could be overly burdensome, and, unwittingly, lead to more consolidation in this sector.