DCi®

DIALYSIS CLINIC, INC.

A Non-Profit Corporation

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June 22, 2015

The Honorable Orrin Hatch
Chairman
Senate Committee on Finance
219 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Committee on Finance
219 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Johnny Isakson
131 Senate Russell Office Building
Washington, DC 20510

The Honorable Mark Warner
475 Senate Russell Office Building
Washington, DC 20510

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson and Senator Warner:

On behalf of Dialysis Clinic, Inc. (DCI), I am pleased to have this opportunity to submit comments on your May 22 letter to stakeholders on chronic care in Medicare. DCI is a nonprofit provider of care for patients with kidney disease. DCI was founded in 1971 (two years before Medicare covered dialysis services) to save the lives of 5 patients in Nashville, TN. We currently care for more than 14,500 patients in more than 230 clinics in 28 states. In addition, we run three Organ Procurement Organizations, located in Tennessee, New Mexico and Northern California. Because of the hard work of the staff of DCI Donor Services, more than 500 people received a kidney transplant in 2013.

Over the last four years, we have looked at opportunities to improve care for patients with kidney disease and have learned that if we really want to improve care for patients with kidney disease, and decrease the cost of care, we need to go upstream and work with them before they need to receive dialysis. Currently we provide chronic kidney disease (CKD) Care Coordination for 3,000 patients in 28 different communities. Our primary goal for managing these patients is to keep them off dialysis. If we are unable to keep these patients off dialysis, we would like to at least push back the start of dialysis, have them be better prepared for dialysis, and have their first dialysis treatment in an outpatient clinic instead of a hospital. In addition, we would like to make it more likely that they will receive a pre-emptive kidney transplant and avoid dialysis.

We applaud your efforts to combat chronic disease and we answered many of your listed questions in our reply, however to start, we wanted to provide an example of how we use CKD Care Coordination to treat chronic kidney disease and to keep patients out of our dialysis chairs inside our clinics. In effect, your *Question #8 – Ways to more effectively utilize primary care* *providers and care coordination teams in order to meet the goal of maximizing health care outcomes for Medicare patients living with chronic conditions* is the heart of what we do at DCI, so we shall begin there.

Our Goal: Keeping Patients off Dialysis – A Real Life Example

The following is a summary of the stages of chronic kidney disease for the patients currently managed by our CKD Care Coordinators. Please keep in mind that a patient does not need to start dialysis once they are at Stage 5 CKD. We are currently managing more than 500 patients with stage 5 CKD and working to keep them off dialysis.

- Stage 5: 18%
- Stage 4 late: 24%
- Stage 4 early: 23%
- Stage 3b: 21%
- Stage 3a: 8%
- Stages 1-2: 6%

DCI currently provides CKD Care Coordination for all of these patients free of charge. We are excited about our initial outcomes, but realize that this program will not be viable long-term unless we can be reimbursed for this type of innovative care.

Over the last two years we have built infrastructure to be able to manage the overall care for patients on dialysis for the Center for Medicare and Medicaid Innovation's (the Innovation Center) Comprehensive End Stage Renal Disease (ESRD) Care Initiative (CEC). We are a finalist to participate in the CEC in three locations and plan to start on July 1, 2015. We have found that the infrastructure that we have built for the CEC can also be very effective for management for patients with CKD and not on dialysis.

In preparation for the CEC, we have partnered with a broad variety of health care providers. For the three ESRD Seamless Care Organizations (ESCOs), we have owners, non-owner participants, and partners who are:

- Nephrologists
- Health systems
- Accountable Care Organization (a partner, prohibited from being an owner in the ESCO per the CEC rules)
- Hospitalists
- Access Surgeons
- Home Health Providers
- Palliative Care Provider
- Hospice Provider

We have learned that we can easily extend our partnership for the management of ESRD patients in the ESCO to also partner with these providers to improve care for patients with CKD. Patients with CKD are an extremely expensive population and, to our knowledge, have not received the benefit of an overall care management program to improve health. Although 9.2% of the population has CKD, these beneficiaries represent 18.2% of the cost for the Medicare program. Many of these patients have heart disease, diabetes or both heart disease and diabetes. The average cost for a patient with Medicare coverage is $9,806 per year; in contrast, the average cost for a patient with CKD is $20,162 per year. On average, a patient with CKD and heart disease costs $27,810 per year and a patient with CKD, heart disease and diabetes costs $34,631 per year. 2014 USRDS ADR. Volume 1. Chapter 6. Table 6.1.

The cost for a patient with CKD increases as the patient progresses to the next stage of CKD. Based on 5% Medicare Claims for 2011, the cost by stage is:

- CKD Stage 3: $24,289 per year
- CKD Stage 4: $32,977 per year
- CKD Stage 5, not on dialysis: $38,904 per year
- CKD Stage 5, on dialysis: $84,879 per year

Based on the above summary, CMS would have $3,800 savings for every *month* that we are able to push back the start of dialysis.

While there is much to be done to avoid the onset of kidney disease, we see stage 3b (meaning a glomerular filtration rate (GFR) of 30 - 45) as the "tipping point" to begin working with a patient to improve his or her health and avoid progression. We estimate that about 2% of patients have stage 3b kidney disease (National Health and Nutrition Examination Survey (HANES) data, 2007-2012, assuming that 33% of patients with stage 3 CKD have stage 3b CKD). We recommend focusing primarily on those patients with either heart disease or diabetes (or both). Our current practice is to provide one-on-one education and coordination with a nurse. At stage 3b, the nurse is able to sit down with the patient, explain that the patient is already halfway to the dialysis clinic (because he or she has lost more than half of his or her kidney function) and that we would like to work with the patient to improve control of his or her hypertension or diabetes and slow the progression of his or her kidney disease. Based on our experience, we know that after this conversation, many patients become more involved in their care and improve their management of blood pressure or diabetes. We hope to be able to establish that the cost of care for these patients is decreased as their control of hypertension and diabetes improves and hope to also show that the progression of the patient's kidney disease is slowed once the patient better manages his or her comorbidities.

If a patient's kidney disease progresses to stage 4 (GFR 15 - 30) or stage 5 (GFR < 15) CKD, we work with patients to empower them to choose their best choice at the transition in care. We see transplant as the ideal therapy for a patient with kidney failure and have seen that many patients, when given a chance to make this decision before they start dialysis, will select transplant as their ideal therapy, get on a transplant list once their GFR drops below 20, and work towards receiving a kidney transplant and avoiding dialysis. Unfortunately, nation-wide less than 3% of patients receive a pre-emptive kidney transplant. 2014 USRDS ADR. Vol. 2. Ch. 1. Figure 1.1. In our Nashville, TN CKD program, we are currently following 87 patients with a GFR < 30 and not on dialysis. Of these patients, more than 12% have selected transplantation as their ideal therapy and are in the process of being evaluated for a pre-emptive transplant.

Not all patients are able to receive a transplant and therefore it is important for each patient with stage 4 CKD to decide his or her best choice at the transition in care. Instead of making the assumption that a patient would choose dialysis, we believe that it is important to first ask the patient if he or she is interested in receiving dialysis. According to recent published data, outcomes are similar for certain patients if they select medical management without dialysis instead of dialysis. Osasuyi Iyasere and Edwina A. Brown. Mortality in the Elderly on Dialysis: Is This the Right Debate? *Clin J Am Soc Nephrol* 10: 920–922, 2015; Sarbjit V. Jassal and Diane Watson. Dialysis in Late Life: Benefit or Burden. *Clin J Am Soc Nephrol* 4: 2008–2012, 2009. In our program in Spartanburg, SC, we are following 92 patients with a GFR < 20. Of these patients, more than 20% have selected medical management without dialysis.

If a patient selects medical management without dialysis, our Care Coordinator will meet with the family or advocate for the patient, and explain to them that for certain patients this is a reasonable choice. We also make it clear to the patient and his or her family that we will not abandon the patient, and continue to closely follow the patient with his or her nephrologist. If the patient would benefit from palliative care, we will arrange for that service to be provided by a palliative care provider. If the patient is eligible for hospice and is interested in hospice, we will arrange for that service to be provided by a hospice provider. Following this process with the patient, we have found that few patients change their mind at the point that dialysis would be necessary, and that patients are able to have a peaceful transition to end of life.

If a patient selects dialysis, we talk with the patient about home dialysis. We see home dialysis as the optimal form of dialysis care, since patients at home are more engaged in their care and have more independence, and since they do not need to go to a dialysis clinic for a four hour treatment, three times a week. However, nationwide, less than 9% of patients who started dialysis in 2012 started dialysis at home. 2014 USRDS ADR..Vol2. Ch. 1. In our Spartanburg, SC CKD program, 29% of patients who started dialysis in 2014 and received CKD Care Coordination selected home dialysis. In contrast, 0% of the patients who did not receive CKD Care Coordination in Spartanburg, SC selected home dialysis in 2014.

If a patient selects in-center dialysis, we talk with the patient about the importance of having a permanent access, preferably a fistula. In 2011, more than 81% of patients nation-wide started dialysis with a catheter. 2013 USRDS ADR Vol. 2. Ch. 1. Fig 1.22. These patients are more likely to have an infection, more likely to be in the hospital, and less likely to live. To us, the single most important thing that we can do to help a patient receiving hemodialysis is to create a situation in which the patient does not have a catheter.

If the patient decides to have the permanent access placed, we will have a fistula placed early, so that it can mature *before* the patient starts dialysis. It can take four months for a fistula to mature, sometimes longer. If the fistula is not mature at the time that the patient starts dialysis, the patient will need to start with a temporary catheter, with the risks noted above. In our Spartanburg, SC program, we have been effective at placing fistulas early, so that it can be used for the first dialysis treatment. In Spartanburg, 73% of patients who received CKD Care Coordination and started dialysis in 2014 *started with a fistula and never had a catheter*.

With our Care Coordination program, we partner with the patient's nephrologist to increase the frequency of patient visits. If the nephrologist sees the patient once a month, our Care Coordinator also sees the patient once a month, with the net effect that the patient is seen every two weeks. By following the patient more closely, we are able to push back the start of dialysis since we are able to treat symptoms as they arise.

We are also seeing that we can start a patient as an outpatient, and avoid the first hospitalization before dialysis, if the patient is closely followed by our Care Coordinator. We estimate that we save Medicare $26,000 for each patient that starts dialysis as an outpatient, avoiding the hospitalization before dialysis. [Analysis done by William MacBain, Gorman Health Group, utilizing Medicare 5% Claims data and 2013 USRDS data] In Spartanburg, SC, 58% of the patients who received CKD Care Coordination and started dialysis in 2014 started as an outpatient, avoiding the first hospitalization before starting dialysis. In contrast, in the same community, only 2% of those patients who started dialysis in 2014 and did not receive CKD Care Coordination were able to start as an outpatient.

Question #1 – Improvements to Medicare Advantage for patients living with multiple chronic conditions

Patients with CKD often have numerous comorbid conditions, including hypertension and diabetes. Patients with CKD and hypertension or diabetes are more costly, with a greater opportunity to improve their care and decrease their cost of care. We hope to start a few pilot programs with Medicare Advantage plans to better coordinate care for CKD patients with a per patient per month fee in which we would put a portion of our fees at risk while sharing in a percentage of savings once a threshold level of savings has been reached. We would look forward to sharing our results.

Question #2 – Transformative policies that improve outcomes for patients living with chronic diseases either through modifications to the current Medicare Shared Savings ACO program, piloted alternative payment models (APMs) currently underway at CMS, or by proposing new APM standards

We will be starting three ESCOs on July 1, 2015. We currently provide CKD Care Coordination in these locations and are using the infrastructure developed for the ESCOs to improve care management for patients with CKD. We would be very interested in extending the CEC to include late stage CKD.

In addition, we anticipate that there is an opportunity for us to partner with ACOs to manage patients with stage 3b, stage 4 and stage 5 CKD. Under such collaboration we anticipate that there would be a per patient per month fee, with a portion of the fees at risk, and the opportunity to share in a portion of any savings.

Question #3 – Reforms to Medicare's current fee for service program that incentivize providers to coordinate care for patients living with chronic conditions

We note that the Centers for Medicare and Medicaid Services (CMS) currently allows for a physician practice to receive a chronic care management (CCM) services fee for every month in which 20 minutes of care coordination is provided to patients meeting certain conditions. Because of the intensity of services provided to patients with CKD in our program, we do not expect that we will be able to cover all of our direct costs for Care Coordination following this process. However, it would offset part of the cost for CKD care coordination if we were able to bill for these services following the same process.

Question #4 – The effective use, coordination and cost of prescription drugs

Patients with CKD have highly complex medication regimens and disproportionately higher total cost of care compared to the general Medicare population. Clinical outcomes remain poor and lack of optimization of medication therapy may be one factor. Medication management services meaningfully improves clinical outcomes in patients with diabetes and hypertension; two common disease that cause and increase progression of CKD.

Early identification of CKD and interventions to improve medication prescribing and utilization will help prevent or slow kidney disease and eventual progression to dialysis. The need to provide consistent, comprehensive medication therapy management (MTM) services to CKD patients is imperative. DCI currently provides MTM services that meet or exceed CMS MTM requirements. We will provide population-wide pharmacovigilance to all patients in our three ESCOs and are interested in expanding this service to patients with CKD, not on dialysis. Through MTM and pharmacovigilance efforts, our MTM program improves patient medication use and safety, assists in medication reconciliation coordination and reduces unnecessary medication cost.

A patient with CKD has a high likelihood of having a Medication Related Problem (MRP). An MRP is defined as an, "undesirable event experienced by the patient which involves, or are suspected to involve, drug therapy, and that interferes with achieving the desired goals of therapy." In addition, as CKD progresses, the prevalence of MRPs rises.

Whenever MTM services are provided to patients with CKD, a typical medication review identifies an average of 3.2 clinically important and distinct MRPs. Additionally, medications are implicated in nearly 50% of hospitalizations; considered the sole reason for admission 18% of the time, and considered a contributor but not the sole cause for admission 29% of the time when a CKD patient is admitted to the hospital.

With our current MTM management of patients on dialysis, we have found similar results. We expect that we will see the same opportunities to improve care when we expand our MTM services to patients with CKD, not on dialysis. In an analysis of 207 hospitalizations in patients on dialysis since January 2015, medications were implicated in 39.6% (n =82) of hospitalizations. Of those, 36.6% (n = 30) and 57.4% (n=43) could have been definitely avoided or possibly avoided; respectively.

In another evaluation of patients on dialysis, nearly 50% of MRPs identified were pre-existing, while another 50% occurred during hospitalization (26.7%) or at discharge (25.5%). This suggests that more than 70% of MRPs could be addressed by MTM during routine care (in-center, pre-existing MRPs) and at transition back to the dialysis unit (discharge MRPS) potentially preventing readmission. Taking those points into consideration it is not surprising that dialysis patients receiving MTM services from DCI after discharge from the hospital had fewer hospitalizations (1.8 ± 2.4 vs 3.1 ± 3; p=0.02) and a trend toward reduced lengths of stay while hospitalized (9.7 ± 14.7 vs 15.5 ± 16.3 days p=0.06).

Within the DCI MTM program, we have identified 2918 MRPs in 913 unique patients on dialysis (mean 3.2 per patient). The number of MRPs decreases as we continue to provide quarterly MTM services for these patients. Since January 2015, DCI MTM provided 285 post hospitalization reviews in 190 unique dialysis patients. Of those hospitalization events, the 30 day readmission rate was only 14.7%; much less than the expected 32.5% readmission rate.

Question #5 – Ideas to effectively use or improve the use of telehealth and remote monitoring technology

The incorporation of telehealth technology and processes is of great interest in the medical community. We will utilize telehealth for the provision of Medication Therapy Management services for the 3 ESCOs serving dialysis patients. We anticipate that we will deliver over 1,800 patient-pharmacist MTM telehealth video conferences each year. Over the past two years from the DCI MTM location in Albany, NY over 200 unique telehealth (i.e., video conferencing) MTM encounters were provided to patients located in several states including CA, TN, and SC and will soon be provided to patients located in NJ and NY. This is an interdisciplinary program, involving pharmacists, nurses and physicians. Recently a component of our program description and interim results of a NY - CA based telehealth initiative were presented at the 2014 American Society of Nephrology meeting in Philadelphia, PA. Our abstract and poster entitled "Telehealth delivery of medication therapy management (MTM) in ESRD patients" described a local (MD, RN in California) and remote (RPh in New York) interdisciplinary team approach that resulted in improved patient medication management. We are interested in expanding this use of telehealth services for MTM to include patients with CKD, not on dialysis.

Question # 6 – Strategies to increase chronic care coordination in rural and frontier areas

We see great opportunities to improve CKD Care Coordination for patients in rural and frontier areas. If given the opportunity, we would be interested in implementing a pilot in Montana and central Missouri.

Question #7 – Options for empowering Medicare patients to play a greater role in managing their health and meaningfully engaging with their health care providers

The primary purpose of our Care Coordination program is to empower patients to play a greater role in managing their health and meaningfully engaging with their health care providers. By providing one on one in person education, instead of telephonic education, our Care

Coordinators are able to learn about a patient's life goals and then work with the patient to help him or her have the life he or she wants, without having his or her kidney disease get in the way.

During the first visit, the care coordinator talks with the patient for up to an hour and a half. The patient has the opportunity to ask any questions that he or she may have, and a plan for care is started. The Care Coordinator continues to meet with the patient until he or she is able to better manage his or her other medical conditions or until he or she selects his or her optimal choice at the transition in care. For a patient choosing a therapy at the transition in care, the Care Coordinator will continue to work with the patient to help the patient implement his or her choice.

We will also implement a system of periodic electronic check-ins for our patients with CKD. These check-ins will provide important information to our patients concerning their kidney disease. We expect that the combination of in person care coordination and electronic patient engagement will maximize the likelihood that patients will be engaged in their care.

We will be periodically evaluating patient engagement in the CEC using the Patient Activation Measure (PAM). We would be interested in extending this evaluation back to patients with CKD if this would be of benefit.

Conclusion

We are pleased that you have dedicated so much time and interest in tackling the difficult battle against chronic disease. We are more than willing to make ourselves available as a resource to you and your staffs at any time. We encourage the Finance Committee and the bipartisan chronic care working group to work with those who are treating chronic kidney disease, as it truly is a major health issue that needs to be addressed and can help prevent individuals from needing dialysis. As a nonprofit provider, we place the patient first in all the decisions we make. We would be glad to discuss any of these suggestions in greater detail at any time. If you have any questions, please feel free to contact me at 615-342-0435 or doug.johnson@dciinc.org.

Sincerely,

Doug Johnson, MD
Vice Chairman of the Board