DIALYSIS CLINIC, INC.

A Non-Profit Corporation

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January 26, 2016

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 in response to your Bipartisan Chronic Care Working Group Policy Options Document. DCI is a nonprofit provider of care for patients with kidney disease. DCI was founded forty-five years ago (two years before Medicare covered dialysis services) to save the lives of five patients in Nashville, TN. We currently care for more than 15,000 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 2014.

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 3,500 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, allow them to be better prepared for dialysis so that their first dialysis is not in a hospital, as well as increase their likelihood of being a candidate for transplant. We note that we are currently managing more than 600 patients with stage 5 kidney disease without the use of dialysis. We have learned that we can safely and efficiently manage these patients and keep them off dialysis until the point that it is necessary for them to transition to their next step in care.

As we have expanded our CKD Care Coordination program, and refined our interventions for patients with stage 3 (GFR 30 – 60) and stage 4 (GFR 15 – 30) CKD, we are learning that much can be done to improve the care of patients with CKD, regardless of whether they may progress to needing dialysis. There are also great opportunities to decrease the cost of care as we implement a more systematic approach to care for these patients. A patient with stage 3 CKD is twice as expensive as the typical Medicare patient; a patient with stage 4 CKD is three times as expensive. A patient with CKD, congestive heart failure, and diabetes (which are common comorbidities) is more than three times as expensive as the typical Medicare patient.

We see kidney disease, both CKD and end stage renal disease (ESRD), as the prime model of a chronic illness. Several factors underscore this. First, both CKD and ESRD don't exist alone—they are accompanied by multiple co-morbidities, including diabetes and congested heart failure. Secondly, kidney disease, including and especially ESRD, can exist over many years and is therefore the epitome of chronic illness that demands multimodal, highly coordinated care. Kidney disease should be a prime focus for the new care models that the Committee seeks to encourage and we were pleased to see specific policies related to ESRD listed and believe that much can be done with many of the chronic care initiatives. Over 20 million Americans suffer from kidney disease, at an estimated cost to the Medicare program of more than $50 billion in 2013, representing 20% of all Medicare spending in this group. In addition, Medicare fee-for-service spending for ESRD beneficiaries rose by 1.6%, from 30.4 billion in 2012 to 30.9 billion in 2013, accounting for 7.1% of the overall Medicare paid claims costs. Clearly, both CKD and ESRD are very important issues that need to be addressed in a more comprehensive, coordinated manner than currently.

In response to the issue areas that were listed in your letter, we wish to focus on the following:

Expanding Access to Home Hemodialysis Therapy

DCI applauds the Working Group for the inclusion of this policy and we support the proposal of expanding Medicare's qualified originating site definition to include free-standing dialysis facilities in any geographic area. However we hope that this policy would also include home peritoneal dialysis and not just home hemodialysis. At DCI, 89% of patients benefitting from dialysis at home use peritoneal dialysis instead of home hemodialysis.

We see both home hemodialysis and peritoneal dialysis as important options in dialysis care. Dialyzing at home allows more independence, better patient satisfaction and costs Medicare less. Any change to remove potential barriers to a patient starting home dialysis should be made. Many patients must travel long distances for their monthly physician visit. If a patient were able to have a portion of those visits by telehealth at a nearby clinic, this would substantially decrease the burden on some patients who would otherwise need to travel a longer distance.

We also recommend that the home should be an originating site, in addition to a dialysis clinic. For healthier patients, allowing a telehealth option from the patient's home could give a patient the convenience they much need. 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.

However, we note that the Working Group could go further to benefit care to patients, and decrease barriers to choosing home dialysis, by extending the telehealth option to the current requirement for support services provided by the dialysis provider. If a patient can avoid travel to visit a nephrologist in person, but still must visit the clinic for support services, the benefit from telehealth is minimized.

To address your question on safeguards, we would recommend that healthy patients have at least one in-person nephrologist visit every other month. This frequency would match the current every other month requirement for support services provided by the dialysis provider. In addition, we recommend that dialysis provider home programs be encouraged to use telemedicine to improve monitoring for patients who do not come to the clinic on a monthly basis.

Although not directly mentioned in your paper, we also want to point to the financial benefit of achieving higher levels of patients on home hemodialysis or peritoneal dialysis. The Government Accountability Office's (GAO) November 2015 report on home dialysis noted that a barrier to home dialysis is limited nephrologist reimbursement. If a nephrologist is able to have a monthly visit via telehealth instead of not being able to bill the monthly capitation payment for a patient who is doing well because the patient does not visit on a monthly basis, nephrologists would have less of a financial disincentive to care for patients dialyzing at home.

Providing Medicare Advantage Enrollees with Hospice Benefits

DCI supports the proposal to include the hospice benefit under Medicare Advantage plans. At the time that any patient chooses hospice, the last thing we should be doing is forcing a disruption in their care team, even if they are no longer receiving curative or chronic care. This would allow providers to continue to provide care for MA patients with CKD, who have chosen medical management without dialysis and for MA patients on dialysis who choose to stop dialysis.

DCI has established a CKD Care Coordination Program, "Reach Kidney Care", in 28 locations, involving 3,500 patients, to educate patients on how they can stay healthier and thereby avoid, or at least delay dialysis. One of our primary interventions is supporting a patient who chooses medical management without dialysis. We are seeing that between 10 – 20% of patients who are transitioning to the next step in care are choosing medical management without dialysis rather than starting dialysis. As part of our program, DCI wishes to continue to provide services for the patient and the patient's family, once the patient starts hospice. However, under current MA plans, the patient would transfer immediately to traditional fee-for-service Medicare once she/he starts hospice and any care from their Reach Kidney Care program would be suspended. This is the worst time to have an abrupt handoff in care and the most important time to continue to provide support to the patient and their family. If all Medicare Advantage plans were to be responsible for hospice care, we would be able to continue to serve the kidney patient during the most critical time.

We are currently in negotiations with a community-based Medicare Advantage plan to provide care for approximately 2,000 patients with CKD. One of the clinical challenges to management of these patients is that the MA plan will no longer be responsible for a patient once the patient selects hospice care. We see a smooth transition to end of life as a critical opportunity to improve care for our patients and consider this to be the worst time for us to abandon our patients. We are concerned that with the current structure patients who would choose hospice may not make this choice if they learn that they will lose the support from a CKD Care Coordinator at this time.

Allowing End Stage Renal Disease Beneficiaries to Choose a Medicare Advantage Plan

DCI supports the proposal to allow all beneficiaries on ESRD, regardless of when the condition began, be permitted to enroll in a Medicare Advantage plan. We feel that all ESRD patients should have a choice in all of their care, including the type of treatment and what type of insurance plan works best for that individual. High quality MA plans may be able to provide better care and with additional policy changes (as stated in your working group policy options document) to Medicare Advantage plans for chronic care patients, there may be many more MA plans suited to serve ESRD patients.

If Congress adopts this change in policy, there will need to be a carefully constructed set of transition safeguards. Also, on an ongoing basis, consideration should be given as to whether a new ESRD beneficiary should be entitled to a Special Enrollment Period (SEP), or be eligible to apply under the next Annual Enrollment Period (AEP), when they can better compare plan costs, benefits and provider networks.

Providing Continued Access to Medicare Advantage Special Needs Plans (SNPs) for Vulnerable Populations

While traditional Medicare Advantage plans already serve ESRD patients, by virtue of their having been enrolled prior to their onset of ESRD, not all are well equipped to care for these patients with multiple, severe chronic conditions. If greater flexibility is given to general MA plans to better serve chronically ill patients (such as ESRD or CKD), we would recommend a trial period, as was done for SNPs.

A better policy alternative may be to improve and grow the Chronic Condition Special Needs Plans (C-SNP) option. Currently, CMS recognizes 15 chronic conditions in the C-SNP program. One of those is ESRD, which offers a care plan focused specifically on the needs of ESRD patients. These plans are designed around an ESRD patient and therefore can better align care for many ESRD beneficiaries. CMS also allows for C-SNPs which address multiple conditions. We would recommend that the Working Group specifically authorize C-SNPs around four, closely related conditions; CKD, diabetes, mellitus, cardiovascular disease and congestive heart failure.

Medicare has been focused on treatment of beneficiaries with kidney failure, through ESRD, but has largely neglected the potential to improve beneficiary health and lower costs by going upstream to address chronic kidney disease. Medicare spending for patients with CKD aged 65 and older exceeded $50 billion in 2013, representing 20% of all Medicare spending in this age group. Moreover, CKD is closely associated with other comorbidities including diabetes and congestive heart failure.

Yet, only 7.7% of patients with Stage 3 CKD even know they have kidney disease, and only half with Stage 4 CKD, whose kidneys are now seriously compromised, know they have kidney disease. Left untreated or poorly managed, these patients may progress to end stage disease requiring dialysis. The cost to the Medicare program alone is stark, growing from $23,680 per year at Stage 3, to $84,645 per year on dialysis.

Both an ESRD C-SNP and a CKD (and related comorbidities) C-SNP should be specifically authorized under a permanent SNP program, thereby giving plans, providers and patients, greater ability to plan and effectively implement C-SNPs for patients with chronic conditions.

Improving Care Management Services for Individuals with Multiple Chronic Conditions

DCI has seen firsthand the benefit of improved care coordination with CKD (and ESRD) patients, including through the work of non-physician health professionals. Not only do we see a clear clinical benefit, but we also anticipate that we will see substantial cost savings in your policy options paper. The criteria for a patient for the potential new code could be any of those listed in the paper (five or more chronic conditions, one chronic condition in conjunction with Alzheimer's or a related dementia, or a chronic condition combined with impaired functional status). Under the Centers for Medicare and Medicaid Services' (CMS) current policy for billing under CPT code 99490, a patient must have two or more chronic conditions, among other requirements. There must also be a comprehensive care plan in place. Importantly, CMS rules provide not only for non-physician providers, such as nurse practitioners to provide services directly, but also permit time spent by clinical staff to provide chronic care management (CCM) services under *general* supervision to count toward the current 20 minute/month limit.

Currently, we use nurses, dietitians and social workers to provide care coordination. If more non-MD/DO health care providers could be considered qualified health professionals, and be able to use the CCM code (99490), or be considered clinical staff, it may allow more patients to have the opportunity to participate in a care management model. Nephrologists and primary care providers are stretched thin in their daily schedules and having nurses (or other care providers) serve in this role could greatly assist in patient care.

We commend the working group's efforts on improving care management for those with multiple chronic conditions. As you move forward in creating policy, we hope a continued dialogue will occur with providers and payers on the best way to reimburse and increase the quality of care.

Addressing the Need for Behavioral Health among Chronically Ill Beneficiaries

This year, a mental health measure was added to the ESRD Quality Incentive Program (QIP). The measure is depression. At DCI we are currently implementing a plan to address depression for patients on dialysis. However, we are learning that in many communities once a patient who is depressed is identified, there is no next step in the process. ESRD patients deal with depression, anxiety and other mental health disorders primarily due to the disease that keeps them in a dialysis chair several days a week. Better integration of care for those with serious chronic diseases is necessary. We believe if patients who needed mental health services were able to get them, they would become a better and more engaged patient overall.

CMS, through the Center for Medicare and Medicaid Innovation (CMMI), launched the Comprehensive ESRD Care Initiative (CEC) in October 2015. DCI was chosen to participate in three of the twelve ESRD Seamless Care Organizations (ESCOs). ESCOs have been established to test new payment and service delivery options for ESRD beneficiaries. They currently screen for several aspects of behavioral health (depression, anxiety, substance abuse and alcohol abuse). Any recommendations that GAO conduct a study on the integration of behavioral health and primary care in Accountable Care Organizations (ACOs) should also include ESCOs. We would note that CMS lists ESCO's as among its current ACO models.

Adapting Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees

Medicare Advantage plans can offer additional supplemental benefits beyond the standard, required Medicare Part A and B benefits. For example, under Enhanced Disease Management (EDM), plans can offer benefits and services focused on target groups needing specialized case management and/or educational activities. Supplemental benefits do have to be "health related" which CMS approves on a plan-by-plan, annual basis. CMS has become more inclusive of supplemental benefits and the types of professionals who can provide them.

The provision of supplemental benefits has functioned "a la carte" thus far, which offers a flexible approach. It could be improved by also packaging supplemental benefits by chronic condition which would be preapproved, thereby making it more likely that plans would offer them. It would be extremely beneficial if Medicare Advantage plans could alter their plan design for patients with ESRD or CKD.

Expanding Supplemental Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees

DCI applauds your policy to expand supplemental benefits for chronically ill patients in MA. As a nonprofit, we often go above and beyond what is covered in order to provide better care for our patients. In our daily course of care, we find that providing a nutritional supplement greatly increases the quality of care for our patients. Our analysis of our nutritional supplement program found a 29 percent decrease in mortality for those patients on an automated nutritional supplement protocol; similar benefits were found in an analysis of the Fresenius nutritional supplement program. Medicare Advantage plans can offer group nutrition education, some one-on-one, medical nutrition therapy and even some meals, but only for a limited time, typically a couple weeks. While this may be appropriate in the period immediately following an acute episode, it falls short of what is needed for those with a chronic condition such as ESRD.

Increasing Convenience for Medicare Advantage Enrollees through Telehealth
As stated in a previous question, dialyzing at home allows more independence, better patient satisfaction and can cost Medicare less overall. Any change to remove potential barriers to a patient starting and continuing on home dialysis should be made. Many patients must travel long distances for their monthly visit. If a patient were able to have a portion of those visits by telehealth, this would substantially decrease the burden on patients, as well as their family and caregivers, who would otherwise need to travel to a dialysis clinic. Therefore, we support your policy to permit MA plans to include certain telehealth services in its annual bid, and home hemodialysis and home peritoneal dialysis patients should be allowed to use such services.

Providing ACOs the Ability to Expand Use of Telehealth

Once again, dialyzing at home can be a better option for many patients, including those patients in ESCOs. We ask that any change applied to Accountable Care Organizations be applied to ESRD Seamless Care Organizations as well. As we note above in our response on telehealth, both the home and the dialysis clinic should both be considered as originating sites. For healthy patients, we would again, recommend at least one in-person nephrologist and clinic visit every other month.

Developing Quality Measures for Chronic Conditions

DCI supports the recommendation to develop quality measures for chronic conditions and believes that such measures will benefit both CKD and ESRD patient populations. Medicare has been focused on treatment of beneficiaries with kidney failure, through ESRD, but has largely neglected the potential to improve beneficiary health and lower costs by going "upstream" to address chronic kidney disease, which not only leads to kidney failure but is also strongly associated with cardiovascular disease and metabolic disorders, most especially diabetes. Beneficiaries are often unaware that they have CKD until it is well advanced. There are elements in the existing Medicare program that can help identify those at risk and promote better coordination of their care: the annual wellness visit along with high risk assessment; diabetes screening; cardiovascular screening; chronic care management services; and Part D's Medication Therapy Management program. Currently they all operate as separate and distinct payment provisions. More could be done to coordinate their delivery to focus on CKD.

Moreover, with the enactment of the Medicare Access and CHIP Reauthorization Act (MACRA), Medicare's current disjointed and overlapping quality and performance measures will be consolidated into a single merit-based incentive payment system (MIPS). The measures that are incorporated into MIPS can be honed to incentivize physicians and other clinicians to better identify, educate, and care for patients with CKD. DCI believes that overall outcome measures must be developed and used to assess more accurately the quality of the care provided by physicians, as well as the entire care team. Scoring highly on the MIPS' outcome measures (both quality and cost) should be the basis of incentive rewards for physicians, nurses, and the whole care team.

Encouraging Beneficiary Use of Chronic Care Management Services

As discussed above, the use of the current CCM code and a proposed higher level code can improve care to many beneficiaries. Both codes would still be subject to the beneficiary 20% coinsurance which could remain a barrier, particularly a high level code with a higher payment level. Therefore DCI supports waiving the beneficiary co-pay in these instances. Any initiative to promote chronic care management is good policy, however we hope that you would go beyond just waiving an $8 co-pay. More still needs to be done to increase patient engagement especially in ESRD and CKD.

Many patients do not even know they have kidney disease, until it is too late. Others are ill-prepared to transition to dialysis when it can no longer be avoided. Starting dialysis is a life-changing event, making it critical that patients be engaged in the decisions about their options, and the management of their care when starting. DCI has been working for several years with patients to accomplish these objectives through:

- Chronic Kidney Disease Care Coordination
- Pre-Dialysis Education with Navigation Services
- Transition Care Coordinators
- Family and community outreach & mobilization

Across each of these practices, the goal is to empower patients to play a greater role in managing their health and meaningfully engaging with their health care providers. DCI believes that the potential of having patients and families manage their own health has barely been tapped. In fact, our current system of care emphasizes the professional side almost to the exclusion of real patient involvement.

Any new approach to improving the care provided to patients at risk for, or living with, chronic illness must incorporate this potential if meaningful improvements are to be made in the incidence and prevalence of these disease states, the quality of care, and the cost of care. This belief is based on our many years of caring for patients with renal disease, not just those with ESRD.

By providing one-on-one and small group in-person education, care coordinators, educators, and navigators 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 their kidney disease get in the way. It is also a means by which patients can be made aware of their options, such as home dialysis rather than in-center care. As a result, we see significantly higher use of home care, which can lead to a high quality of care (with decreased use of medications, hospital visits, etc.) and a better quality of life. As we noted earlier, our Reach Kidney Care program educates and works with patients on how they can stay healthier and thereby avoid, or at least delay, dialysis. And, if dialysis is necessary, to know their options, including home dialysis, as well as be better prepared with access via fistula, rather than catheter. They do this by working one-on-one with a care coordinator. 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 of care gets started. The care coordinator continues to meet with the patient until the patient 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.

Empowering patients also means mobilizing families and the larger community to promote healthy living habits and to enlist individuals who can help others with similar health problems. Peers, as well as healthy individuals and family members, can help patients with the many challenges they have in daily life, such as: personal hygiene, proper taking of medication, exercise, nutrition, and emotional problems, such as depression. These individuals effectively become "coaches," and/or peer mentors, who have the back-up of nurses and doctors by means of the many digital tools we now have at our disposal to achieve better health outcomes. We should point out that this component of the overall approach we are proposing to increase the engagement of individuals in their own health has the additional advantage of filling a great need identified by our patients -- reducing the isolation that they feel as ESRD patients.

Eliminating Barriers to Care Coordination under Accountable Care Organization

While the working group's document refers generally to ACOs, we urge that it specifically include ESCOs as well. Indeed, in its most recent statement on ACOs, CMS now explicitly includes the recently launched ESCOs as part of the broader ACO community. If ESCOs could waive or decrease standard Medicare Part A and Part B cost-sharing responsibilities, including deductibles and coinsurance payments, based on specific patient outcomes, patient engagement could greatly improve. We note that CMS does not currently allow non-large dialysis organizations (LDOs) in the ESCO program to accept downside risk. Until non-LDOs are given the opportunity to accept downside risk, non-LDO ESCOs should also benefit from this change.

Regarding whether items or services should be defined through rule-making or left to the discretion of an ACO, we would recommend that both options be allowed. Congress could authorize and then CMS, through notice and comment, provide a list of services. At the same time, Congress could provide authority to the Secretary to also consider ACO requests, case by case.

Regarding the issue of beneficiaries with Medigap or employer provided supplemental coverage, the workgroup points to an unfortunate irony. Many beneficiaries who do not have such supplemental coverage for coinsurance, copays and deductibles, are the very beneficiaries who need better chronic care. They tend to be older and lower income and less likely to afford Medigap or have employer provided coverage, and would benefit from waived copays, coinsurance and deductibles.

Expanding Access to Prediabetes Education

Diabetes is one of two primary causes of kidney disease and DCI believes it is critical to go upstream to make it less likely that individuals are adversely impacted by diabetes. Therefore we support this recommendation to expand access to prediabetes education.

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