Home Dialyzors United

January 25, 2016

Honorable Orrin Hatch, Chairman
Honorable Ron Wyden, Ranking Member
United States Senate Committee on Finance
Dirksen Senate Office Building
Washington, DC

Re: Chronic Care Working Group Policy Options

Dear Senators Hatch, Wyden and Committee Members:

Home Dialyzors United (HDU) is pleased to have the opportunity to submit comments on the Bipartisan Chronic Care Working Group Policy Options Document and its proposed changes. We appreciate the committee's overall goal of improving the care and treatment of Medicare beneficiaries with multiple chronic conditions and expanding the use of telehealth strategies. Utilizing emerging, but proven, technologies to improve the lives of those with chronic diseases is necessary to ensure the best quality of life outcomes for patients.

The members and board of directors of HDU share those goals and we also look forward to assisting the Committee to ensure that those objectives are met for End Stage Renal Disease (ESRD) patients.

HDU, a 501(c)(3) non-profit organization, is the only dialysis patient group dedicated to home dialysis. The HDU Board of Directors and committees are composed entirely of volunteers who have been directly impacted by ESRD. Our mission is to inspire, inform, and advocate for an extraordinary quality of life for the home dialysis community through education, information and support.

Numerous studies have shown that patients with End-Stage Renal Disease (ESRD) who dialyze at home, using either peritoneal dialysis (PD) or home hemodialysis (HHD) have a much better quality of life and excellent treatment outcomes, including increased survival rates and fewer hospitalizations. For most patients with ESRD, dialysis is the primary option when renal replacement therapy (RRT) is needed, and the overwhelming majority of these patients undergo dialysis in outpatient dialysis centers. Few of these centers offer home dialysis, and of those that do, most only offer PD. In fact, only 2 percent of dialyzors in the U.S. currently use HHD.

Despite these findings, 90% of patients who need dialysis are treated in-center, most spending three to four hours, three times per week, connected to a dialysis machine. The treatment itself can be disabling, stressing the heart and other vital organs and may contribute to premature death. Transportation time to and from the center and extended fatigue from rapid treatments also contribute to poor quality of life and entire “lost days.” Although some centers offer treatment shifts that start after 5:00 P.M., most patients must undergo their in-center treatments during the day, making it difficult to work or engage in other life activities. Patients are often discouraged from being active partners in their care. With conventional dialysis treatments, many patients live to dialyze, rather than dialyze to live.

We know from personal experience that, with the right dialysis treatment, patients with ESRD (and their families and care partners) can lead a normal life, enjoy family and friends, and pursue employment, education, volunteer, and leisure activities. Home hemodialysis usually offers gentler, more frequent, and/or extended time dialysis, which translates into a quicker post treatment recovery, fewer side effects, and a more normal diet. Home patients enjoy more freedom and flexibility to live a normal life.

Historical Context of Dialysis Treatment

In October, 1972, Section 2991 of Public Law 92-603 created the National End Stage Renal Disease Program that extended Medicare benefits to cover the cost of medical care for most individuals with ESRD. As new laws and policies are considered, we strongly encourage the committee to bear in mind the original Congressional Mandate in the Social Security Act:

> (6) It is the intent of the Congress that the ***maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated*** and that the ***maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment***. The Secretary shall consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.
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> SSA Section 1881(c)(1)(A)(i)(6)

The United States Renal Data System (USRDS) is a national data system that collects, analyzes, and distributes information about chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States.

The USRDS is funded directly by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). USRDS staff collaborates with members of Centers for Medicare & Medicaid Services (CMS) and others, sharing data and actively working to improve the accuracy of ESRD patient information. In its 2011 and 2012 Annual Data Report, the USRDS stated:

> “Thrice-weekly treatment may be inadequate for addressing the critical problems of persistent fluid overload, hypertension, LVH, and recurrent vascular access infections and complications.”

ESRD treatment is, in itself, unique. It is one of only a few conditions on the Social Security Disabilities Impairments list that includes the need for time consuming, lifelong treatments to sustain life. HDU ardently believes that minimizing the intrusion of dialysis into the daily lives of patients and their families can be accomplished by better utilization of home dialysis

However, HDU also fully realizes that improving care coordination and quality of care while reducing Medicare costs is a formidable challenge. To assist those efforts, HDU would like to offer comments to the Working Group on specific sections of the Policy Options Document as they relate to home dialysis.

Receiving High Quality Care in the Home

HDU agrees that the team approach to coordinated care in a safe and familiar environment is paramount for ESRD/dialysis patients. Care in one's own home allows dialysis patients not only treatment flexibility but the ability to be in control of their lives which translates into superior outcomes.

Expanding the Independence at Home Model (IAH)

HDU supports expanding the Independence at Home Program, and substituting a hierarchical condition categories (HCC) risk calculation for beneficiary eligibility in lieu of the current requirement of a non-elective hospitalization within 12 months of his or her IAH program participation. We would specifically support an IAH program targeting the chronic kidney failure population.

Choice of dialysis. In the U.S., there are *seven* ways to do dialysis, which cleans wastes and water out of the blood after the kidneys fail. But, 89% of Americans with kidney failure do just **one** type of treatment: “Standard” in-center hemodialysis (HD)— 3.5 hours of treatment three times a week, far less than in any other country, at the highest possible cost (about $60,000 per year, per person), and with the poorest outcomes of any option.

Expanding Access to Home Hemodialysis Therapy

HDU supports not only the measures that make home dialysis available to more ESRD patients but also the policies regarding increased use of telehealth to facilitate optimal care in the home setting.

We believe that telemedicine can be an effective substitute for most of the required monthly visits to the clinician. However, initially, HDU would support a face-to-face meeting every three or six months, or whenever requested by the patient. In order to promote high quality of dialysis in the home, we would also include the utilization of telehealth meetings for care planning and the documentation of that participation. The home dialyzor patient's home should qualify as an originating site for CMS payments under the telehealth regulations.

HDU also requests that the Committee carefully consider the alignment of new research and technology with current regulatory policy to facilitate the development and approval of home dialysis friendly innovations. We urge the Committee to expedite the delivery of new developments. A recent example of this is the FDA fast tracking of research projects and clinical trials, three of which are dialysis related.

Expanding access to home hemodialysis therapy cannot occur without breaking down existing barriers to its use. HDU feels there are several major barriers:

1) Dialysis centers are profit centers for corporations. Since the inception of the ESRD Medicare bundle, there has been a proliferation of brick and mortar dialysis centers and the consolidation of dialysis centers. Small dialysis centers have a difficult time surviving in a milieu dominated by large providers who utilize volume purchasing and corporate strategem seeking to satisfy shareholders rather than patients. Consolidation can also mean limited choice of treatments for patients and further travel times.

HDU was particularly interested in the recent GAO findings about trends in dialysis. With the increased capacity to provide in center hemodialysis (7.3%) surpassing the increase in in-center population (6.8%), there is a financial incentive to keep patients in-center, thereby utilizing surplus chairs. Centers that do not operate at capacity lose revenue.

2) When asking patients why they don't consider home hemodialysis as a treatment modality, the universal response, and the greatest barrier, is not having a care partner. HDU believes that this is an outdated requirement. One solution for eliminating the need for a care partner during home hemodialysis

treatments would be the additional availability of telehealth monitoring. However some patients might feel that real time monitoring of their home treatments is intrusive, in which case we recommend that an additional option of informed consent be available to the patient and the care team.

3) HDU is also concerned about the demographic changes in dialysis population, especially as baby boomers reach retirement age. Even though incident patients are now oftentimes older with more comorbidities, these factors alone should not be an automatic deterrent when working with a patient and family to select a treatment modality. Rather, each case should be evaluated individually, based on physical capabilities, patient preference and lifestyle.

4) Lack of education about home hemodialysis permeates all facets of care. Despite the mandate that patients be educated about all dialysis modalities, most patients and families receive their information about modality choice from word of mouth, other patients and/or the social media. Currently, approximately 2% of dialysis patients are being treated with home hemodialysis. Yet, when surveyed, over 90% of nephrology professionals would choose home dialysis (if transplant was not an option), with the vast majority of those choosing home hemodialysis for themselves. The majority of hospital personnel, nephrologists, nephrology fellows, and even first responders lack information or experience with home hemodialysis. Too many patients begin dialysis emergently which often results in a disabling in-center mindset of “learned helplessness.”

Advancing Team Based Care

Addressing the Need for Behavioral Health Among Chronically Ill Beneficiaries

The proposal to expand access to mental health services for people with chronic diseases is vital to dialysis patients, especially because depression can be a major impediment to “compliance” with medical prescriptions. Depression impacts all facets of quality of life and has been shown to be an independent predictor of mortality in the ESRD population.

Identifying the Chronically Ill Population and Ways to Improve Quality

HDU strongly supports the appropriate payment of those who participate in the Medicare program and agree that providers should be evaluated on the quality of the care that is delivered.

The options paper stresses that any policy recommendations must be budget neutral but ESRD is a unique condition. When ESRD is viewed alone, many of the HDU recommendations may appear to cost more but when hospitalizations, physician services and complications of dialysis that require additional medical treatment are considered, the cost picture may change. With the incidence of CKD increasing by 20% annually, this perspective must be broadened even further to include reducing the number of age appropriate ESRD patients receiving disability payments and increasing the number of employed taxpayers.

HDU also further recommends asking Congress to mandate that dialysis costs and payment rates be analyzed separately for each modality to remove payment incentives for any one type of treatment.

Payment for home hemodialysis should allow for more frequent and longer dialysis than the traditional in-center model of three times per week. The assumption should be that more frequent, slower hemodialysis is considered medically necessary and recognizing that the reduced labor and supply costs to dialysis centers when patients dialyze at home could reduce payment cost per session.

Developing Quality Measures for Chronic Conditions

The ESRD QIP is supposed to ensure that the center does not short-change patient care in its pursuit of profit, but the QIP is still a long way from ensuring that patients receive high quality care that provides them with an optimal quality of life, based on the patients’ values. For example, the QIP measures do not capture whether a facility consistently observes required infection control protocols. (We note that, under the CMS Survey and Certification Program, dialysis facilities must be surveyed before the facility can be certified to receive Medicare payments for their services, but that subsequent surveys are not conducted as often as needed.)

HDU strongly encourages the inclusion of more measures in the QIP that are important to patients– that is, to move ESRD care from adequate dialysis to optimal care. For example, for many patients, traditional in-center dialysis, which occurs during the workday, precludes maintaining gainful employment. According to 2010 USRDS statistics, only about 20% of chronic kidney failure patients, ages 18-54, are currently employed. Many persons with ESRD would prefer to work for a living, rather than living on disability benefits, but they do not have access to dialysis that will support their efforts to work. Moreover, persons with ESRD who are able to earn a living are also able to pay income taxes. In other words, patients who can dialyze at home, at their own rates of speed and dialysis intensity, and on their own schedules, may save the government thousands of dollars in health care spending and disability payments during their lifetime of treatments. HDU urges movement in the direction of real patient-centric outcome measures.

Empowering Individuals and Caregivers in Care Delivery

HDU strongly urges the Committee to include patients and care partners in every aspect of the care delivery process. Who better to offer input than those who live with chronic kidney failure every day? With the increased emphasis on patient engagement and patient empowerment, the Committee has the opportunity to be a leader in formulating a real paradigm shift.

While HDU believes that well designed studies and the resultant statistical data are a vital component of research, development and delivery of better treatment, we also feel that often patient and care partner involvement is left out of the equation. While scientific data derived from RCTs contribute to improvements, they do little to assess quality of life and the ability of patients and families to lead a normal life. There is no other chronic disease that, on a daily basis, affects literally every single aspect of life from the kitchen table to the bedroom and even into the broader community. Due to the nature of treatment, chronic kidney failure (ESRD) directly impacts the entire family.

In conclusion, we urge that the Committee support a “home first” culture by fostering not only new developments but also the education of all patients and health care personnel about the medical benefits and lifestyle advantages of home dialysis therapies.

Home Dialyzors United thanks the Committee for the opportunity to submit comments to the Committee and would be happy to meet with you to further the goals delineated in the Chronic Care Working Group Policy Options Document.

Sincerely,

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