National Renal Administrators Association

January 26, 2016

The Honorable Orrin Hatch
Chairman
Senate Finance Committee
219 Dirksen Senate Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
221 Dirksen Senate Building
Washington, D.C. 20510

The Honorable Johnny Isakson
United States Senate
131 Russell Senate Building
Washington, D.C. 20510

The Honorable Mark Warner
United States Senate
475 Russell Senate Building
Washington, D.C. 20510

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

The National Renal Administrators Association (NRAA) appreciates the opportunity to review and comment on the policy options document that was released by the Senate Finance Committee's Chronic Care Working Group in December. The NRAA shares the goals of the Working Group and strongly supports efforts to help improve and assist patients with chronic conditions through concrete improvements to the Medicare and Medicaid programs.

NRAA is a voluntary organization representing independent, regional and community based dialysis providers throughout the United States. NRAA represents primarily small and medium-sized dialysis organizations. Our 218 member companies operate over 1400 dialysis facilities. We treat nearly 127,000 patients in urban, rural and suburban locations throughout 44 states and three territories.

The policy initiatives being considered by the Working Group come at a critical time for patients with End-Stage Renal Disease (ESRD). The University of Michigan Kidney Epidemiology and Cost Center's US Renal Data System (USRDS) Coordinating Center recently released *The 2015 Annual Data Report: Epidemiology of kidney disease in the United States*[1]. The study found that the prevalence of end-stage renal disease is increasing in the United States. The size of the hemodialysis population and peritoneal dialysis population is over 60 percent larger than it was in 2000, and use of home dialysis increased 52 percent between 2003 and 2013. The patients we serve – including children – face challenges every day to carry out their daily lives while dealing with chronic kidney disease. These challenges often are compounded by the fact that these patients suffer from multiple chronic conditions, including diabetes, hypertension and cardiovascular disease. As such, the patients with ESRD that our members treat and serve each

[1] United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

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day stand to benefit the most from programmatic improvements to help vulnerable patients with chronic illness.

Several of the initiatives outlined in the Working Group's "Policy Options Document" have the potential to deeply impact individuals with chronic kidney disease and the providers who serve them. These include proposals to: (1) expand access to home dialysis therapies; (2) allow Medicare beneficiaries with ESRD greater opportunities to enroll in Medicare Advantage (MA) plans; (3) extend permanently or on a long-term basis the MA Special Needs Plan program for individuals with chronic illness; (4) expand chronic care management services, including behavioral health care, in the Medicare fee-for-service program; and (5) expand access under Medicare Part B for evidence-based lifestyle interventions that help people with prediabetes reduce their risk of developing the condition. Below, we offer for the Working Group's consideration, NRAA comments on these specific proposals and several others contained in the December 15, 2015 Policy Options document.

Expanding Access to Home Hemodialysis Therapy (*Page 7*)

Proposal Under Consideration: Under current law, telehealth visits for Medicare beneficiaries receiving dialysis treatment are subject to originating site limitations. In addition, Medicare requires beneficiaries receiving dialysis treatment in the home to receive a monthly clinical assessment. The Working Group's December 2015 policy options document proposes to expand Medicare's qualified originating site definition to include freestanding renal dialysis facilities in any geographic area. The Working Group also sought comments on a policy that would expand the availability of telehealth for patients receiving home therapy.

NRAA Comments: Many home therapy dialysis patients must travel long distances for their monthly visits. Increasing the availability and use of telehealth would substantially decrease the burden on patients who would otherwise need to travel to a dialysis clinic. This is particularly true for patients who reside in rural areas. Therefore, NRAA generally supports policies that would improve access to telehealth services, in part by loosening Medicare's originating site limitations. NRAA strongly supports allowing freestanding dialysis facilities to serve as originating sites for telehealth visits. NRAA also views home therapy dialysis as an improvement in patient care – more independence leads to improved patient satisfaction and, in many cases, could improve health outcomes. Therefore, we suggest that the Working Group consider broadening its proposed approach to include both the patient's home and expanding Medicare's qualified originating site definition to include freestanding renal dialysis facilities.

At the same time, we believe that for safety and clinical effectiveness reasons, dialysis patients—even those primarily receiving home support services through telehealth—benefit from face-to-face visits with dialysis clinics. To that end, NRAA suggests that home therapy dialysis patients who are receiving telehealth services in the home and are deemed "stable" by their physician be required to visit their dialysis clinic in person at a minimum of once every three months. As defined in 42 CFR 494.80(d), a patient is unstable if "he or she has had extended or frequent hospitalizations, or a marked deterioration in health status, or a significant change in psychosocial needs..." or "…when he or she is determined by the interdisciplinary team to have poor nutritional status, unmanaged anemia, and inadequate dialysis concurrently." Patients who

are deemed unstable by their treating physician should be required to visit a clinic on a more frequent basis, or, more frequently than once every three months. The NRAA believes these criteria should be flexible enough to allow providers to exercise appropriate clinical judgment/make appropriate clinical determinations regarding the stability of patients receiving telehealth services, and to accommodate for changing health conditions over time.

The NRAA also wants to bring to the Working Group's attention that, in addition to current limitations on telehealth services, there are other barriers to care for dialysis patients receiving home care that must be addressed to improve access and treatment for dialysis patients. Another barrier to home therapy dialysis is limited nephrologist reimbursement. The disparities in reimbursement impact most acutely those ESRD patients who receive care in rural areas of the country. An October 2015 report from the Government Accountability Office (GAO)[2] found that monthly Medicare payments to physicians for managing the care of home patients are "often lower than for managing in-center patients even though physician stakeholders generally said that the time required may be similar." If the Working Group and Committee seek to improve access to appropriate home care for ESRD patients, they also should consider improving the reimbursement for physicians managing the care of patients in the home. The NRAA stands ready to work with policy leaders to develop specific, appropriate improvements in reimbursement policy to ensure that patients receiving home dialysis services have access to necessary and appropriate care.

Providing Medicare Advantage (MA) Enrollees with Hospice Benefits *(Page 8)*

Proposal Under Consideration: The Working Group is considering requiring MA plans to offer the full scope of the hospice benefit provided under traditional Medicare. In addition, MA reimbursement may be adjusted to account for this additional benefit and the MA star quality measurement system would need to be updated to include measures associated with hospice care.

NRAA Comments: The NRAA generally is supportive of expanding MA coverage for hospice care. We believe that, with appropriate protections, allowing Medicare beneficiaries eligible for hospice to remain with their MA plan could improve care transitions and better serve both patients and their families during what is considered a critical transition period. At the same time, NRAA is very concerned that many MA plans do not adhere to Medicare payment guidelines. In addition, in our experience, too many MA plans restrict provider choice, offer unreasonably low reimbursement rates to providers, impose substantial and unnecessary paperwork requirements, and fail to provide timely and appropriate information to allow patients and their families – especially those suffering from chronic illnesses such as kidney disease – to obtain adequate information on available care and treatment options.

Therefore, NRAA strongly recommends providing additional oversight of the billing, payment and disclosure practices of MA plans. We also urge the Working Group and members of the Committee on Finance to consider providing ESRD patients, and others with critical chronic care needs, with additional protections under MA plans. For example, MA protections should be augmented to ensure that patients have access to adequate customer service support and appeal

[2] End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis, GAO-16-125: Published: Oct 15, 2015. Publicly Released: Nov 16, 2015.

rights to report and address limitations on care and differences between information provided at time of enrollment and subsequent provision of benefits.

Allowing ESRD Beneficiaries to Choose a Medicare Advantage (MA) plan (*Page 9)*

Proposal Under Consideration: The Working Group is considering allowing all beneficiaries with End-Stage Renal Disease (ESRD), no matter when the condition began, be permitted to enroll in a MA plan. Payment to MA plans for beneficiaries with ESRD would be adjusted to take into account this change.

NRAA Comments: The NRAA appreciates that broadening MA enrollment opportunities for ESRD patients enhances beneficiaries' care choices, and also may reduce total beneficiary out of pocket costs and improve care coordination. Despite these potential benefits, however, expanded MA enrollment may present significant challenges for both ESRD patients and the providers who serve them, without additional reforms. These challenges are especially pronounced for ESRD patients in rural areas of the country.

Should the Working Group and Committee on Finance move forward with policies that would allow broader MA enrollment options for ESRD patients, the NRAA strongly recommends that the Committee simultaneously adopt enhanced protections for beneficiaries with ESRD who enroll in MA plans, and providers who serve them. Such policies should be designed to ensure, at a minimum, that the billing and payment practices of MA plans be revised so that ESRD patients have access to adequate customer service support, such as satisfaction surveys. There also should be hotlines and other mechanisms available for both patients and providers to report plans and plan practices that reduce access to care, impose significant cost-sharing or paperwork burden requirements and do not deliver benefits that were promised upon initial enrollment.

In addition, the NRAA strongly urges the Working Group and Committee to require a robust study of MA payment, access, cost-sharing, provider network, customer service and information-dissemination practices before enacting policy changes that would expand MA enrollment for ESRD patients.

NRAA members, especially those serving patients in rural areas of the country, routinely experience barriers to providing care to ESRD when dealing with MA coverage. For example, MA plans unilaterally retract payments to ESRD providers, claiming that we do not follow Medicare billing guidelines. Often, these retractions are unfounded, and based on misreading by MA plans of basic Medicare payment and coverage policies. Appeals for these payment denials can take years to resolve, putting independent ESRD providers at financial risk. Some of our members also experience routine denials of Medicare dialysis add-on payments. Even after submitting proper paperwork and citing clear Medicare payment rules, MA plans have failed to make appropriate payment adjustments or even acknowledge their reimbursement errors. Because of overly restrictive MA plan travel limitations, many of our patients are unable to travel without facing undue financial or practical hardship.

The NRAA welcomes the opportunity to assist the members of the Working Group and Senate Finance Committee in adopting responsible policies to enhance ESRD patient choice and ensure

that they truly have access to affordable care. We recognize that expanded opportunities to enroll in MA plans can be an important component of this strategy. However, given some of the concerns outlined briefly above, we want to work with the Working Group members and Committee to ensure that additional analysis takes place before such changes are put in place and appropriate protections and oversight of MA plans accompany any expansion of ESRD patient enrollment opportunities.

Providing Continued Access to Medicare Advantage (MA) Special Needs Plans for Vulnerable Populations (Page 10)

Proposal Under Consideration: The Working Group is considering either a long-term extension or a permanent authorization of Medicare special needs plans (SNPs), including SNPs that enroll beneficiaries in need of institutional level of care (I-SNPs), SNPs that enroll beneficiaries eligible for both Medicare and Medicaid (D-SNPs), and SNPs that enroll beneficiaries with certain chronic diseases (C-SNPs).

NRAA Comments: As stated above, NRAA members often find that the billing and payment practices of MA plans – including subsets such as Special Needs Plans (SNPs) – may limit access to care or lead to care limitations for vulnerable patient populations, including those with ESRD. Therefore, the NRAA has serious concerns with a long-term extension or a permanent authorization of SNPs that serve these chronically ill patients at this time. At a minimum, appropriate government agencies, such as the General Accounting Office, should undertake a thorough examination of information dissemination, network adequacy, payment, billing, access and support services practices of MA plans prior to expanding on a long-term basis opportunities for ESRD patients to enroll in SNP plans that treat chronically ill patients.

Addressing the Need for Behavioral Health among Chronically Ill Beneficiaries (*Page 12*)

Proposal Under Consideration: The Working Group is considering developing policies that improve the integration of care for individuals with a chronic disease combined with a behavioral health disorder. Policies would encourage care integration whether the beneficiary elects enrollment in traditional Medicare FFS, a Medicare FFS Alternative Payment Model, or a MA plan.

NRAA Comments: A study on *The Prevalence of Depression in Chronic Kidney Disease (CKD)*[3] found that almost 23 percent of patients in the study were found to have interview-based depression and 40 percent of patients self-rated themselves as having depression. Another study on *The Prevalence of Symptoms in End-Stage Renal Disease: A Systematic Review*[4] found that almost 40 percent of patients had anxiety based on symptom prevalence.

Currently, there are very few options to improve care for patients with behavioral health issues. NRAA believes that care integration is critical for patients with behavioral health issues and we

[3] Palmer, S., et al. (2013). Prevalence of Depression in Chronic Kidney Disease: Systematic Review and Meta-analysis of Observational Studies.

[4] Murtagh, F., Addington-Hall, J, Higginson, I. The Prevalence of Symptoms in End Stage Renal Disease: A Systemic Review. Adv Chronic Kidney Dis. 2007; 14: 82-89

support the development of policies that seek to improve the integration of care for these individuals. The NRAA, therefore, recommends that Medicare policy be changed to expressly allow a range of licensed mental health providers to provide onsite services in dialysis facilities to ESRD patients. These providers should be permitted to code and be reimbursed for those services. Patients in the dialysis facility receiving treatment could easily receive mental health services during their treatment. These patients spend so many hours per week in dialysis that it is often a struggle to get them to go to other providers for their healthcare. Therefore, a policy supporting coordinated mental health care services at dialysis centers would help improve overall care.

Encouraging Beneficiary Use of Chronic Care Management Services *(Page 23)*

Proposal Under Consideration: The Working Group is considering waiving the beneficiary co-payment associated with the current chronic care management code as well as the proposed high severity chronic care code.

NRAA Comments: The NRAA feels that this proposal coincides with another policy proposed in the Working Group Options Paper – Improving Care Management Services for Individuals with Multiple Chronic Conditions (Page 11). The Chronic Care Code was created as an incentive for the marketplace to find savings in the coordination of the care that is delivered. NRAA believes that waiving the beneficiary co-payment would help to remove a barrier to Chronic Care Management Services. Therefore, NRAA is supportive of the policy change being considered.

Expanding Access to Prediabetes Education *(Page 26)*

Proposal Under Consideration: The Working Group is considering recommending that Medicare Part B provide payment for evidence-based lifestyle interventions that help people with prediabetes reduce their risk of developing diabetes. The Secretary would be required to establish criteria for this program in accordance with the standards under the National Diabetes Prevention Program established by the Centers for Disease Control and Prevention.

NRAA Comments: The NRAA supports this proposal. Diabetes is one of two primary causes of ESRD and policies that encourage early intervention and prevention of diabetes, if properly implemented and proven effective, could be very helpful in reducing the incidence of ESRD. We want to be sure that funding for expanded prediabetes education not be taken from other programs, or by reducing reimbursement for needed treatments for patients with chronic illness, including kidney disease.

NRAA feels that, in order for this program to be successful, appropriate oversight of this new program is essential. Medicare should implement a system for tracking fraud and abuse once the funds have been allocated to these training programs to help ensure that the funds are not wasted. Medicare should develop a packaged training program, and ongoing oversight, with specific criteria detailing:

- Minimum qualifications for who can provide and bill for the service (RN educators, dietitians, clinical specialists)

- A maximum number of training sessions
- Minimum mandated program content (to include patient training competency testing)
- A method to measure success so the program cannot permanently exist without the ability to measure its effectiveness
- Criteria to determine and oversee eligible participating providers (such as nurses, dietitians, clinical social workers, and others) who have the training and qualifications to provide such training and education for patients.

Study on Obesity Drugs *(Page 30)*

Proposal Under Consideration: The Working Group is considering requiring a study to determine the use and impact of obesity drugs in the Medicare and non-Medicare populations. The study could: specifically detail the utilization of such drugs and any subsequent impact on medical services that are directly related to obesity, including by subpopulations determined by the extent of obesity; examine medical interventions for individuals not taking obesity drugs; and examine the experience of MA-PDs that cover obesity drugs as a supplemental benefit.

NRAA Comments: Obesity is the number one predictor[5] of type 2 diabetes. Obesity and diabetes are major causes[6] of Chronic Kidney Disease (CKD) and ESRD. Hypertension, along with obesity and diabetes, are considered "highly interrelated"[7] and contribute to the "development and progression of renal disease." A study on utilization of obesity drugs and any subsequent impact on medical services that are directly related to obesity would help to understand the link between obesity and these obesity-related illnesses.

Conclusion

NRAA appreciates your consideration of these recommendations for improving care for Medicare patients with chronic conditions, especially those with Chronic Kidney Disease and End Stage Renal Disease. We stand ready to work with you, be a resource to your staff and continue ongoing dialogue with the Working Group and members of the Senate Finance Committee to improve care for ESRD patients. If you have any questions, please do not hesitate to contact Marc Chow at mchow@nraa.org or 215.564.3484 (ext. 2294).

Sincerely,

Helen Currier
President

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[5] Obesity Society: Your Weight and Diabetes, February 2015.
[6] Obesity and diabetic kidney disease, Med Clin North Am. 2013 Jan; 97(1):59-74. doi: 10.1016/j.mcna.2012.10.010. Epub 2012 Nov 27, Department of Physiology and Biophysics, University of Mississippi Medical Center, Jackson, MS 39216-4505, USA..
[7] Obesity and diabetic kidney disease, Med Clin North Am. 2013 Jan; 97(1):59-74. doi: 10.1016/j.mcna.2012.10.010. Epub 2012 Nov 27, Department of Physiology and Biophysics, University of Mississippi Medical Center, Jackson, MS 39216-4505, USA..