



FRESENIUS MEDICAL CARE

June 22, 2015

By Electronic Mail to: chronic_care@finance.senate.gov

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

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

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

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

Dear Senators Hatch, Wyden, Isakson, and Warner:

Fresenius Medical Care North America (“FMCNA”) is pleased to provide comments in support of the Committee’s initiative to improve chronic disease care in the Medicare program. We appreciate your efforts to address and improve care for the chronically ill through innovations and new programs in Medicare Advantage (“MA”) and in traditional fee-for-service (“FFS”) systems. As a company dedicated to serving individuals with renal and other complex chronic diseases, we are especially enthusiastic about working with you to make the Medicare program more efficient and more responsive to the needs of individuals with chronic diseases.

ABOUT FMCNA

FMCNA is the world’s leading provider of products and services for people with chronic kidney failure. Our 2,200 outpatient dialysis clinics serving 170,000 individuals in the United States provide dialysis therapy, a vital blood cleansing procedure that substitutes the function of the kidney in the case of kidney failure. In addition, FMCNA creates high-performance specialized networks that provide care for the full spectrum of needs presented by chronically ill individuals. Individuals with End Stage Renal Disease (“ESRD”), a disabling and complex chronic condition, frequently confront other co-morbid conditions that require hospitalization and visits to other specialists. FMCNA coordinates among those sites of care through clinical networks that include hospitalist, cardiology and vascular care, and laboratory, pharmacy and urgent care services, all among providers, specialists and the dialysis facility. FMCNA’s

integrated care management programs are designed to reach individuals with ESRD in all settings, including the home, producing efficiency, consistency and quality in care delivery.

Our recommendations for the Committee are two-fold. First, FMCNA urges the Committee to adopt S. 598, the Chronic Kidney Disease Improvement in Research and Treatment Act of 2014, co-sponsored by Senators Crapo (R-ID) and Cardin (D-MD). S. 598 would end decades of discrimination against individuals with ESRD and allow them to enroll in MA plans. Second, we urge the Committee, in general, to constitute new delivery system changes in an inclusive, open fashion that allows all entities – providers, groups of providers, pharmacies and/or health plans – to assume leadership over new payment models, and not to limit leadership by virtue of Medicare designation or corporate structure or affiliation alone.

INDIVIDUALS WITH ESRD DESERVE ACCESS TO COMPREHENSIVE COORDINATED CARE MEDICARE ADVANTAGE PLANS PROVIDE

MA plans are a popular alternative to traditional Medicare and in most instances plans provide high-quality, coordinated care for beneficiaries with complex medical conditions, making MA even more appealing for individuals with chronic disease, like ESRD, over the fragmented traditional FFS program. Unfortunately, not all Medicare beneficiaries are allowed to enroll in an MA plan. Under a Social Security Act rule established in 1997, beneficiaries with kidney failure are prohibited from enrolling in MA plans (unless they were already in an MA plan when their kidneys failed),¹ denying them the same benefit choices and program advantages available to other beneficiaries on the basis of their disease alone. The Medicare Payment Advisory Commission has regularly advised Congress to eliminate the unfair MA enrollment prohibition since 2000.²

This unfair MA “lockout” denies care coordination and additional benefits not available in FFS Medicare to a high cost, complex population that needs those most. Unlike FFS Medicare, MA plans have flexibility to redistribute clinical resources to address unique patient needs and to provide more integrated, coordinated care, which can be especially impactful to beneficiaries with ESRD. Dialysis care requires up to four hours of treatment three times per week along with the management of other chronic conditions and prescription drug regimens that are best organized by “seamless” systems like those offered by MA plans.

¹ Social Security Act § 1851(a)(3)(B). An individual with ESRD is not eligible to enroll in an MA plan because they are specifically excluded as an “eligible individual.” Exceptions exist for MA beneficiaries who develop ESRD who may remain in their plans, for beneficiaries to enroll in certain MA Special Needs Plans (“SNPs”), and for individuals with ESRD covered by an employer-based plan, who may enroll in an MA plan offered by the same insurer when they become Medicare eligible.

² MedPAC, “Report to Congress: Medicare Payment Policy,” March 2000, pg. 129.

Moreover, allowing beneficiaries with ESRD to enroll in MA plans could help patients with low incomes and those unable to afford supplemental Medigap insurance. MA plans can have lower deductibles and copayments and are required by law to cover all beneficiary costs above a set threshold, protecting beneficiaries from catastrophic health care costs.

FMCNA itself knows that patient experience in an MA environment is better than it is in FFS Medicare. In head-to-head comparison of FMCNA patients between January 1, 2012 and December 31, 2012, FMCNA compared the clinical outcomes for a like population between those in MA plans and those in FFS. On an adjusted basis, FMCNA found no difference in mortality between the two groups, and a slightly lower number of hospital admissions in the MA population compared to the FFS population. These improvements are significant given that the MA patients with ESRD were, in general, older and more likely to be diabetic, have cardiovascular disease, have catheters and have lower albumin (i.e. worse nutritional status) than their counterparts in FFS Medicare.

S. 598 would end the decades-long discrimination that continues to deny MA resources to individuals based solely on their disease or chronic condition, in this case the disabling and complex patient who has ESRD. FMCNA strongly urges the Committee to enact S. 598 so that the clinical benefits of complex care management can flow to the individuals who need them most. S. 598 also makes other improvements in kidney disease education and in improving the accuracy of Medicare's ESRD prospective payment system, which FMCNA also supports.

DESIGN NEW CARE MODELS FOR COMPLEX CHRONICALLY ILL INDIVIDUALS THAT ENCOURAGE COMPETITION AND PROMOTE SEAMLESS CARE

Since the early 2000s, FMCNA has partnered with health plans in CMS demonstration projects and in special needs plans, a type of MA plan, and have offered comprehensive clinical services and care management outside of the dialysis facility itself. On balance, individuals with ESRD who had access to seamless, comprehensive care in demonstration projects and in special needs plans showed improved outcomes compared to individuals enrolled in traditional Medicare.

In particular, FMCNA's participation in a five year Centers for Medicare and Medicaid Services demonstration project in which FMCNA assumed leadership and clinical and financial responsibility for a broad array of services required by individuals with ESRD resulted in significantly improved health outcomes and achieved cost savings of 5.1% in 2008. When providing direct management and clinical coordination services to individuals with ESRD

beyond the dialysis facility, FMCNA was able to show improvements in mortality, hospitalizations, readmissions, physician visits and skilled nursing home stays.³

Given the complex, costly nature of ESRD, FMCNA has worked for decades to identify care improvements, innovations and opportunities to reduce spending. Among the many costs associated with dialysis care, certain remain fixed: the dialytic procedure, related dialysis drugs, and nephrology costs are well set. Variable Part A costs, however, including hospitalization, other specialist services and supportive care pharmacy and drugs represent opportunities for savings, but only if individuals with ESRD are managed seamlessly, so that non-dialysis costs associated with complication and other co-morbid conditions are controlled by effective medical management. FMCNA excels at this level of care integration and medical management for the complex chronically ill, and we see no reason why, as the Committee considers new models to advance care for high cost populations, like those with ESRD, FMCNA itself cannot assume leadership over them. Our experience, and our clinical and economic resources as an efficient provider, make us well suited to take the helm of care management for individuals with chronic kidney disease, ESRD and other complex chronic diseases.

FMCNA is uniquely positioned to deliver on the promise of chronic care improvement by deploying nephrologists to be principal care providers, by utilizing the dialysis clinic as a patient's "medical home," by coordinating services for multiple clinical and psycho-social conditions, by promoting healthier lives and anticipating patient needs before crisis, and by supporting it all with an information technology infrastructure that facilitates coordination on a real time basis.

With these advanced resources and our years of experience in chronic care management, FMCNA and other efficient, multidisciplinary organizations like us should be called on to lead new care models the Committee is considering for the chronically ill. FMCNA urges the Committee to approach innovative models for chronic disease care that are not dependent on a single operational or organizational structure for leadership, and to look to it and to other sophisticated providers, pharmacies, and suppliers to not only take leadership over complex patient populations, but to assume financial risk for the cost of their care. Limiting leadership in such new models to conventional health insurance carriers would deny the Medicare program critical expertise and advancements in patient-centered chronic disease care that dialysis organizations like FMCNA are squarely positioned to provide.

With our experience in demonstration programs and in special needs plans, and in light of our corporate commitment to integrated care that includes patient contact and services in virtually every setting of the chronic disease patient's journey, FMCNA is eager for leadership

³ Arbor Research: *ESRD Demonstration Disease Management Evaluation from 2006-2008; the First Three Years of a Five Year Demonstration*, December 8, 2010.

opportunities that would allow it to offer seamless care services beyond the limited set of traditional dialysis services included in the Medicare prospective payment system or “bundle.”

In particular, FMCNA would support a new model for ESRD care that attributes beneficiaries to a dialysis facility (beneficiaries would retain the right to opt out), for which FMCNA would be paid a capitated per member per month amount to cover the full range of care, with the potential for guaranteed savings (compared to FFS spending) in the first three years. FMCNA would be held to quality thresholds on renal specific quality measures, with bonus and penalty provisions depending on performance.

Individuals with ESRD represent a significant expense to the Medicare program. According to the United States Renal Data Service, they represent just over one percent of the overall Medicare population but account for more than seven percent of total Medicare spending. They frequently have unmet healthcare needs that result in suboptimal outcomes. FMCNA has the expertise to improve outcomes for this population and the scale to aggregate our risk and deliver predictable costs to CMS. Accordingly, FMCNA urges the Committee consider a provider-driven model for seamless ESRD care that we assert will meet or exceed the Committee’s objectives for better policy and, just as importantly, the patient’s expectation for better performance.

Thank you for your attention to our views and ideas. Opening access to MA for individuals with ESRD is an immediate measure the Committee can take to improve the care of a complex costly population. Allowing efficient dialysis organizations and other providers to apply their clinical expertise in chronic disease management to improving the lives of individuals with chronic disease is a powerful longer term policy investment that will produce measurable improvements in care, patient life quality, and Medicare spending.

If you have any questions, or would like to discuss any of these concepts in further detail, please do not hesitate to contact Robert Sepucha, Senior Vice President, Corporate Affairs, at 781-699-4028.

Best Regards,

A handwritten signature in black ink, appearing to read 'Robert Sepucha', with a stylized, cursive script.

Robert Sepucha
Senior Vice President, Corporate Affairs