FRESENIUS MEDICAL CARE

January 26, 2016

Via electronic mail
chronic_care@finance.senate.gov

The Honorable Orrin 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, Widen, Isakson and Warner:

On behalf of Fresenius Medical Care North America ("FMCNA") and the more than 170,000 individuals with End Stage Renal Disease ("ESRD") we treat, I write to thank the Chronic Care Working Group ("CCWG") for closely investigating how best to improve care delivery for individuals living with chronic conditions. For too long, the unique health needs of the chronically ill have gone unexamined. Redesigning the care delivery system to better manage these needs will not only improve the health and quality of life for millions of individuals, it will also help reduce system-wide health care costs.

We were especially gratified to see that the CCWG included in its recently released blueprint the potential to eliminate the outdated and discriminatory restriction on Americans with ESRD enrolling in Medicare Advantage ("MA") plans. In addition, we support several other provisions in the blueprint, including permanently authorizing Medicare Advantage chronic special needs plans ("C-SNPs") and expanding the use of telehealth, to name a few. This letter seeks to elaborate on our support of several of the initiatives set forth in the blueprint and to answer several questions posed by the CCWG.

As you know, individuals with kidney failure are among the sickest in the nation. In addition to the required four-hour dialysis treatments three times per week, the average ESRD patient has a number of comorbities - ranging from diabetes and hypertension to cardiac illness, bone disease and depression, among others. FMCNA believes no patient population can greater benefit from a coordinated approach to care. Recent legislative and regulatory activity has encouraged more coordinated care for this beneficiary population. The creation of the ESRD Prospective Payment System in 2011 and the ESRD Seamless Care Organizations in 2015 were important steps toward better integrating the care for these beneficiaries. However, FMCNA believes we can do more, and the initiatives set forth in the blueprint

– especially allowing access to MA plans for those with kidney failure – are a critical third chapter in this narrative.

Allowing ESRD Patient Access to MA Plans

As you know, individuals diagnosed with ESRD become eligible for Medicare regardless of age. Of the 660,000 individuals in the U.S. with ESRD, approximately 64 percent or 416,808 patients currently utilize Medicare for their primary coverage. A small portion of FMCNA's patient population who have previously qualified for Medicare and selected a MA plan *prior to the onset of ESRD* is permitted to continue with that coverage. Not surprisingly, given the ban on enrollment following onset of ESRD, the overall MA enrollment rate in the ESRD populations lags the general population significantly.[1] This disparity in enrollment is troubling, especially since our own experience indicates that our MA population fares as well or better clinically than our fee-for-service ("FFS") population, despite the fact that the MA population is older and possesses more comorbidities than their FFS counterparts.[2]

Put simply, there is no compelling reason that Medicare beneficiaries who have already been diagnosed with ESRD should not have the same opportunity to benefit from MA plans' integrated models of care as those beneficiaries were fortunate enough to enroll in an MA plan prior to having been diagnosed with ESRD. No other disease state confers such a discriminatory impact on its victims, and we firmly support Congressional action to permanently eliminate this statutory oddity. By allowing those with ESRD to access MA plans, Congress would finally provide this entire population with access to improved care coordination, which in turn can lead to better clinical outcomes as well as savings for the entire Medicare program. Not surprisingly, the Medicare Payment Advisory Commission ("MedPAC") has recommended eliminating the prohibition on ESRD beneficiaries enrolling in an MA plan for almost 15 years.

We look forward to continuing to work with your group and welcome any additional thoughts or questions you may have. We now address the more technical questions you posed in your Blueprint:

A. Evaluating Benchmarks and Bids for ESRD Patients in MA Plans

In analyzing proper benchmarking for this population, it is critical to note that MA plans currently receive a risk-adjusted payment for their ESRD enrollees. This risk adjustment methodology for ESRD patients is separate and distinct from the risk adjusted payments they receive for their non-ESRD enrollees[3] that has recently come under criticism.

[1] Currently, approximately 14 percent of FMCNA ESRD patients are enrolled in MA plans, whereas approximately 31 percent of the general Medicare population is enrolled in MA plans, according to the Kaiser Family Foundation.

[2] Data setting forth these health outcomes is attached to this letter.

[3] i.e. those with chronic kidney disease ("CKD") who have not yet progressed to ESRD, or kidney failure.

Unlike the bidding and benchmark capitated payment model that governs the vast majority of MA per member, per month payments, MA plans are paid a more granular, risk-adjusted payment based on a state-wide average of ESRD spending in traditional Medicare that reflects actual ESRD treatment type (dialysis, transplant, and functioning graft status). CMS has determined that this payment is more accurate for ESRD patients because the standard CMS-HCC model does not make the same important treatment distinctions. Such distinctions are critical in predicting the relative cost of treating the patient. CMS further refines MA ESRD payments by adjusting for demographics, comorbid conditions, new enrollee status, and community versus institutional setting.

FMCNA is currently partnering with MA plans to ensure that ESRD beneficiaries have access to the care without driving excessive spending. Since the early 2000s, we have participated with health plans in CMS demonstration projects and in MA special needs plans (SNPs), and have offered comprehensive clinical services outside of the dialysis facility itself. On balance, individuals with ESRD who had access to seamless, comprehensive care in demonstration projects and in SNPs showed improved outcomes compared to individuals with ESRD who were enrolled in traditional Medicare.[4] As we continue to see, better outcomes in preventive and chronic care can reduce acute care spending in the long run.

We believe plan experience with current ESRD beneficiaries, the relative small number of people this policy would affect compared to the overall MA population, and the current unique risk adjustment methodology combine to demonstrate there is no need to adjust the bid and benchmark process if all ESRD beneficiaries were allowed the choice to enroll in MA plans.

B. Establishing and Recognizing Proper Quality Metrics for ESRD MA Participation

The CCWG has also inquired as to what quality measures are available to ensure that ESRD beneficiaries can make informed choices about enrolling in an MA plan. FMCNA supports the work of our two primary coalitions, The Kidney Care Council and Kidney Care Partners, in determining and establishing such measures. Not surprisingly, because there are so few ESRD MA enrollees, The National Committee for Quality Assurance (NCQA) health plan rankings does not maintain an ESRD specific measurement. In fact, NCQA does not report on condition-specific domain measures for many conditions most common in the Medicare population. At this point, ESRD beneficiaries can currently assess an MA plan's overall quality through NCQA's publicly reported patient satisfaction domain scores. ESRD beneficiaries also can look to CMS' own general star ratings for MA plans for additional information on plan performance.

FMCNA would be supportive of the development of a clinically valid measurement domain that provides an accurate assessment of the quality of care for ESRD patients by individual MA plans. However, ESRD patients should not be forced to wait for the development of such an approach before they are afforded the choice to enroll in an MA plan.

[4] We fully expect these trends to continue, which is why we launched C-SNPs for ESRD beneficiaries in three new metropolitan markets in 2016, including Dallas, Raleigh-Durham and San Diego.

Home Dialysis and Telehealth

The CCWG has inquired about ways to increase the utilization of home dialysis through telemedicine. We were pleased to see the CCWG's proposal to expand Medicare's definition of a qualified originating site to include free-standing renal dialysis facilities in any geographic area. This determination will prove more convenient for those on home dialysis who are already significantly burdened by their disease and its ongoing treatment. Even more importantly, we support a patient's home being considered a qualifying site. Home dialysis is a unique treatment option that requires a special commitment by both the patient and their family, and we acknowledge the important role telemedicine can play in this treatment modality. While we recognize that the Working Group's proposal specifies home hemodialysis, we believe that patients using any home dialysis modality should be eligible to take advantage of telehealth options.

FMCNA also joins with KCC and KCP to recommend that home dialysis patients be required to visit a physician face-to-face a minimum of every three months (as opposed to the currently required monthly visits). These face-to-face visits would allow the physician to determine the efficacy of the treatment, examine the access site, and engage with the patient to assess his or her overall health status. Our dialysis facilities maintain the necessary expertise to work with patients in conjunction with a physician-led telemedicine visit. Advances in technology encourage us that, when properly monitored via telehealth visits, the home dialysis patient may reduce his or her face-to-face physician visits from monthly to quarterly.

Extending SNPs Permanently

The CCWG has also proposed a permanent or long-term extension of SNPs. As part of the deliberation of this proposal the Committee asked a broader overarching question on flexible benefit design in the Medicare Advantage program. FMCNA does not have a position or experience on that issue to provide any meaningful comment on special needs plans writ large. However, as noted above, we have extensive experience in operating a C-SNP for the ESRD population, including as part of a five-year demonstration with CMS during which we improved mortality by 24 percent and reduced hospitalizations by 20 percent by year three of the program. We believe C-SNPs are another critical path to providing integrated and coordinated care management services to Medicare beneficiaries with ESRD, which is why we launched C-SNPs for this population in three new metropolitan markets in 2016, including Dallas, Raleigh-Durham and San Diego. Like MedPAC, we believe the tailored benefits and specific expertise of SNPs can play an integral role in caring for the ESRD population. We therefore support the CCWG's proposal to move away from year to year extensions of SNPs in lieu of a long term or permanent reauthorization of SNPs. This change would bring a welcome degree of certainty needed to allow these plans to evolve to best serve the needs of vulnerable populations.

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Improving Chronic Care Management Services for Individuals with Multiple Chronic Conditions

We are supportive of the CCWG's proposal to establish a new high-severity chronic care management code that clinicians could bill under the Physician Fee Schedule. As you may know, Medicare beneficiaries with ESRD suffer multiple chronic conditions. For example, approximately three-quarters of those with ESRD suffer from hypertension, with some studies estimating that the incident rate of hypertension among these patients is closer to 90 percent. In addition, diabetes accounts for nearly 50 percent of the people who start treatment for kidney failure each year. Unfortunately, dealing with multiple comorbidities is a fact of life for most Americans with ESRD. By compensating clinicians for the increased costs of managing these comorbidities, which are especially challenging for patients as complex as those with ESRD, the new chronic care management ("CCM") code proposed by the CCWG would immeasurably help improve care coordination.

We would firmly support the creation of such a code, but we would urge Congress to ensure that, as board certified physicians specially trained in the treatment of renal disease, nephrologists be allowed to use the CCM code where appropriate. As those with the most expertise in dealing with the unique needs of dialysis patients, nephrologists often become the principal care physician for these patients. In addition to addressing their dialysis needs, many nephrologists (and their nurses, physician assistants and the like) also are forced to manage these patients' other chronic conditions. By being at the center-point of care, they help coordinate among other specialists and bear the burden of other costs associated with chronic care management. A CCM code would help offset these costs and eliminate any disincentive towards providing this kind of much needed care.

Conclusion

We again thank the CCWG for its decision to explore the restriction on those with ESRD from electing to enroll in an MA plan. FMCNA continues to take important steps toward care integration that we believe will provide higher quality, more comprehensive care for our patients while at the same time reducing overall Medicare spending.

I look forward to continuing to work with you on this and other issues. Please do not hesitate to contact me at robert.sepucha@fmc-na.com with comments or questions at any time.

Sincerely,

Robert Sepucha
Senior Vice President Corporate Affairs

Fresenius Medical Care North America

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