Fresenius Medical Care North America
Response to Ways & Means Rural and Underserved Communities
Health Task Force RFI

FMCNA appreciates the opportunity to respond to the Request for Information issued by the Ways & Means Rural and Underserved Communities Health Task Force.

FMCNA is the largest integrated supplier in the country of services and products for individuals undergoing dialysis due to End Stage Renal Disease (ESRD). FMCNA provides ongoing dialysis treatment for more than 210,000 patients through a network of more than 2,600 dialysis facilities and 50,000 employees nationwide. During October 2019, 10.2 percent of all dialysis treatments in FMCNA facilities were rendered to patients who reside in small towns (population: 2,500-9,999) or rural areas (population: <2,500) and another 12.3 percent of treatments were rendered to patients who reside in micropolitan areas (population: 10,000-49,999). Furthermore, home dialysis utilization exceeds 16 percent in small towns and rural areas.

Below please find our response to a few of the questions posed in the RFI.

1. What are the main health care-related factors that influence patient outcomes in rural and/or urban underserved areas? Are there additional, systems or factors outside of the health care industry that influence health outcomes within these communities?

Telehealth services have become a critical component to accessing necessary medical services, particularly for patients in rural areas who may have limited access to a range of healthcare providers. The use of telehealth services in rural areas can reduce transportation challenges and travel and wait times for patients and decrease burdens within the healthcare system.

According to a report recently released by the Federal Communications Commission (FCC), 26 percent of Americans in rural areas (who could most benefit from telehealth services) lack access to broadband speeds necessary to utilize an interactive video communications system. Only 1.7 percent of Americans in urban areas lack such access.

Congress has continued to recognize the value of telehealth services, and in the Bipartisan Budget Act of 2018 (BBA), expanded the availability of telehealth services to Medicare beneficiaries receiving home dialysis. The extension of telehealth services to home dialysis patients has, unfortunately, had a less positive impact than it potentially could have due to limitations placed on telehealth reimbursement by CMS's unnecessarily narrow definition of "a telecommunications system."

2. What successful models show a demonstrable, positive impact on health outcomes within rural or underserved communities, for example initiatives that address: a) social determinants of health (particularly transportation, housing instability, food insecurity); b) multiple chronic conditions; c) broadband access; or d) the use of telehealth/telemedicine/telemonitoring?

Medicare beneficiaries with end stage renal disease (ESRD) who dialyze at home typically experience improved quality of life, prolonged life, increase in likelihood of transplantation,

decreased medication costs, reduction in costly hospitalizations for cardiovascular complications, and the ability to continue or return to work.[1] Use of telehealth for home dialysis patients is especially beneficial for those in rural or underserved communities where monthly face-to-face visits would require lengthy travel. The BBA allows Medicare beneficiaries to receive these monthly clinical assessments via telehealth after the initial three months of treatment (with a face-to-face assessment required at least once every three months thereafter).

However, CMS's narrow interpretation of the statutory language has limited the use of telehealth in rural areas where broadband access is limited. The statutory framework for payment for telehealth services requires that payment be made for telehealth services that are furnished "via a telecommunications system." This term is not defined in the statute, and CMS has defined the term "interactive telecommunications system" in regulation as having, "at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner." The regulation adds that telephones, facsimile machines, and electronic mail systems *do not* qualify as interactive telecommunications systems.

This narrow interpretation is not required by statute. CMS could revise its definition of interactive telecommunications system to allow for audio-only communications between a patient and a provider, or Congress could consider updating statutory language to allow for broader use of telehealth in rural areas.

[1] Finkelstein FO, Schiller B, Daoui R, et al. At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney Int. 2012;82(5): 561-569. 2. Spanner E, Suri R, Heidenheim AP, Lindsay RM. The impact of quotidian hemodialysis on nutrition. Am J Kidney Dis. 2003;42(1 suppl):30-35. 3. Weinhandl ED, Lie J, Gilbertson DT, Arneson TJ, Collins AJ. Survival in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. J Am Soc Nephrol. 2012:23(5):895-904. 4. FHN Trial Group. In-center hemodialysis six times per week versus three times per week. N Engl J Med. 2010:363(24): 2287-2300. 5. Weinhandl E, Liu J, Gilbertson D, Arneson T, Collins A. Transplant incidence in frequent hemodialysis and matched thrice-weekly hemodialysis patients. Poster presented at National Kidney Foundation Spring Clinical Meeting, 2012. 6. Tennankore K, Nadeau-Fredette AC, Chan CT. Intensified home hemodialysis: clinical benefits, risks and target population. Nephrol Dial Transplant. 2014;29(7):1342-1349. 7. Jefferies HF, Virk B, Schiller B, Moran J, McIntyre CW. Frequent hemodialysis schedules are associated with reduced levels of dialysis-induced cardiac injury (myocardial stunning). Clin J Am Soc Nephrol. 2011;6(6):1326-1332. 8. Jaber BL, Schiller B, Burkart JM, et al. Impact of short daily hemodialysis on restless legs symptoms and sleep disturbances. Clin J Am Soc Nephrol. 2011;6(5); 1049-1056.