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November 22, 2017

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Nashville, TN

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Cranbury, NJ

Centers for Medicare & Medicaid Services

Department of Health and Human Services

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Washington, D.C. 20201

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Seattle, WA

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Dear Ms. Verma,

EDAC Chair

Chris Brown
Cranbury, NJ

The Kidney Patient Advisory Council (KPAC) of the Forum of ESRD Networks appreciates the opportunity to comment on the Proposed Local Coverage Determination (LCD): Frequency of Hemodialysis by the Medicare Administrative Contractors.

EDAC Vice-Chair

Susan Caponi, MBA, RN, BSN
Lake Success, NY

The KPAC is composed of patient representatives from each of the 18 ESRD Networks. Our focus is to improve patient's quality of care and quality of life by supporting the ESRD Networks System and the ESRD patient communities throughout the United States and Territories.

KPAC Chair

Derek Forfang
San Pablo, CA

The MACs proposed LCD limits the coverage of hemodialysis to three treatments per week unless there is documentation from the prescribing physician including orders "for each and every additional sessions outside the usual 13/14 treatments per month." In addition, the proposed policy requires documentation in the Plan of Care (POC), monthly documenting the need for additional dialysis treatments based on acute clinical conditions.

KPAC Vice-Chair

Joseph Karan
Land O Lakes, FL

The KPAC feels strongly that this proposed LCD will harm both in-center hemodialysis patients and patients on home hemodialysis. Many patients need treatments beyond three times a week to keep stable and functioning and by importantly helping to keep keep patient's blood pressure in control, to manage fluid weight, to improve their general health and wellbeing, and to improve their chance of survival. Many of us have benefited from additional treatments, which keep us out of the hospital and allow us to function better and have a better quality of life. An important result of kidney patients getting their necessary treatments is the reduction in cost as there are fewer hospitalizations and fewer major health crises. CMS efforts, through the ESRD Network System, have reduced hospitalizations and re-admissions. We feel the LCD proposal would be contrary to these goals, raising cost and lowering the quality of care, quality of life and the chance of survival and longevity for patients. We do not want to be in the hospital or lose the quality of life many kidney patients strive hard to maintain.

Members-At-Large

Natasha Avery, DrPH, MSW, CHES
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Louis Diamond
MB, ChB, FACP, FCP(SA)
Washington DC

Andrew Howard, MD, FACP
Alexandria, VA

Forum Coordinator

Dee LeDuc
Birchwood, WI

Also, the proposed LCD is counter to the CMS Strategic Goals with the focus to “Put Patients First.” The first piece of that strategy is to “Empower patients and doctors to make decisions about their health care.” This proposal would eliminate the ability for shared decision-making, leaving patients and their families without a voice. It also leaves patients with a cookie cutter approach to treatment that doesn’t work for all of us.

The proposal is also counter to another piece of the CMS Strategy, that is, “to support innovative approaches to improve quality, accessibility and affordability.” The home modalities of treatment have been encouraged by CMS to improve quality of care, to ease and increase accessibility of treatment, and to reduce cost and improve outcomes. This proposal would once again remove patients and their families from engaging in more innovative approaches that improve the quality of care and quality of their lives.

The last part of the CMS Strategy to “Put Patients First” is to “Improve the CMS customer experience.” As already stated, we as customers feel strongly this will worsen our experience as we do our best to manage and to deal with this difficult life threatening disease.

The patients on the Forum’s KPAC would like to share our real stories to help you better understand our position and comments above. Please see addendum #1 attached to this letter.

There is substantial Medical Evidence demonstrating the benefits of more frequent hemodialysis beyond three times a week for many patients. These reports were identified by the Forum’s Medical Advisory Council and are attached as addendum #2 to this letter.

Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script, appearing to read "Derek Forfang", is written in black ink on a light-colored background.

Derek Forfang
Chair, Kidney Patient Advisory Council
National Forum of ESRD Networks

Addendum #1

KPAC Member: Maggie Carey, Dialysis & Transplant Patient, Michigan

I am the second on four generations of ESRD patients. My mother died on hemodialysis in the 1980s from a blood-borne infection. I am sustaining a transplant. My son (in his 40s) is on home-hemodialysis. My granddaughter, age 15, is watching us and learning how to live with this disease. I would like to take this opportunity to explain the situation my son is facing.

He had a double nephrectomy over 2 years ago. He is a business owner and single father. His business is sole support for him and his daughter. He has private medical insurance which is about to cap for dialysis coverage and he will be transferring to Medicare in less than four months. He was also the ONLY patient at his 40-chair unit who was NOT on disability.

He is a big man – not fat, but over 6-foot-tall and built like a linebacker. In-center hemodialysis left him so wiped out that working and maintaining the business that he had founded became impossible. Between the time on dialysis and the hours recovering from it, he had little or no time for work. He also suffered from innumerable infections and was in the emergency room at least once a month. He, therefore, made the decision to change modalities.

Peritoneal Dialysis was his first choice, but it was unable to pull enough fluid and his clearance requirements were not being met. During those 8 weeks, he was hospitalized twice with respiratory failure resulting in cardiac arrest. He coded twice in the ambulance and was in Cardiac ICU for over 2 weeks on each occasion. Both times, I packed my bags and headed down with the expectation of burying my son.

My son is now on home-hemodialysis with NxStage and is thriving. He can dialyze 4 times a week with an extra run added when he feels the fluid building up around his lungs. He is back to working full time again and has saved the business. His daughter is seeing a rainbow at the end of the storm and is less apprehensive about her own future on dialysis. And he is fulfilling the CMS directive to increase home dialysis.

Please, please, please do not pull the option for the extra runs from my son. His life literally hangs in the balance here. Even if he could sustain life on in-center dialysis (which his ER history does not support) it would result in the loss of his livelihood and he would join the long line of dialysis patients living on disability. This is NOT a good use of taxpayer dollars.

Thank you for your consideration

KPAC Member: David Rosenbloom, Kidney Dialysis & Transplant Patient, California

I spent 6 ½ years on dialysis as follows:

May 2002 - March 2006: **in-center HD, 3x/wk** - continually tired, weak and depressed; very long recovery after each treatment (8 hrs. or more); Weekends especially bad, with 2-day

layoff from treatment; no longer in control of my life; could not work full-time at own custom woodworking business; income suffered markedly.

March 2006 - Nov. 2006: **HD at home on a Fresenius 2008H, 4x/wk.**; requested doing my own dialysis at home after my live kidney donor was rejected five days before scheduled transplant surgery; trained to self-cannulate and operate full-size dialysis machine at home; my nephrologist applied for permission to do 4th treatment and was approved by CMS; energy greatly improved as well as appetite; regained independence by controlling my own treatments, timing and duration; able to work four days a week in my business; didn't need to sleep as much.

Nov. 2006 - Aug. 2008: **HHD with NxStage System One; 6x/wk treatments - each 3 ½ hrs.long**; immediate increase in energy, well-being, alertness and personal drive; could now work in my business 7 days/wk.; could also travel freely with portable machine; recovery time after treatments never more than ½ hr.

Aug. 2008: received successful cadaver kidney transplant at USC University Hospital; released from hospital five day after surgery; required no further dialysis since; transplanted kidney stable.

KPAC Member: Robin Blomberg, Dialysis Patient, Washington

Kidney patients need your help. The new CMS rule that limits kidney patients' lifesaving dialysis treatments to 3 times a week will cause havoc with many patients' quality of life and life span. People are individuals and need to be treated as such. Health care is about providing patients with care that meets their needs. Currently the U.S. has one of the highest mortality rates for ESRD patients in the world. Limiting much needed treatments will only increase these numbers. Limiting much needed dialysis treatments will also increase the cost of healthcare as patients will have more hospitalizations to address the effects of lack of needed treatments.

I do ask why this rule is thought to be in the best interests of patients. Is it because keeping people alive and allowing them to have some sense of a quality of life is not cost effective? Is it because kidney patients are valued less because they have a serious disease? If you were in the position dialysis patients are would you want someone limiting your chance to live?

Please don't allow limiting dialysis treatments. Give kidney patients hope.

KPAC Member: Joseph Karan, Dialysis & Transplant Patient, Florida

I wanted to write about my medical experience as a dialysis patient.

I went on in-center dialysis in January 2009. For the next six months of treatments I was hospitalized three (3) times. My overall health was below what I expected and was a determining factor for all three (3) admissions costing over \$145,000.

A nurse asked me if I would consider Home Modalities as a treatment option. I investigated both Peritoneal and Home Hemodialysis treatments and decided on Home Hemodialysis.

I was on Home Hemodialysis for over four (4) years. Within the first 30 days I was able to discontinue all blood pressure medication. I began to thrive instead of survive.

The most amazing aspect of my Home hemodialysis treatments is that over the next four years I was in the hospital one (1) time and it was not kidney related. I am a staunch advocate for home modalities. The extra treatments ENDED MY HOSPITAL ADMISSIONS. It was a win-win situation for both the payer and the patient.

Addendum #2

Johansen, K.L., Zhang, R., Huang, Y., Chen, S., Blagg, C., Goldfarb-Rumyantzev, A., Hoy, C., Lockridge, Jr., R.S., Miller, B., Eggers, P., Kutner, N.: Survival and Hospitalization Among Patients Using Nocturnal and Short Daily Compared to Conventional Hemodialysis: A USRDS Study. *Kidney International* 76: 984-990, 2009

Pauly RP, Gill JS, Rose CL, et al. Survival among nocturnal home haemodialysis patients compared to kidney transplant recipients. *Nephrol Dial Transplant Off Publ Eur Dial Transpl Assoc – Eur Ren Assoc.* 2009;24(9):2915-2919. doi:10.1093/ndt/gfp295.

Culleton BF, Walsh M, Klarenbach SW, et al. Effect of frequent nocturnal hemodialysis vs conventional hemodialysis on left ventricular mass and quality of life: a randomized controlled trial. *JAMA.* 2007;298(11):1291-1299. doi:10.1001/jama.298.11.1291.

FHN Trial Group, Chertow GM, Levin NW, et al. In-center hemodialysis six times per week versus three times per week. *N Engl J Med.* 2010;363(24):2287-2300. doi:10.1056/NEJMoa1001593.

Rocco MV, Lockridge RS, Beck GJ, et al. The effects of frequent nocturnal home hemodialysis: The Frequent Hemodialysis Network Nocturnal Trial. *Kidney Int.* 2011;80(10):1080-1091. doi:10.1038/ki.2011.213.

Lindsay RM, Heidenheim PA, Nesrallah G, Garg AX, Suri R, Daily Hemodialysis Study Group London Health Sciences Centre. Minutes to recovery after a hemodialysis session: a simple health-related quality of life question that is reliable, valid, and sensitive to change. *Clin J Am Soc Nephrol CJASN.* 2006;1(5):952-959. doi:10.2215/CJN.00040106

Jaber BL, Lee Y, Collins AJ, et al. Effect of daily hemodialysis on depressive symptoms and postdialysis recovery time: interim report from the FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study. *Am J Kidney Dis Off J Natl Kidney Found.* 2010;56(3):531-539. doi:10.1053/j.ajkd.2010.04.019.

Garg AX, Suri RS, Eggers P, Finkelstein FO, Greene T, Kimmel PL, Klinger AS, Larive B, Lindsay RM, Pierratos A, Unruh M, Chertow GM. Frequent Hemodialysis Network Trial Investigators. Patients receiving frequent hemodialysis have better health-related quality of life compared to patients receiving conventional hemodialysis. *Kidney Int.* 2017 Mar;91(3):746-754.

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. doi:10.1038/ki.2012.168.

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 CJASN.* 2011;6(5):1049-1056. doi:10.2215/CJN.10451110.

Foley RN, Gilbertson DT, Murray T, Collins AJ. Long interdialytic interval and mortality among patients receiving hemodialysis. *N Engl J Med.* 2011;365(12):1099-1107 doi:10.1056/NEJMoa1103313.