Hello. My name is Luke Santillo with DaVita. I would like to expand on some of the comments made by S. Bryson Fleming II, MD in regards to the proposed 2020 State Medical Facilities Plan (SMFP) as it relates to dialysis.

Over the last 20+ years, providers applied for center expansions, station relocations, and new centers, without a stated-need determination in the Semi Annual Dialysis Report (SDR). The addition of a stated-need determination methodology in the State Medical Facilities Plan (SMFP) unnecessarily limits providers from meeting patient need and without a timely remedy to address center growth. These limits will have unintended consequences and create scenarios where providers, who can prove a need for additional stations, are not allowed to apply, and must wait months for the next published SMFP before taking action. There are other medical services appropriately regulated through the SMFP without an annual stated-need determination. When providers apply for station expansions and new centers, we must meet the performance standard of 80% station utilization, or 3.2 patients per station, by the end of operating year one. The construct needed to ensure dialysis providers do not build more facilities and add more stations than needed, thereby increasing the cost of dialysis care, already exists through the this performance standard. Therefore it is unnecessary, and we believe harmful, to add a stated-need determination in the SMFP, especially when coupled with the latency of the data that will now be reported only annually. Removing the station need determination from future SMFPs and moving to a "policy approach," a course of action suggested by the Chief of Healthcare Planning and Certificate of Need, will ensure providers can timely meet the needs of patients.

We recognize the need to move toward aligning dialysis service reporting to the SMFP and appreciate the efforts made by the SHCC, Acute Care Services Committee, and the Healthcare Planning and Certificate of Need staff to involve providers in ensuring this transition is successful and limits impact to patients. We understand methodology petitions for the SMFP are due in the Spring and recognize that it is not likely the 2020 SMFP stated-need methodology for dialysis services will be changed this year. We do feel it is important to communicate our concerns now, in concert with some of our nephrologist partners, like Dr. Fleming, to educate State Healthcare Coordinating Council Members (SHCC) members and to advocate for changes to the 2021 SMFP.

An example of how the stated-need determination methodology is problematic is the case of Franklin Township Dialysis in Macon County. When the January 2018 SDR was published, Franklin Township showed a need for a two-station expansion from nine to eleven stations. The patient census at Franklin Township increased from 22 patients on 12/31/2016 to 37 patients on 6/30/2017. An application was submitted in March, 2018, subsequently approved, and the stations put in use by October, 2018. When applying the stated-need determination methodology in the draft 2020 SMFP, Franklin Township would not have been eligible for an expansion (Exhibit A). A draft 2018 SMFP, released mid-2017, containing census data from 12/31/2016 would produce a station need determination of zero stations for Franklin Township for all of 2018. Under the stated-need determination of the SMFP, a station expansion application for Franklin Township would have been delayed until March, 2019, at the earliest, with stations made available for use sometime in the Fall of 2019. This unnecessary delay in adding stations when needed will reduce patient choice of where and when they dialyze and is against the spirit of the basic principles covering dialysis station need.

Thank you for your time and I'm happy to answer any questions the SHCC might have.

Exhibit A

0	0.097744	9.097744	0.157895 3.473684 25.47368 9.097744 0.097744	3.473684	0.157895	3	6	19	22	61.11%	6	6	0	0	0	6	Franklin Township Dialysis
stations	2.b.vi	2.b.v	2.b.iv	2.b.iii	2.b.ii	2.b.i	12/31/16) 12/31/15) All Stations	12/31/15)	12/31/16)	SMFP	12/31/2016	Total	Certified Certified Not Issued Pending	Not Issued	Certified	Certified	Facility Name
# of								data from	data from	Rate - 2018 data from	Jo		Decision	Approved/	Not		
Proposed								(census	(census	Utilization	Stations as		Submitted/	CON	/penssi		
								Census	Census	20.00	Certified		п		CON		
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CHAPTER 9 END-STAGE RENAL DISEASE DIALYSIS FACILITIES

Basic Principles

- 1. New facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care.
- 2. As a means of making ESRD services more accessible to patients, one goal of the N.C. Department of Health and Human Services is to minimize patient travel time to and from the facility. Therefore, end-stage renal disease treatment should be available within 30 miles from the patients' homes. In areas where it is apparent that patients currently travel more than 30 miles for in-center dialysis, proposed new facilities that would serve patients who are farthest away from operational or approved facilities should receive favorable consideration.
- 3. The State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for: home training and backup for facility-based patients suitable for home dialysis or in a facility that is a reasonable distance from the patient's residence; ESRD dialysis service availability at times that do not interfere with ESRD patients' work schedules; and services in rural areas.

Assumptions of the Methodology

- 1. Home patients will not be included in the determination of need for new stations. Home patients include those that receive hemodialysis or peritoneal dialysis in their home.
- 2. Facilities may have at least one dialysis station dedicated to training of home dialysis patients. If so, these stations are included in the planning inventory.
- 3. Under the facility need methodology, any facility at 75% utilization or greater as of the current reporting date may apply to add dialysis stations.
- 4. Facilities that are eligible to add stations based on the facility need methodology may add the number of stations calculated by the methodology, up to a maximum of 20 stations in a single calendar year.
- 5. Facilities certified and in operation at least 9 but less than 21 months do not have a need determination in the SMFP. Rather, they may apply to add stations based on Condition 1 in the Facility Need Methodology.

Facility Need Determination Methodology

A dialysis facility located in a county that has no county need determination in the current SMFP may apply for additional stations under one of the two following conditions.

Condition 2: Pertains to facilities certified and in operation at least 21 months as of the data cutoff date for the current SMFP (*Table 9B*).

- a. A facility may add stations if its utilization reported in the current SMFP is at least 75%, or 3.0 patients per station per week or greater $[((Column\ L/Column\ K)/4) = Column\ M]$.
- b. If the facility's utilization reported in the current SMFP meets Condition 2.a, use the following calculations to determine the number of stations needed:
 - i. Subtract the facility's number of in-center dialysis patients reported in the previous SMFP from the number of in-center dialysis patients reported in the current SMFP (Column L). The difference is the net in-center change for one year. For the 2020 SMFP and Proposed 2020 SMFP only, use Table B in the July 2018 SDR rather than the previous SMFP to obtain the number of in-center dialysis patients for the previous reporting year.
 - ii. Divide the result of Condition 2.b.i by the number of in-center patients from the previous SMFP to determine the projected annual growth rate.
 - iii. Multiply the result from Condition 2.b.ii by the facility's number of in-center patients reported in the current SMFP (Column L).
 - iv. Add the result of Condition 2.b.iii to the number of in-center patients reported in the current SMFP.
 - v. Divide the result of Condition 2.b.iv by 2.8.
 - vi. Subtract the total stations recorded in the current SMFP (Column J) from the result of Condition 2.b.v. The remainder is the number of stations needed (Column N). Round fractions of 0.5 or greater to the next highest whole number.
- c. The facility may apply to add stations to meet the need calculated in Condition 2.b.vi, up to a maximum of 20 stations. When a facility has a need determination, applicants may apply to add any number of stations up to and including the number of stations in the need determination. However, applicants must demonstrate the need for the number of stations applied for in the CON application. When a facility has a need determination, the applicant may apply to add stations up to three times per calendar year, but the total stations applied for in a single calendar year cannot exceed the total number of stations in the facility's need determination, as calculated in Condition 2.b.vi.