

Wake Forest Baptist Health
Petition for Changes in Basic Policies and Methodologies in the 2020 SMFP
End-Stage Renal Disease Need Determinations
March 6, 2019

1. NAME, ADDRESS, EMAIL ADDRESS, AND PHONE NUMBER OF PETITIONER

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2. STATEMENT FOR THE PROPOSED CHANGE

Wake Forest Baptist Health (“WFBH”) requests that a number of changes be made to the basic policies and methodologies in the 2020 State Medical Facilities Plan (“SMFP”). Those proposed changes are as follows:

- A. Convert the Facility Need Methodology for end-stage renal disease (“ESRD” or “dialysis”) services from a need determination to a new policy, Policy ESRD-1. Proposed Policy ESRD-1 would eliminate the publishing of the Semiannual Dialysis Report (“SDR”) but would still permit dialysis providers to expand based on current utilization data. The policy would include the following:
 - i. A facility applicant would be required to be at a current patient capacity of 80% at time of application;
 - ii. The facility applicant would have to prove that an 80% utilization (3.2 patients per station) would be achieved by the end of OY1;
 - iii. The facility could file for up to 10 additional stations;
 - iv. Allow a facility the opportunity to file an application up to three times per year.

- B. Revision of Policy ESRD-2, which allows the relocations of existing dialysis stations within the host county and to contiguous counties, to take into account the elimination of the SDR. Suggested changes include:
 - i. Using the current number of existing and approved dialysis stations in each county for determining whether stations should be relocated across county lines;
 - ii. Allow for an opportunity to file an application two times per year (one within the first half and one within the second half).

- C. The proposed revision to Policy ESRD-2 also will require a revision to several of the Basic Principles and other portions of the SMFP, to eliminate reference to the SDR.

All of these proposed revisions and the reasons therefore are discussed in detail in Attachment 1 hereto.

3. REASONS FOR THE PROPOSED CHANGE

In 2019, the State Health Coordinating Council (the “SHCC”) transferred the initial review of future need determinations for dialysis services from the Long Term and Behavioral Health Committee to the Acute Care Services Committee. In addition, the SHCC created a Workgroup to study proposed changes to basic policies and need determinations in the SMFP for dialysis services. The Workgroup, which includes Healthcare Planning staff and members of the Acute Care Services Committee, has conducted three public meetings with interested parties, on November 14, 2018, January 16, 2019 and February 13, 2019. WFBH representatives have attended each of those meetings.

N.C. Gen. Stat. § 131E-176(25) provides that the SHCC shall conduct each year at least one public hearing before and six public hearings after publishing the Proposed SMFP. If those requirements are met, then the SMFP is exempt from the rule making provisions of the Administrative Procedure Act. N.C. Gen. Stat. §150B-2(8a)k. For many years, need determinations under both the Facility Need Methodology and the County Need Methodology have been made based upon the data in the semiannual dialysis report (“SDR”). The SDR is compiled and published in January and July of each year, based upon North Carolina dialysis facility utilization data reported to Healthcare Planning as of December 31 and July 30.

Healthcare Planning representatives have recently stated their belief that this method of identifying need using the SDR is inconsistent with the certificate of need law, because the data in the SDR is not available for public review and comment before it is published. In addition, the Agency believes that the work required to collect and publish the SDR semi-annually (as opposed to other health services, which are reported annually) is overly burdensome to Healthcare Planning staff. For those reasons, Healthcare Planning has proposed at Workgroup meetings that all need determinations and policies permitting the development of additional dialysis services be based on annual, rather than semiannual data, which data would be available for review and comment prior to being published in the annual SMFP. That change has been a primary topic of discussion at the Workgroup meetings.

WFBH recognizes that the development of the SDR twice a year and the multiple filing dates for ESRD CON Applications increases the workload on Healthcare Planning staff at a level not experienced for other services identified in the SMFP need determinations. However, WFBH is concerned that the proposal submitted by Healthcare Planning staff will not meet the needs of current and future dialysis patients. Unlike other health services, dialysis services in North Carolina are heavily utilized on a continual basis. End stage renal disease is a chronic condition, and if patients do not receive dialysis, they will die. Diseases such as hypertension and diabetes, which disproportionately affect the poor, make the need for dialysis more likely. On average a single dialysis patient utilizes an ESRD treatment facility 13 times per month, or 156 times per year. While hospitals and other acute care services are planned based on geographic concentrations of populations, ESRD treatment facilities are planned based on the geographic dispersion of at least 32 ESRD-confirmed patients within a 30-mile radius.

These facts are borne out by current dialysis facility data. While North Carolina's overall population has grown at a rate of 1.1% per year, the population of ESRD patients statewide has grown at a rate of nearly 4% per year. Statewide utilization of dialysis services was approximately 76%, only 4% less than the 80% standard of care for ESRD services. Any policy which does not adequately address the continued inevitable growth of the ESRD patient population cannot serve the needs of those patients.

Notwithstanding these concerns, it appears that the most likely outcome of the need determination process for the development of ESRD services in the 2020 SMFP will result in the elimination of the SDR. The proposed revisions herein are designed to address both the legal and workload concerns raised by the Agency, while continuing to ensure that dialysis facilities will be developed or expanded based on the most up-to-date data available if the SDR is no longer published. This process will, in turn, ensure that the needs of the current and future dialysis patient population in North Carolina will continue to be met.

Each of the proposed changes discussed herein, along with the reasons for those changes, are explained in detail in Attachment 1 hereto.

A. Statement of the Adverse Effects on the Population

This proposal will have no adverse effect on the dialysis population. To the contrary, the approval of this Petition will ensure that the needs of the dialysis population will continue to be met in a timely fashion.

B. Statement of the Alternatives Considered

WFBH considered several alternatives to this Petition. Those alternatives included:

- 1) Proposing that the SHCC maintain the SMFP need methodologies and the SDR as they currently exist. WFBH believes that the current system adequately meets the needs of current and future ESRD patients in North Carolina. However, because it is apparent that the Agency believes that the workload involved in preparing the SDR places a burden on Healthcare Planning staff and that its publication is not in compliance with the CON law, WFBH has proposed the alternative described herein.
- 2) Accept Healthcare Planning staff's recommended changes and need methodology as discussed during Workgroup meetings. However, WFBH believes that methodology is flawed in part and would not adequately enable existing facilities to grow to meet the needs of their dialysis patients, because all of the facility utilization data on which it relies would be more than a year old before the application is filed.¹
- 3) Submit the proposed alternative contained in this Petition.

¹ WFBH has separately filed comments on the County Need Methodology proposed by Healthcare Planning staff.

4. The Proposed Change Will Not Result in an Unnecessary Duplication of Services

Approval of this petition will not result in an unnecessary duplication of services. Rather, it will ensure that dialysis services will continue to be provided in a manner consistent with the need methodologies and policies contained in the SMFP for many years.

5. The Proposed Change is Consistent with the Three Basic Principles Governing the Development of the SMFP: Safety and Quality, Access and Value

A. Safety and Quality

WFBH agrees with the SMFP's recognition of "the importance of systematic and ongoing improvement in the quality of health services." The requested change is consistent with this principle. Particularly for dialysis patients, access to service close to a patient's home is of primary importance, because as outlined above, dialysis patients must travel to and from dialysis 156 times per year in order to maintain life and overall health. The frequency of care required and the longevity of the service dictate proximity to service as a primary factor in ensuring patient compliance and quality patient outcomes. The proposed policy ensures that patients in need of in-center dialysis will be able to obtain treatment as close as possible to their homes.

B. Access

WFBH also fully supports the principle of "equitable access to timely, clinically appropriate and high quality health care for all the people of North Carolina." As discussed in Section A. above, high quality care for dialysis patients requires access close to patients' homes. Approval of this petition will result in continued timely access to dialysis stations for the medically underserved.

C. Value

WFBH supports the SMFP's definition of "health care value" as "the maximum health care benefit per dollar expended." In this case, the proposed changes to the SMFP will continue to ensure that ESRD services are developed in a timely and efficient manner. Facilities expanding under the new Policy ESRD-1 will continue to use an operational threshold of 80% when projecting future service utilization and avoid the pitfalls of excess capacity and excess utilization.

Conclusion

Because it appears that the SHCC desires to eliminate the SDR process, WFBH believes that the proposal set forth in this Petition is most likely to continue to serve patient needs. WFBH will continue to work with members of the SHCC, Healthcare Planning staff and the other providers of ESRD services in North Carolina to find the most effective alternative for continuing the provision of this essential health service.

ATTACHMENT 1

PROPOSED CHANGES TO SMFP

3. FACILITY NEED METHODOLOGY	REMOVE FROM NEED DETERMINATIONS AND RELOCATE TO NEW POLICY ESRD-1	REASONS
		The Facility Need Methodology is more analogous to a policy, allowing a provider to file even when there is not otherwise a need determination in the county.
	<p><u>Policy ESRD-1: Development of Additional Dialysis Stations Based on Facility Utilization</u></p> <p>A dialysis facility located in a county for which there is no currently approved and published County Need Determination in the current SMFP may file a certificate of need application to request additional dialysis stations if the utilization of its existing and approved in-center dialysis stations is 3.2 patients per station or greater, as of the first date of the month in which the application is filed.</p> <p>The applicant shall demonstrate that all of its existing, approved and proposed in-center dialysis stations will be serving 3.2 patients per station as of the end of the first full operating year.</p>	Proposed policy ensures that only needed stations will be developed, because application must show that it is at 80% utilization as of the date of the application and will continue to be at 80% utilization as of the end of the first operating year of the project.
POLICY ESRD-2	REVISION	REASON
Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:	[No change]	
1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and	1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county as of the first day of the month in which the application is filed;	Sets a specific date on which applicants are required to demonstrate “current” facility census.
2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the	2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county losing	Ensures that stations approved after the SMFP is published will be

number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and	stations as a result of the proposed project, based upon the total number of existing and approved stations reported to Healthcare Planning as of the as of the first day of the month in which the application is filed; and	accounted for in a Policy ESRD-2 application.
3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.	3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis station in the county that would gain stations as a result of the proposed project, based upon the total number of existing and approved stations reported to Healthcare Planning as of the as of the first day of the month in which the application is filed.	Same as above.
	4. The applicant shall contact the Project Analyst assigned to the relevant ESRD service area in which the proposed facility will be located, to verify the total number of existing and approved stations reported to Healthcare Planning in the affected counties.	Shifts the burden to the applicant to verify current county deficits and surpluses prior to filing an application to relocate stations across county lines.
BASIC PRINCIPLES	REVISION	REASON
3. Healthcare Planning will maintain a list of existing facilities and stations, utilization rates and projected need by county that is updated semiannually. Updated projections will be available two times a year on a published schedule.	3. Healthcare Planning will maintain a list of existing facilities and stations, utilization rates and projected need by county that is updated annually in the SMFP.	Reflects elimination of the SDR.
4. Updates of the projections may target counties that have developed sufficient need to warrant consideration for facility expansion or for establishment of a new facility. Actual numbers are not published in the North Carolina State Medical Facilities Plan so they can be updated as appropriate by Healthcare Planning.	[Eliminate entirely]	Since (1) there will be no semiannual updates, and (2) facility need and county surpluses and deficits which do not trigger a County Need are covered in Policies ESRD-1 and ESRD-2, this principle can be eliminated.
DIALYSIS PATIENT DATA	REVISION	
Data on the dialysis population by county and by facility as of June 30, 2018 and as of December 31, 2018 shall be provided by End-Stage Renal Disease providers operating certified dialysis facilities to the	Data on the dialysis population by county and by facility as of December 31, 2018 shall be provided by End-Stage Renal Disease providers operating certified dialysis facilities to the Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section.	Reflects elimination of the SDR.

Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section.		
METHOD FOR PROJECTING NEW DIALYSIS STATION NEED	REVISION	REASONS
Healthcare Planning shall determine need for new dialysis stations two times each calendar year, and shall make a report of such determinations available to all who request it. This report shall be called the North Carolina Semiannual Dialysis Report (SDR). Relocations of existing dialysis stations within a county shall be reviewed independently (see Chapter 3, Category D). The Semiannual Dialysis Reports will use facility, station and active patient data as of June 30, 2018 for the “January 2019 SDR” and as of December 31, 2018 for the “July 2019 SDR.” A new five-year trend line will be established in the “July 2019 SDR” based on data as reported to the Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section for the time period ending December 31, 2018. Need for new dialysis stations shall be determined as follows:	Healthcare Planning shall determine need for new dialysis facilities annually and shall make a report of such determinations to the SHCC for review and publication in the SMFP. Relocations of existing dialysis stations within a county shall be reviewed independently (<i>see Chapter 3, Category D</i>). The SMFP will utilize provider self-reported data submitted for data end date December 31, 2018. A new five-year trend line will be established for the SMFP based on that data. Need for new dialysis facilities shall be determined as follows:	Reflects elimination of the SDR.