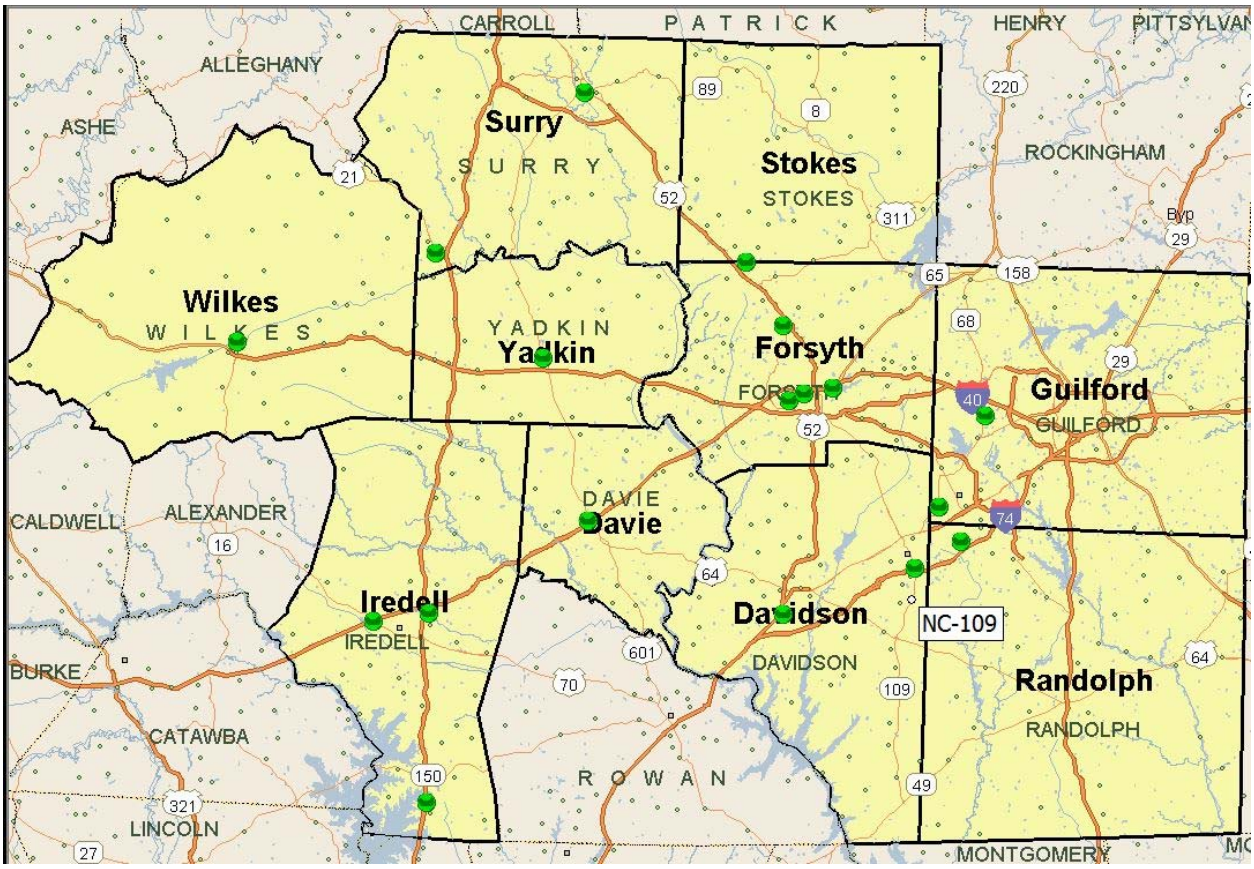
Wake Forest University Health Sciences Dialysis Program
SDR Revision Proposal
April 24, 2018

WHO WE ARE

Wake Forest University Health Sciences dialysis program is the largest non-profit group of dialysis facilities in the state of North Carolina. Collectively, its 18 clinics provide ICH and home dialysis services to more than 1900 patients with locations in 10 counties. The profits from those services stay in North Carolina funding research that may eventually lead to new breakthroughs or perhaps even a means of reversing end-stage renal disease. On average, more than 92% of the services provided go to patients without commercial insurance, who typically fall into one of several disadvantaged groups – the elderly, those living below the poverty level, women, and minorities. While some of the facilities are located in or near major metropolitan areas, many are rural facilities, whose development came about through the CON process. Additionally, Wake Forest Baptist Health an affiliate of Wake Forest University Health Sciences is ranked 25th nationally in Nephrology with survival rates of nephrology patients that are better than average at 80%. Baptist Health provides transplantation services for those ESRD patients who qualify.

Wake Forest Out-Patient Dialysis Locations



HISTORICAL ESRD CON DATA

Over the last twenty years, the dialysis CON system and methodology has worked well for North Carolinians, expanding dialysis services into rural and remote areas and within 30 miles or 30 minutes for patients who otherwise would face tremendous obstacles to receive their care. As the patient population continues to grow, locations and access to care has expanded to meet their needs without costly duplication of services.

SDR Data Date	Total Patients	ICH Patients	Certified Stations	Utilization Rate Average	Number of Facilities	Counties Served	Number of Home Patients	% Home Patients
12/31/1996	7,227	6,069	1,798	84%	93	70	1,158	16.02%
12/31/2006	12,408	11,351	3,569	80%	149	83	1,057	8.52%
12/31/2016	17,650	15,448	4,919	79%	202	87	2,202	12.48%
Growth	144%	155%	174%	81%	117%	24%	90%	

The statewide average utilization rate that hovers near a constant 80% is proof-positive that the SDR, the dialysis methodology that enables expansion when a facility reaches 80% utilization or 3.2 patients per station, and the county need methodology that incentivizes providers to compete to provide services in previously unserved or underserved areas has worked and continues to work well to provide quality care to North Carolinians.

Issues

In order to improve the process of planning for dialysis moving forward, to enhance transparency at every level, and to better distribute the workload of CON analysts, we make the following recommendations:

I. Timing of Data Collection Prevents Public Vetting of ESRD Data

Currently, the ESRD data is collected within 45 – 60 days of the end of the reporting periods, which are June 30 for the January SDR and December 31 for the July SDR as outlined below:

Current SDR Data Collection & Submission Dates

Data End Date	Data Submission Date	Public Comment Period	LTC Committee Meeting	SHCC
June 30	August 15	NONE	September 6	October
December 31	February 15	NONE	April 5	May

We propose to change the data end date and submission dates for both periods, which will allow submission to the LTC Committee and the SHCC, as well as public vetting of the data via the NCDHSR website.

Proposed SDR Data Collection & Submission Dates

Data End Date	Data Submission Date	Public Comment Period	LTC Committee Meeting	SHCC
May 31	July 15	August 15-31	September 6	October
November 30	January 15	February 15 – March 2	April 5	May

The new proposed data end dates allow not only for public vetting of the November 30 data, but also allows the planning section adequate time to compile, verify, and prepare the data for presentation as well as public review.

II. Excessive Workload to Staff Twice a Year

The current ESRD CON rules allow for multiple opportunities to file applications for dialysis station transfers. However, the addition of ***new*** stations using facility need methodology limits providers to only two filing opportunities (March 15th and September 15th.) The increase in facilities statewide has resulted in the number of CON's filed on these two dates to be excessive.

Given that 40% of all CON applications over all provider types are for dialysis, and the bulk of those applications are filed to add dialysis stations via facility-need methodology, additional filing opportunities could help spread the workload to realize more manageable numbers. We propose the following submission dates for ESRD facility need applications followed by a clarification of the related filing rules, which may be affected due to the proposed changes:

- Current facility need methodology remains intact which requires providers to have a utilization rate of 80% or better published in the most recent SDR.

- Submission dates for facility need applications will be expanded to allow for submission of those applications on the following dates provided the applying facility meets the 80% utilization requirement listed, above, in the applicable SDR:

Proposed Facility Need Filing Schedule

SDR for 80% Utilization	Opportunity 1	Opportunity 2	Opportunity 3	Opportunity 4
January SDR	February 15	March 15	April 15	May 15
July SDR	August 15	September 15	October 15	November 15

- Applications for facility need are limited to one per applicable SDR per facility
- This spreads the workload out over several months / submission deadlines
- Allows providers greater flexibility in filing for need resulting in overall better applications

Due to the competitive nature of CON's for a published county need and for need related to a 10-station county deficit, we suggest those applications be limited to filing twice per year.

Proposed County Need or 10-Station Deficit Filing Schedule

SDR for a Published County Need or 10-station Deficit	Filing Deadline
January SDR	March 15
July SDR	September 15

- Allows analysts the ability to review competing applications simultaneously

III. Additional Issues Mentioned by the State Agency

A. Define ICH Patient, Acute Patient, Transient Patient for ESRD Census Reporting Purposes

In recent talks with other providers, there appears to be a disconnect between the definition of what constitutes an ICH patient who should be included in the semi-annual census count submitted to the State Agency for inclusion in the SDR, and the number of patients reported by some providers. The reporting of Acute and Transient patients can lead to inflated utilization rates. In order to remedy any confusion, we propose the following definitions:

ICH Patient – a patient diagnosed with ESRD, who has ***permanently*** transferred their care to a dialysis facility and resides within the immediate and/or contiguous health service area to which the provider is located

Acute Patient – a patient suffering from some form of renal failure that has ***not*** been diagnosed with ESRD and who only requires dialysis on a short-term basis.

Transient Patient – a patient diagnosed with ESRD, who ***temporarily*** receives care at a facility due to reasons of convenience.

New Rule to be included on ESRD data collection forms

Census count must exclude ***Acute*** patients and ***Transient*** patients who have not ***permanently*** transferred their care to the reporting provider's facility.

B. Limit the time frame in which providers must certify *all* stations granted by a single certificate of need, which makes the "available stations" reported in the SDR a more accurate depiction of operational stations in a county.

There is currently no rule, which mandates a provider a limitation on the amount of time by which all ICH stations granted within a single certificate of need must be certified. We propose the following to be included as a ***condition for approval*** with which a project proponent must agree to comply in writing prior to issuance of the CON:

12-Month Timeframe to Certify All Stations of a Multi-Station CON

All dialysis stations issued as part of a multi-station CON award must be certified within 12 months of the ***CMS certification date of any portion of those stations*** or be forfeited back to the State Agency and removed from the ***"available"*** count of stations published by county in the SDR.

C. Verify Station Count Changes from Previous SDR

Currently, the Planning Section must validate the number of stations by facility. When the number of certified stations at a facility reported during SDR data collection differs from the number of certified stations included in the last SDR, the planner must verify the number of stations submitted by the provider is correct. In order to assist the planner and alleviate the confusion, we propose the following:

- If a change in the number of certified dialysis stations has occurred since publication of the last SDR, the provider will appropriately complete the data submission form to reflect that change

and

- Submit a copy of ***any applicable CMS certification letters*** that support the change in the number of certified stations along with the data collection form for each facility.

- Failure to comply will result in **no change** in facility station-count from the last SDR.

Conclusion

It is our hope that like us, the SHCC will see the value of the SDR and how it and its related policies have enabled an expansion of ESRD services throughout all areas of North Carolina. Semi-annual reporting of dialysis patient counts and service availability is critical to maintain ***safety*** via the availability of excellent care providers, ***quality*** via successful patient outcomes, ***access*** via an incentive to expand services to rural and remote areas, and ***value*** via a reduction in costly duplication of services while maintaining process transparency through public review of the data. Expanded application opportunities will allow providers a way by which to keep up with the continually growing ESRD patient population and alleviate the tremendous workload placed upon analysts bi-annually. We look forward to working with the SHCC to maintain the safety, quality, access, and value of service to our patients as together we reach a symbiotic accord.

Respectfully,

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