SUMMARY OF COMMENTS

A technical analysis of the proposed ESRD Modeling Tool, which forms the basis for the Planning Sections, proposed Changes to ESRD Facility Need Methodology has revealed errors in calculations.

A summary to the analysis include:

1. Planning Section Staff's "0402 - Discussion Paper" suggests that the CON-approved stations are not included within Facility Need calculations for the 3 SDR's and Inventory Adjustment is required to account for those stations.

2. Worksheets' formulas within the ESRD Modeling Tool created by the Planning Section demonstrate that Total Stations are included in calculations
   a. Formula cross reference for both Semi Annual & Annual need inclusive of Total Stations

3. Erroneous reference to "No Max Need" cells versus "Need" cells in calculations for 3 SDR's results were compared to annual.

4. Comparison with historical SDR data shows that the Proposed Annual Need methodology will incrementally reduce the ability of providers to meet the patient census growth demands for service.

5. Demonstration of the impact between 3 SDR Calculations and Annual "No Max Need" total shows "Annual" falls short of the 3 SDR's by a large margin.

6. Annual Reporting can work.

My name is William McDonald. I'm here on behalf of the Wake Forest University Health Sciences dialysis facilities as a 17-year employee of Health Systems Management, Inc. I am the Director of Development.

Over the last year, the Planning Section presented information to the SHCC to support the hypothesis that Annual ESRD data reporting can match the effectiveness of the SDR's as far as generating dialysis station needs. To that end, the Planning Section offered the ESRD Modeling Tool, which is used as a basis upon which to propose changes to the ESRD Facility Need Methodology. However, we believe that the ESRD Modeling Tool contains errors which erroneously shows "Parity" between the proposed Annual methodology and existing Facility Need Methodology, when "Parity" does not exist. Our analysis is contained in the document which I have provided to you and will walk through with you now.

THE STATE'S PROPOSED CHANGES TO THE FACILITY NEED METHODOLOGY ARE BASED ON INACCURATE DATA

Page 1 of your handout is an excerpt from the Planning Section staff's *0402 ESRD Discussion Paper,* Pages 3 and 4. The paper attempted to demonstrate the effectiveness of the annual model proposed by the Planning Section while explaining that it was necessary to activate an "Inventory Adjustment" to the results of the 3-SDR's "to account for stations under development." The paper suggests in the highlighted portions that CON-approved stations were not included when facility need was calculated for each of the SDR periods until the Inventory Adjustment was activated. As I will explain further, that assumption is inaccurate.

Page 2 of the handout, contains an analysis based upon the experience of North Burlington Dialysis based on data from the January 2017 SDR, as noted in the bottom table. The SDR's are the data source used in the ESRD Modeling Tool to calculate both Annual and 3 SDR's "need." **Page 2** also contains some examples from the ESRD Modeling Tool along with some red and black arrows, calculating the facility need under the new proposed methodology. This demonstrates that when ***"sur (-) def (+)"*** in the Facility Need Formula was calculated in the ESRD Modeling Tool, both Certified and CON Issued / Not Certified stations **were** included in the calculations, contrary to the statement in the *0402 ESRD Discussion Paper*.

The "Facility Need Formula" on this page, which is the same for each SDR period in the ESRD Modeling Tool, directly references the "Total Stations" cell for every facility for every period for which data is included in the model. Thus, **there is no reason to adjust the inventory projected by the 3 SDR's since both Certified and CON-Approved Stations are already part of the Facility Need Formula**.

Page 2(a) confirms the same SDR data used for Semi was also used for Annual, and "Total Stations" (containing both Certified and CON-approved stations) is referenced for both Annual calculations and Semi calculations. If an Inventory Adjustment were required, wouldn't it be required for both Annual **and** Semi since they use the exact same data and cell references?

However, that's not all. **Page 3** of the handout, provides another example from the ESRD Modeling Tool from the "Semi" need table, which illustrates how the totals generated on the "Summary" sheet were derived from the data. The top table on that page shows when the three "no max need" columns are highlighted and the Inventory Adjustment is set to "0" the total 3 SDR's stations is 1342.85 (circled in red on that table.) The table below that shows the result when the "Inventory Adjustment" is applied reducing the 3 SDR's results to 889.57 (circled in red on that table.

We believe that the Planning Section erroneously totaled the "no max need" cells when they should have totaled the "need" cells. While "no-max" cells calculated facility need without limiting the maximum stations per facility to 10-stations, the "need" cells complied with existing Facility Need Methodology, which requires a limit of no more than 10 stations per period per facility. Both of those columns containing the facility needs included both certified and CON Issued / Not Certified stations in their calculations. We do not see any reason why **all** stations generated by the prior SDR should be added to the station inventory for the current SDR since "CON-Approved not certified stations" for the current SDR **are already included** in the calculations via the "Total Stations" cell reverence.

Given the Planning Section's erroneous assumption that CON-Approved / Not Certified stations were excluded from the facility need calculations for the 3 SDR's, and the use of "no max need" data to represent the 3 SDR's results versus Annual reporting, a way to get an idea of the true results of the comparison is to total the results of the "need" column for 3 SDR's as we have done on **Page 4** of the handout. When actual historical 10-station need is summed, the three SDR's always generate more Facility Need stations than the proposed annual reporting. The net result to the data presented to the Acute Care Committee for passage to the SHCC, reveals that when "no max need" data is summed over 3 SDR periods (Jan 2016 to Jul 2017), the SDR's outperform annual reporting by 450 stations as illustrated on **Page 5** of the handout. **Page 4** shows when actual 10-station need is summed over the same 3 SDR periods, the SDR's produce 1151 potential station needs and outperform annual reporting by nearly 260 stations. If you move one SDR period into the future (Jan 2017 to Jul 2018) on **Page 4**, Actual Need (10-Station Max) outperforms annual need by 290 stations. Additionally, for that same

period, "Presumed No Max Need Inv. Adj. = 1" also outperforms annual need by over 100 stations.

The reason the 3 SDR's outperform Annual Reporting is the age of the data used to calculate the need, which is much more current for 3 SDR's than the data used in the State's proposed plan for annual reporting. Not to say that annual reporting won't work at all, but it does not work as presented by the Planning Section and over time its disparity versus the SDR's will increase, resulting in a loss of patient access to services contrary to the Basic Principles of CON. **Page 4** clearly shows that from Jan 2016 to Jul 2018 that disparity increased from 21.5% to nearly 30%.

Based on the data in the ESRD Modeling tool as presented, we believe that the proposed changes to Facility Need Methodology do not and cannot match the effectiveness of the SDR's at generating stations for the single reporting period shown to the Acute Care Committee nor for any other periods.

How Annual Data Reporting Can Work
We believe annual reporting **can** work as a means for Providers to determine and measure station need that they report in an application for CON. To accomplish this, we have provided an outline of how such a system could work. Please see Handout **Page 6**. While we won't go through **Page 6** due to time constraints, we will tell you that this proposal does not violate any rule, law or policy. This plan will allow for annual reporting of data and publication of that data in the SMFP. It will limit the development of new ESRD facilities to only those which are needed without causing duplication of services. It will serve the public interest, ease a burden on providers and by spreading out the workload, it will also ease a burden on CON Section analysts. Please consider it as a viable alternative to the changes to ESRD Facility Need Methodology proposed by the Planning Section, if you believe as we do that doing so best serves the ESRD patients of North Carolina who are depending on you and ESRD providers to look out for their interests.

We look forward to working with the SHCC, the Acute Care Services Committee, and the Planning Section to resolve these issues prior to approval of the 2020 SMFP.

1. Excerpts 0402 Discussion Paper, pages 3 and 4 – Modeling Tool "Inventory Adjustment" Explanation

- *Assumes that facilities applied for all prior needs (up to 10) in each SDR that showed a need.* It is not feasible for the modeling process to account for the number of stations applied for with total accuracy. Therefore, the model assumes that facilities applied for all of the stations that the current methodology showed they needed, even though it is common for facilities to apply for fewer or not apply at all. This assumption increases the planning inventory. The result is that the model may calculate a need that is lower than the actual need.

The following table summarizes the annual model and compares it to the 3 SDR model. It shows the model presented at the January 13, 2019 Interested Parties meeting. It is important to point out that we can adjust the parameters in the annual model (in "real time") to examine other results.

Number of Facilities				Number of Stations Needed		
With needs in 3 SDRs	With needs in Annual model	3 SDRs=Yes Annual=No	3 SDRs=No Annual=Yes	3 SDRs	Annual	Difference (annual minus 3 SDRs)
98	108	12	22	890	893	4*

* produced by subtraction of actual values, not the rounded numbers shown in the two preceding columns.

The first two columns show that 98 facilities had needs in the 3 SDR model, compared to 108 in the annual model. In 12 facilities, the 3 SDR model triggered needs for a total of 25 stations in facilities where the annual model did not show a need. On the other hand, in 22 facilities, the annual model triggered a need but the 3 SDR model did not. This result means that the annual model produced needs for 42 stations in the 22 facilities that would not have had a need across three SDRs. The annual model produced almost exactly the same number of needs as did the most recent 3 SDRs combined (893 compared to 890). Under the current facility methodology, a single SDR produces need for approximately 400-500 additional dialysis stations.

Incorrect Assumptions:

- Annual model matched the 3 SDR's

- CON-Approved Stations are unknown and missing from the ESRD Modeling Tool

- An "Inventory Adjustment" is required and accurate

The modeling process assumes that facilities applied for all of the stations calculated as needed across 3 SDRs. Changing this assumption affects the needs for the 3 SDR model only, not the annual model. This figure produces an estimate of the number of stations to add to the calculations to account for approved new stations not yet developed. It is important to account for stations under development, but it is not feasible for the current calculations to include the exact data for all time points. We know that facilities often do not apply for all of the stations the SDR methodology produces. In fact, a preliminary analysis showed that facilities apply for about 25% of the stations that the current semiannual methodology produces. Therefore, this parameter will show a lower number of needs across 3 SDRs than if the model assumes that facilities applied for no new stations. The accurate number is between zero and 10, but is not feasible to ascertain the exact number.

2. Total Stations from the ESRD Modeling Tool is the Sum of Certified and CON Issued / Not Certified Stations from the SDR. When "1" is selected for Inventory Adjustment, the previous SDR's need up to 10-stations is additionally subtracted in the equation used to calculate "need."   (24.13 – 20 = 4.1)

ESRD Modeling Tool "semi" Table

1	0 = add nothing to inventory
	1 = add prev 'need' to inventory
	2 = add prev 'no max need' to inventory

DO NOT CHANGE HERE; GO TO SHEET = summary

Facility Need Formula

f_x =IF(CN3=0,BQ5-X5,IF($C/$3=1,BQ5-X5-BM5,IF(CN3=2,BQ5-X5-BN5)))

CN	CO	CP	CQ	CR

			Jan 2017 SDR					Jul 2016 SDR to Jan 2017 SDR					
			X	Y	Z	BM	BN	BO	BP	BQ	BR	BS	BT
Location	FID	Facility Name	Total Stations	Number Stations	InCenter Patients	need	no max need	curr pats per stats	growth rate	proj pats per stats	sur(-) def(+)	need	no max need
Alamance	955786	BMA Burlington	45	45	93	0	0	2.07	-0.088	-26.50	-18.5	0	0
Alamance	956036	Burlington Dialysis	16	24	95	0	5.614385	3.96	-0.059	27.92	6.3	6.309501	6.309501
Alamance	100785	North Burlington Dialysis	20	16	73	0	0	4.56	0.058	24.13	4.1	4.134964	4.134964

Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates*

January 2017 SDR

County	Facility Identification Number	Provider Number	Facility Name	City	Certified	CON Issued/ Not Certified	Certified Stations 06/30/2016	Number In-Center Patients 06/30/2016	Utilization by Percent 06/30/2016	Patients Per Station
Alamance	140092	34-2709	Alamance County Dialysis	Graham	10	0	0	0	0.00%	0.0000
Alamance	955785	34-2533	BMA Burlington	Burlington	45	0	45	93	51.67%	2.0667
Alamance	956036	34-2567	Burlington Dialysis	Burlington	24	-8	24	95	98.96%	3.9583
Alamance	100545	34-2691	Carolina Dialysis - Mebane	Mebane	20	20	20	56	70.00%	2.8000
Alamance	160341	Proposed new site consisting of existing stations	Elon Dialysis	Burlington	0	10	0	0	0.00%	0.0000
Alamance	100785	34-2686	North Burlington Dialysis	Burlington	16	4	16	73	114.06%	4.5625

2

2(a). The formula for both Semi and Annual Need references the **"Total Stations"** cell. "Total Stations" includes both Certified and CON-Approved Stations negating a reason to apply an Inventory Adjustment to Semi Need.

Formula used for **Annual Need**:

In layman's terms:

Proj Pats per stats – Total Stats = sur(-) def (+)

Projected Needed Stations – (Certified & CON Approved Stations) = **Facility Need**

fx =BT5-AA5

	Jul 2017 SDR			Jan 2018 SDR			Jul 2018 SDR			Jul 2016 SDR to Jul 2017 SDR				Jul 2017 SDR to Jul 2018 SDR			
Facility Name	Total Stations	Number Stations	InCenter Patients	Total Stations	Number Stations	InCenter Patients	Total Stations	Number Stations	InCenter Patients	curr pats per stats	proj pats per stats	sur(-) def(+)	annual need	proj pats	sur(-) def(+)	annual need	
BMA Burlington	45	45	94	45	45	96	42	45	98	2.09	30.94	-14.06	0.00	36.49	-5.51	0.00	
Burlington Dialysis	16	24	96	14	24	101	13	24	98	4.00	32.59	16.59	16.59	35.73	22.73	20.00	
North Burlington Dialysis	16	16	68	16	22	74	16	22	75	4.25	23.93	7.93	7.93	29.54	13.54	13.54	
Carolina Dialysis - Mebane	20	20	65	27	20	71	27	20	70	3.25	30.79	10.79	10.79	26.92	-0.08	0.00	
Alamance County Dialysis	10	10	22	10	10	28	10	10	45	2.20	7.86	-2.14	0.00	32.87	22.87	20.00	
	4865	4909	15432	4880	4996	15727	4875	5023	15927				893.08			1084	

Formula used for **Semi Need**:

In layman's terms:

Proj Pats per stats – Total Stats = sur(-) def (+)

Projected Needed Stations – (Certified & CON Approved Stations) = **Facility Need**

fx =IF(CN3=0,BW5-AA5,IF(CN3=1,BW5-AA5-BS5,IF(CN3=2,BW5-AA5-BT5)))

FID	Facility Name	Jan 2017 SDR			Jul 2017 SDR			Jul 2018 SDR				proj pats per stats	sur(-) def(+)	need	no max need	proj pats per stats	sur(-) def(+)	need	no max need	sur(-) def(+)	need	no max need
		Total Stations	Number Stations	InCenterP atients	Total Stations	Number Stations	InCenterP atients	Total Stations	Number Stations	InCenterP atients												
955786	BMA Burlington	45	45	93	45	45	94	45	45	96		26.50	-18.5	0.00	0.00	30.01	-14.99	0.00	0.00	-14.36	0.00	0.00
956036	Burlington Dialysis	16	24	95	16	24	96	14	24	101		27.92	11.9	10.00	11.92	30.63	14.63	10.00	14.63	19.21	10.00	19.21
100785	North Burlington Dialysis	20	16	73	16	16	68	16	22	74		24.13	4.1	4.13	4.13	18.34	2.34	2.34	2.34	9.17	9.17	9.17
100783	Carolina Dialysis - Mebane	20	20	56	20	20	65	27	20	71		20.00	0.0	0.00	0.00	26.84	6.84	6.84	6.84	-2.76	0.00	0.00
140092	Alamance County Dialysis	10	0	0	10	10	22	10	10	28		0.00	-10.0	0.00	0.00	6.88	-3.13	0.00	0.00	1.14	0.00	0.00
		4875	4802	15184	4865	4909	15432	4880	4996	15727			376.1		431.8		384.6		455.8		390.3	455.3

2(a)

3. NO MAX NEED Used to Project 3 SDR's Stations

fx =SUM(BT3:BT205)

Location	FID	Facility Name	Total Stations	Number Stations	InCenter Patients	need	no max need	need	no max need	need	no max need		
					Jan 2017 SDR								
Alamance	955786	BMA Burlington	45	45	93	0	0	0	0	0	0		0 = add nothing
Alamance	956036	Burlington Dialysis	16	24	95	10	11.92389	10	14.63158	10	19.20638		1 = add prev 'nee
Alamance	100785	North Burlington Dialysis	20	16	73	4.134964	4.134964	2.339041	2.339041	9.165441	9.165441		2 = add prev 'no
Alamance	100783	Carolina Dialysis - Mebane	20	20	56	0	0	6.841518	6.841518	0	0		
Alamance	140092	Alamance County Dialysis	10	0	0	0	0	0	0	0	0		DO NOT CHANGE HERE; GO
						376.0663	431.7865	384.6406	455.7564	390.2933	455.3069		

CN: 0

AVERAGE: 447.6165696   COUNT: 3   SUM: 1342.849709

semi | annual | listing | summary | fac_view

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fx =SUM(BT3:BT205)

Location	FID	Facility Name	Total Stations	Number Stations	InCenter Patients	need	no max need	need	no max need	need	no max need		
					Jan 2017 SDR								
Alamance	955786	BMA Burlington	45	45	93	0	0	0	0	0	0		0 = add nothing to i
Alamance	956036	Burlington Dialysis	16	24	95	6.309501	6.309501	8.322078	8.322078	10	10.8843		1 = add prev 'need'
Alamance	100785	North Burlington Dialysis	20	16	73	4.134964	4.134964	0	0	9.165441	9.165441		2 = add prev 'no ma
Alamance	100783	Carolina Dialysis - Mebane	20	20	56	0	0	6.841518	6.841518	0	0		
Alamance	140092	Alamance County Dialysis	10	0	0	0	0	0	0	0	0		DO NOT CHANGE HERE; GO TO
						228.3256	253.7315	275.164	317.2206	277.0693	318.6179		

CN: 1

AVERAGE: 296.5233352   COUNT: 3   SUM: 889.5700055

3

semi | annual | listing | summary | fac_view

4. Calculating Need Annually Will Increasingly Reduce the Ability of Providers to Meet Patient Needs

	Actual Need (10-Stat. Max)	Actual No Max Need Inv. Adj. = "0"	Presumed No Max Need Inv. Adj. = "1"	annual need	Annual Need - Actual Need	% Difference in Annual Need and Actual Need
Jan 2016 to Jul 2017	1167	1385	942	960	-207	21.5%
Jul 2016 to Jan 2018	1151	1343	890	893	-258	28.9%
Jan 2017 to Jul 2018	1273	1535	1089	983	-290	29.5%

Actual Need (80% Utilization / 10-Station Limit) consistently out-performs the State's Proposed Plan using Annual Data.

If you look at the Jan 2017 to Jul 2018 period, the 3 SDR's outperform Annual, (1089 vs. 983) even with the erroneous "Inventory Adjustment" in place that reduced the previous 3 SDRs total to 890.

This disparity between Annual and Semi increases as the total ESRD patient population grows. From Jan 2016 to Jul 2018, the % difference rises from 21.5% to nearly 30%.

The compilation of these facts shows irrefutably that the State's Proposed Plan does not create "parity" with the SDR's and should not be approved for the 2020 SMFP.

4

5. "Annual" produces 450 less stations than the 3-SDR's

This value changes the "3 SDR" results ONLY.

Value	Description	Equivalent Value (do not change)	Inventory adjustments: from previous SDR to the current SDR, based on previous need
75	Utilization Criterion (eligibility to add stations)	3	0
1	Growth rate multiplier		0 = add nothing to inventory
70	Utilization threshold to determine number of stations needed	2.8	1 = add up to 10 stations from previous need
20	Maximum number of stations needed		2 = add all stations from previous need

These values change the "Annual" results ONLY.

"0" means only stations that were actually added to the inventory are included in the inventory.

Agency's Plan

Plans	Descriptions	Annual	Difference (Annual minus 3 SDRs)
		1/1/2016 - 12/31/2016	
	Stations	893	-450

Results

Plans	Descriptions	3 SDRs
		January 2017 July 2017 January 2018
	Stations	1343

1343 is reduced to 890 when Inventory Adjustment = 1 to show Annual "parity" to the SDR's

The SDR's are subject to:
80% Utilization Eligibility to File
80% Utilization of Potential Stations
10 Station Max
All Stations Up to 10 Added from Prior SDR's

The Agency's Plan is subject to:
75% Utilization Eligibility to File
70% Utilization of Potential Stations
20 Station Max
Only Actual CON Stations Added

5

6 - Annual Reporting Can Work
While Conforming to the Performance Standards and the Law

- Keep Facility Need Methodology – a process by which providers can add stations when not county need published.

- Providers report facility data annually for inclusion in the SMFP as an inventory report that is published. (County data will be used by the Planning Section to determine geographic need distribution by service area.)

- Keep the Performance Standards at 10A NCAC 14C .2203 unchanged at 80% utilization and 10 stations

- Allow providers to apply to add "facility needed stations" 4 times per year, for up to 10 stations total the first half of the year and up to 10 stations total the second half of the year, provided they can calculate a need for additional stations using the following formula:

  i. *Current Utilization Rate is >/=80%*
  ii. *(((Current ICH Census - SMFP ICH Census) / Months since SMFP data date) x 12)/SMFP ICH Census = Growth Rate*
  iii. *Current ICH Census + (Growth Rate x Current ICH Census) = Projected ICH Census*
  iv. *(Projected ICH Census / 3.2) – (Certified & Approved ICH Stations) = Needed Additional Stations*
  v. *Providers may round up fractions of 0.5 or more in Step iv. and apply for up to a maximum of 10 stations during a six-month period*
  vi. *Providers must prove 80% utilization of additional stations by the end of OY1 of the proposed project*
  vii. *A Facility Need is not determined to exist unless it is reported in an application for CON*

- This plan does not change County Need Determinations, it allows for annual reporting and data publication in the SMFP, it provides a means by which providers can meet patient needs timely, it maintains the intent of Facility Need Methodology, and it serves the public interest. It also relieves a burden on providers who need to expand to meet patient demand without requiring modification of the Performance Standards, while spreading out application submittal to ease the burden on the State Agency's analysts.