Written Comments Filed by Wake Forest University Health Sciences Concerning FMC Hickory Home Program, Project I.D. No. E-011436-17

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N.C. Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
809 Ruggles Drive
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January 2, 2018

RE: Written Comments regarding: FMC Hickory Home Program / Relocate the home hemodialysis training and support program and two dialysis stations from FMC Hickory to the existing FMC Hickory Home Program facility / Project ID No. E-011436-17

Dear Ms. Wilson and Ms. Halatek:

Wake Forest University Health Sciences ("WFUHS") submits the following written comments regarding the certificate of need ("CON") application filed on November 15, 2017 by Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Hickory Home Dialysis Program (hereinafter "FMC Hickory Home") for the December 1, 2017 review cycle to relocate the home hemodialysis ("HH") training and support program and two dialysis stations from the FMC of Hickory dialysis facility to FMC Hickory Home's existing freestanding facility for peritoneal dialysis ("PD") home training in Catawba County.

Wake Forest University Health Sciences ("WFUHS") is a non-profit corporation, organized under the laws of the State of North Carolina, which owns 16 certified dialysis facilities in 8 North Carolina counties offering in-center dialysis and home dialysis training services, and has received approval pursuant to the Certificate of Need Law ("CON Law") to develop and operate a 17th facility in Randolph County. Through its dialysis facilities, WFUHS provides both in-center hemodialysis ("ICH") and training and support for patients performing peritoneal dialysis or hemodialysis at home.

WFUHS does not provide dialysis services in Catawba County. However, WFUHS does provide dialysis services to Catawba County ICH and home dialysis patients. WFUHS anticipates that the specific proposal at issue could directly impact services provided at WFUHS' existing facilities who serve those patients. WFUHS is concerned about the precedent that may be set if the FMC Hickory Home application is approved. FMC Hickory Home's projected need methodology is not reasonable for a number of reasons, which are discussed below. Under any circumstance, further analysis of HH services in North Carolina needs to be conducted before the CON Section begins permitting providers to develop independent HH facilities.

In addition, pursuant to N.C. Gen. Stat. §131E-185(a1)(2), WFUHS requests that a public hearing be held on the FMC Hickory Home CON application due to its potential impact on the number of available dialysis stations in Catawba County.

WFUHS' specific comments are addressed below under the headings of the CON Section's CON application form.

ANALYSIS

SECTION A – IDENTIFICATION

The applicant describes in Section A that its project is intended to "Relocate the entire home hemodialysis training and support program, and its two hemodialysis stations dedicated to home hemodialysis training and support, from the FMC Hickory facility to the FMC Hickory Home Program, a separate end stage renal disease treatment center." Further, the applicant states that Policy ESRD-2 applies to the proposed project.

Given the assertions in Section A, WFUHS bases the following analysis on the application's ability to comply with Policy ESRD-2 and other related review criteria.

SECTION B - "CRITERION (1)" - G.S. 131E-183(a)(1)

"The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service*, health service facility, health service facility beds, **dialysis stations**, operating rooms, or home health offices that may be approved."*

As recognized by the applicant, Policy ESRD-2 applies to the FMC Hickory Home application. Policy ESRD-2 provides:

> *"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:*
>
> *(1) Demonstrate that the proposal shall not result in a deficit in the 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*
>
> *(2) Demonstrate that the proposal shall not result in a 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."*

FMC Hickory Home proposes to relocate two ICH stations from FMC Hickory to FMC Hickory Home and covert them to HH stations. The applicant states that since the dialysis stations would remain in Catawba County, neither a deficit nor a surplus would be created by their transfer and therefore, the application complies with Policy ESRD-2.

However, this is not correct. The SMFP need methodology for dialysis stations is based solely on the ***ICH*** station need. Principle 5 of the 2017 SMFP provides that "[h]ome 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." 2017 SMFP, page 374; see also, Wake Forest Univ. Health Sciences v. N.C. HHS, Div. of Facility Servs., 180 N.C. App. 327, 331, 638 S.E.2d 219, 222 (2006) ("The Agency asserts and this Court agrees that it is implicit in the policies set

forth, as well as in the action sought by Petitioners, i.e., the transfer of dialysis stations, that only in-center patients would be considered in determining whether the application complies with ESRD-2.") The county inventory of ICH stations includes all of the 12 dialysis stations at FMC Hickory. If two of those ICH stations transfer to FMC Hickory Home and convert to HH stations, they will effectively become unavailable for use by ICH patients, since ICH services are only allowed in ICH facilities. Further, utilization of those stations by ICH standards would fall to zero. Thus, by relocating two ICH stations for FMC Hickory to FMC Hickory Home ***and*** converting them to provide solely HH services, FMC Hickory Home is removing those stations from the Catawba County ICH station inventory.

As set forth in Table D from the July 2017 SDR (shown below), which applies to this review, Catawba County has a one-station deficit. If the FMC Hickory Home application is approved, Catawba County ICH patients would no longer have 70 ICH stations available; they would have only 68 ICH stations available and the county deficit would increase from a one-station deficit to a three-station deficit, which is inconsistent with the applicant's claims regarding no change in the dialysis station inventory for Catawba County as a result of this proposal. Therefore, the applicant fails to comply with ESRD-2, since its removal of stations from ICH use results in a station deficit in Catawba County.

Table D: ESRD Dialysis Station Need Determinations by Planning Area

County/ Multi-County Planning Area	12.31.12 Total Patients	12.31.13 Total Patients	12.31.14 Total Patients	12.31.15 Total Patients	12.31.16 Total Patients	Average Annual Change Rate for Past Five Years	Projected 12.31.17 Total Patients	12.31.16 Home Patients	12.31.16 Percent Home Patients	Projected 12.31.17 Home Patients	Projected 12.31.17 In-Center Patients	Projected 12.31.17 In-Center Station Utilization	Projected Total Available Stations	Projected Station Deficit or Surplus	County Station Need Determination
Alamance	290	285	308	319	340	0.041	354.0	34	10.0%	35.4	318.6	100	127	Surplus of 27	0
Alexander	42	34	40	39	37	-0.023	36.2	4	10.8%	3.9	32.3	10	10	0	0
Alleghany	5	7	11	8	5	0.081	5.4	1	20.0%	1.1	4.3	1	0	**1**	0
Anson	77	78	91	87	90	0.043	93.8	6	6.7%	6.3	87.6	27	31	Surplus of 4	0
Ashe	22	21	14	21	19	0.006	19.1	9	47.4%	9.1	10.1	3	0	**3**	0
Beaufort	97	108	114	125	125	0.066	133.3	25	20.0%	26.7	106.6	33	31	**2**	0
Bertie	61	58	66	55	66	0.031	68.0	8	12.1%	8.2	59.8	19	20	Surplus of 1	0
Bladen	106	87	89	98	103	-0.001	102.9	17	16.5%	17.0	85.9	27	26	**1**	0
Brunswick	134	135	145	133	136	0.005	136.7	28	20.6%	28.1	108.6	34	41	Surplus of 7	0
Buncombe	247	258	270	248	257	0.011	259.9	58	22.6%	58.7	201.3	63	82	Surplus of 19	0
Burke	101	111	117	124	124	0.053	130.6	10	8.1%	10.5	120.1	38	36	**2**	0
Cabarrus	176	187	211	212	216	0.054	227.6	36	16.7%	37.9	189.7	59	56	**3**	0
Caldwell	107	102	110	125	130	0.052	136.8	15	11.5%	15.8	121.0	38	34	**4**	0
Camden	17	15	13	13	9	-0.140	7.7	2	22.2%	1.7	6.0	2	0	**2**	0
Carteret	78	79	61	70	76	0.005	76.3	16	21.1%	16.1	60.3	19	26	Surplus of 7	0
Caswell	30	34	46	48	56	0.174	65.7	2	3.6%	2.3	63.4	20	11	**9**	0
Catawba	182	198	217	245	248	0.081	268.2	37	14.9%	40.0	228.2	71	70	**1**	0

Additionally, there is currently no *other* policy in place that would allow the transfer of certified dialysis stations (regardless of their use) from an existing ICH facility to a PD-only facility in a manner which would essentially remove those dedicated stations from the county's ICH inventory. The ability to add or transfer dialysis stations is currently limited to the SMFP need determinations and Policy ESRD-2. Therefore, because FMC Hickory Home's proposal is not consistent with the *"applicable policies and need determinations in the State Medical Facilities Plan,"* the application is non-conforming with Criterion 1.

SECTION C - "CRITERION (3)" - G.S. 131E-183(a)(3)

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

In Section C, pages 17-18 and Section P, pages 67-68, the FMC Hickory Home application acknowledges that in order to demonstrate need for the project, the applicant must comply with the Performance Standard at 10A NCAC 14C.2203(b), which requires a demonstration of at least 3.2 patients per station per week. This requirement is based upon the SMFP need methodology, which assumes 100% utilization of a dialysis stations occurs when each station serves at least four patients per week. Dialysis station need is in turn based upon a determination that existing facilities are operating at 80% utilization (3.2 ICH patients per station).

FMC Hickory Home applicant takes a different tack, assuming that based on the need for approximately 25 HH training sessions lasting six hours per day over a six week period, one station can train up to eight patients on an annual basis. The applicant then applies the methodology in 10A NCAC 14C.2203(b) to conclude that one station is needed to train every seven patients over the course of its year in order to meet the standard of 3.2 patients per station per week.[1] Thus, the requirement FMC Hickory Home sets for demonstrating a need for two HH stations is to serve at least 14 HH patients over the course of a year.

Assuming, for the sake of argument, that training 14 HH over the course of a year sufficiently demonstrates the need for two dedicated HH stations, the FMC Hickory Home application's proposed methodology does not meet this standard. First, the applicant relies upon its current census of seven Catawba County patients and two patients from other counties (for a total of nine patients) as of June 30, 2017. The application then grows the Catawba County HH population based upon the July 2017 SDR Catawba County average annual change rate ("AACR") of 8.1% per year. FMC Hickory Home projects no growth in the number of out-of-county home hemodialysis patients. Based on these assumptions, FMC Hickory Home projects to serve a total of 10 HH patients in OY 1 and 11 HH patients in OY 2. Thus, the applicant's projected utilization does not meet the performance standards to demonstrate need for the project.

FMC Hickory Home attempts to cure its current utilization deficiency by arguing that, in reality, FMC of Hickory has served at least 15 HH over the course of 2017, and that it is reasonable to assume that its past experience should continue at FMC Hickory Home. FMC Hickory Home bases this assertion on the following chart, which is contained on page 18 of the application.

[1] FMC Hickory Home "suggests" on page 16 of the application that the performance standard in 10A NCAC 14C.2203(b) of 3.2. patients per station per week is not applicable. That argument is inconsistent with prior Agency determinations, finding applications to develop new home hemodialysis services non-conforming where the application did not meet the performance standard requirements. See, e.g., Required State Agency Findings, BMA Cabarrus County Home Dialysis, Project I.D. #F-8755-11, pp. 9, 25. At any rate, FMC Hickory Home's "suggestion" is irrelevant for purposes of this review, because the applicant *chose* to use the rule's requirements as the basis for its need methodology.

FMC Hickory HH Census 2017 YTD	
Beginning Census	9
New patients trained and began home hemodialysis	2
New patients began training but stopped short of completion	1
Deaths	1
Changed modality / Returned to In-center dialysis	1
Patients received transplant	1
Total Patients relying on dialysis stations	15

However, this chart duplicates patients and consequently overstates the number of HH patients FMC of Hickory has served. The total number of HH patients trained should not include the first row. As a practical matter, most of the "beginning census" likely was comprised of HH patients who had already ***begun or completed*** their six-week training program in 2016. Unlike ICH patients in a facility like FMC Hickory, those patients would have no need for additional dialysis treatments in FMC Hickory Home. Further, FMC Hickory Home would not be certified to provide in-center hemodialysis treatments to home hemodialysis patients.

Given BMA's determination that 14 patients trained on two dialysis stations equates 80% utilization, we look at the projections BMA puts forth on page 15 of their application for BMA Hickory Home:

Total Projected Patients by County of Residence

County	OY 1			OY 2			County Patients as a Percent of Total	
	In-center Patients	Home Hemo Patients	Peritoneal Patients	In-center Patients	Home Hemo Patients	Peritoneal Patients	OY 1	OY 2
Catawba		8.5	24.3		9.2	26.3	76.7%	78.0%
Alexander			1			1	2.3%	2.2%
Buncombe		1			1		2.3%	2.2%
Burke		1	3		1	3	9.3%	8.8%
Caldwell			2			2	4.7%	4.4%
Lincoln			1			1	2.3%	2.2%
Rutherford			1			1	2.3%	2.2%
Total *		10.5	32.3		11.2	34.3	100%	100%

Methodology:

	HH	PD
Begin with Catawba County ESRD patients dialyzing at FMC Hickory (HH) and FMC Hickory Home Program (PD) on June 30, 2017	7	20
Project this population forward for six months to December 31, 2017, using one half the Catawba County Five Year Average Annual Change Rate.	7 X 1.0405 = 7.28	20 X 1.0405 = 20.8
BMA projects this population forward for one year to December 31, 2018.	7.28 X 1.081 = 7.87	20.8 X 1.081 = 22.5
Add patients from other counties. This is the projected certification date of this project and the date the two programs are combined. This is the beginning census for each modality, December 31, 2018.	7.87 + 2 = 9.87	22.5 + 8 = 30.5
BMA projects the Catawba County patient population forward for 12 months to December 31, 2019.	7.87 X 1.081 = 8.51	22.5 X 1.081 = 24.3
Add patients from other counties. This is the ending census for each modality, for Operating Year 1.	8.51 + 2 = 10.51	24.3 + 8 = 32.3
BMA projects the Catawba County patient population forward for 12 months to December 31, 2020.	8.51 X 1.081 = 9.20	24.3 X 1.081 = 26.3
Add patients from other counties. This is the ending census for each modality, for Operating Year 2.	9.20 + 2 = 11.2	26.3 + 8 = 34.3

As the calculations demonstrate, BMA projects to serve 10.51 home hemodialysis patients, rounded down to 10 home hemodialysis patients[5] at the end of Operating Year 1. Home

BMA projects that it will begin services at BMA Hickory Home with 9.87 patients on home hemodialysis, and that by the end of OY1, the facility will have 10.51 patients on home hemodialysis.

The difference in those two numbers should equate the number of patients who successfully utilized the home hemodialysis training stations, completed home hemodialysis training, and for whom BMA Hickory Home could bill for home hemodialysis treatments in addition to the existing home hemodialysis patients.

$$10.51 - 9.87 = 0.64 \textit{ or about } 1 \textit{ patient}$$

From the end of OY1 to the end of OY2, BMA Home Hickory projects its total home hemodialysis patient census to increase from 10.51 to 11.2. The difference in those two numbers should equate the number of patients who successfully utilized the home hemodialysis training stations, completed home hemodialysis training, and for whom BMA Hickory Home could bill for home hemodialysis treatments in addition to the existing home hemodialysis patients it previously trained.

$$11.2 - 10.51 = 0.69 \textit{ or about } 1 \textit{ patient}$$

CMS requires that any ESRD facility seeking to add home hemodialysis services have at least one new home hemodialysis patient to train before certification survey of that service. Thus, at least one of the "new" patients BMA predicts based on growth of the current home hemodialysis population must train prior to certification. This means that of the 15 patients BMA projects to "rely" on the two dialysis stations, none will actually complete home hemodialysis training during OY1 after Medicare certification. BMA will be unable to bill for home hemodialysis services until the facility is certified to provide home hemodialysis services.

Patients that have already been trained to perform home hemodialysis would not return for complete "re-training" consisting of 25 days of training sessions.. While some portion of those "beginning" patients may return for re-training should they experience a change in circumstance or home dialysis partner, the FMC Hickory Home does not address this issue. Instead, FMC Hickory Home's pro formas assume that all of those "beginning patients" will all train for at least 25 days. Because that is not accurate, FMC Hickory Home has overstated the HH population during the first year of operation.[2]

Realistically, it appears that FMC Hickory trained at most ***three*** HH patients since June 2017 – two who trained and began HH and one who began training for stopped short of completion. The three patients who died, changed modality or received a transplant would be part of that "beginning census." Based upon the projected increase in overall HH patients from OY1 to OY2, it appears

[2] This same flaw in FMC Hickory Home's analysis applies to the methodology on page 15 of the application. The population of seven HH patients at FMC Hickory as of June 30, 2017 will not grow by a specific percentage, because each of those seven HH patients will *cease* receiving HH dialysis at FMC Hickory after completion of their six-week training course. Without more specific historical HH data (which FMC Hickory Home does not provide), there simply is no mathematical formula which realistically can be applied to determine future HH utilization at FMC Hickory Home.

BMA only projects to serve or train one new patient for home hemodialysis. Again, this is far short of the 14 home hemodialysis patients to be trained *each year* in order to meet the utilization requirement BMA has set for itself.

Because these stations are for HH "training," it is reasonable to assume that patients requiring HH training make up the proposed facility census used to determine station utilization. Based on the information in Section C, it appears BMA will only fully train one patient during OY1 prior to certification and train one patient in OY2. Two patients fall shy of the 14 patients BMA states must utilize or receive home hemodialysis training on its two proposed stations and are required to meet the 3.2 patients per station utilization requirement. Indeed, one new patient per year does not even justify development of ***one*** home hemodialysis station.

As a practical matter, FMC Hickory Home's HH utilization is much more likely to fluctuate over the course of a year and from year to year. This fact is demonstrated in the limited actual facility HH data included in FMC Hickory Home's application (and confirmed in the January 2018 SDR), showing that FMC Hickory's HH population *dropped* from 12 on December 31, 2016 to 9 on June 30, 2017, which is a -25% growth rate. This is inconsistent with the 8.1% annual growth rate used by the applicant to project HH patients.

For the same reasons, the five-year AACR for Catawba County *ICH* patients is not a good determinant for future *HH* growth. HH service is relatively new, and the number of patients willing and able to rely on this modality is not nearly so predictable. The number of patients who make up the HH census only represent a tiny portion of the total dialysis population. Of the 260 patients the applicant serves in Catawba County, HH patients (9 total) make up 3.4%. FMC Hickory Home's recent decrease from 12 to 9 represents a 25% ***reduction*** in patients using that modality. This makes complete sense because, as noted above, unlike ICH patients, once HH patients are trained, they don't come back to the facility. Therefore, annual HH growth would be based solely on *new* HH patients, as opposed to the annual growth in an ICH facility, based on *existing* and new patients. The small numbers of overall HH patients, coupled with the different manner in which growth occurs in the HH population versus the ICH population, illustrate the unreliability of the applicant's HH projections based on the county ICH AACR.

Finally, FMC Hickory Home likely *possesses* the data from FMC Hickory to have presented a five-year AACR of HH patients at the facility, which would have demonstrated whether the five-year AACR for Catawba County *ICH* patients is similar to *HH* growth over the same time period. Similarly, FMC Hickory Home's parent company Fresenius Medical Care likely has nationwide dialysis facility data which could have determined whether there is any similarity between the ICH and HH patient annual growth. We suspect that that the applicant did not use either FMC Hickory or national data because neither data set supported that conclusion.

At any rate, having failed to demonstrate that there is any connection between Catawba County ICH AACR data and the potential growth in home hemodialysis, there is no documentation in the FMC Hickory Home application to demonstrate that the applicant can reasonably be expected to treat enough patients in OY 1 and OY 2 to demonstrate the need for two HH stations, nor why those stations are needed more by the HH population than the ICH population which they currently

serve. As a result, the applicant fails to demonstrate the need for the proposal and is non-conforming with the Performance Standards and with Criterion 3.[3]

SECTION E - "CRITERION (4)" - G.S. 131E-183(a)(4)

> *Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.*

Because FMC Hickory Home has failed to demonstrate conformity with Criterion 3, it has not proposed an effective alternative and cannot be approved.

SECTION G - "CRITERION (6)" - G.S. 131E-183(a)(6)

> *The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.*

As discussed under Criterion 3 above, FMC Hickory Home's utilization projections are unreliable, and the applicant fails to show a need for the project. For the same reasons, FMC Hickory Home's CON application is non-conforming with Criterion 6.

SECTION N - "CRITERION (18a)" - G.S. 131E-183(a)(18a)

> *The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.*

As shown under Criteria 3, 4 and 6, the FMC Hickory Home proposal will not have a positive impact on the cost effectiveness, quality, and access to the services proposed. The removal of ICH stations from use by the large ICH population in the county, which decreases those patients' access to services has not been justified based on the information put forth by the proponent. Therefore, the project is non-conforming with Criterion 18a.

SECTION P - "RULES" - G.S. 131E-183(b)

The FMC Hickory Home application is non-conforming with the following applicable rules.

[3] Further, even if the FMC Hickory Home application were able to demonstrate the need for one (but not two) HH station, it could not be conditionally approved. Page 44 of the FMC Hickory Home application proposes to serve isolation patients, as is required under federal dialysis facility Medicare certification rules. However, the facility could not serve both regular and isolation patients if it only had one station.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

As discussed under Criterion 3, the FMC Hickory Home CON application does not demonstrate a need for 3.2 stations per week and is nonconforming with this rule.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

As discussed under Criterion 3 above, the application fails to adequately provide all assumptions, including a reasonable methodology supporting the projected patient origin. Therefore, the FMC Hickory Home application is nonconforming with this rule.

CONCLUSION

In conclusion, because the FMC Hickory Home application's methodology for determining need for home hemodialysis stations is overstated and flawed, the application should be denied.

Further, and perhaps more important, the Agency needs to take the time to look at this issue on a broader basis, solicit input from all providers of dialysis services in the State, and determine what need, if any, there is for HH stations in ESRD facilities serving only home dialysis patients. There currently is no standard in the SMFP for determining need for HH stations. Agency staff have begun collecting data from existing facilities regarding their total HH and PD patients for several years, but that data was only publically reported for the first time in the July 2017 SDR. Before allowing applications such as this to go forward, the Agency and the State Health Coordinating Council (the "SHCC"), as well as the various stakeholders involved, need to discuss and develop plans, standards and rules which would promote reasonable development of HH services. WFUHS would support meetings with Agency staff and the other providers of dialysis services in North Carolina, in order to develop a policy which meets the needs of North Carolina residents for this important service.

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Thank you for the opportunity to provide these comments and your careful consideration of these important issues. Please contact William McDonald at (229) 387-3528 or Kimberly Clark at (229) 387-3527 with Health Systems Management, Inc., with any follow up regarding these comments. You may also contact me directly at (336) 716-1025.

Respectfully Submitted,

Russell Howerton, M.D.
Chief Medical Officer and VP Clinical Operations