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NORTH CAROLINA COU	URT OF APPEALS
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FLETCHER HOSPITAL INC. d/b/a) ADVENTHEALTH) HENDERSONVILLE,) Petitioner-Appellee,) v.)	
NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION, Respondent-Appellant,)	From the Office of Administrative Hearings Contested Case No. 22 DHR 02385 (Buncombe County)
and)	
MH MISSION HOSPITAL, LLLP, Respondent-Intervenor- Appellant.	
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RESPONDENT-INTERVENOR-APPELLANT MH MISSION HOSPITAL, LLLP'S BRIEF

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RESPONDENT-INTERVENOR-APPELLANT MH MISSION HOSPITAL, LLLP'S BRIEF

STATEMENT OF THE CASE

Petitioner-Appellee Fletcher Hospital Inc. d/b/a AdventHealth Hendersonville (collectively "AdventHealth") commenced this action by filing a Petition for Contested Case Hearing on 23 June 2022 contesting the decision of the Respondent North Carolina Department of Health and Human Services, Division of Health Services Regulation, Certificate of Need Section (the "Agency" or the "CON Section") conditionally approving a CON application filed by MH Mission Hospital, LLLP ("Mission") to build a Free Standing Emergency Department ("FSED") in Candler, North Carolina (R.p. 10). Following a Consent Motion to Intervene filed on 8 July 2022 by Mission (R.p. 842), the Office of Administrative Hearings entered an Order Allowing Intervention on 11 July 2022 (R.p. 848). AdventHealth, the Agency, and Mission all filed motions for summary judgment on 15 February 2023. A hearing was held by the Honorable David Sutton, Administrative Law Judge on 27 February 2023 (R.p. 888). A Final Decision granting summary judgement in favor of AdventHealth was entered on 17 March 2023 reversing the decision of Agency (R.p. 892-907).

Mission filed and served a Notice of Appeal on 14 April 2023 (R.p. 908). On 14 April 2023, the Agency filed a Notice of Appeal (R.p. 912). The record was settled by stipulation on 7 July 2023, filed in the Court of Appeals on 21 July 2023, and docketed on 25 July 2023 (R.p. 929). By order of this Court dated 14 August 2023, Appellants were granted an extension of time to file their appellate briefs until 9 October 2023.

STATEMENT OF THE GROUNDS FOR APPELLATE REVIEW

Administrative Law Judge Sutton's Final Decision denying Mission's and the Agency's Motions for Summary Judgment, granting summary judgment in favor of AdventHealth and reversing the decision of the North Carolina Department of Health and Human Services, Division of Health Services Regulation, Certificate of Need Section is a final decision subject to N.C. Gen. Stat. § 131E-188(b). An appeal therefore lies to the Court of Appeals pursuant to N.C. Gen. Stat. § 7A-27(b).

STATEMENT OF THE FACTS

The annual State Medical Facilities Plan ("SMFP") is the State's guiding document for CON-regulated health care services, facilities and equipment. In some cases, the SMFP establishes a "need" for certain CON-regulated health care assets. In such cases, the need determination established by the SMFP sets a determinative limit on the number of such assets that can be awarded in a given health planning service area. For other types of CON-regulated assets, the SMFP does not establish need determinations at all. In those cases, any CON applicant must establish the "need" for their proposed project in whatever manner they see fit. Freestanding emergency departments are not included in the list of health service facilities for which the SMFP provides a

projection of need based on an SMFP methodology. In other words, there is no predetermined, preestablished "need determination" by the CON Section in the annual SMFP for FSEDs as there are for other types of CON-regulated services, such as acute care beds among others. Under these circumstances, an applicant does not need to show that there is a need determination in the SMFP as required by N.C. Gen. Stat. § 131E-183 to propose to build a FSED. However, applicants proposing to build a FSED must still demonstrate a need for the project proposed in the application. N.C. Gen. Stat. § 131E-183(a)(3).

To demonstrate need, a CON applicant is permitted to develop its need methodology in any way it sees fit, so long as the underlying data, assumptions and related methodology are found by the Agency to be reasonable and adequately supported. There is no one way, nor any right or wrong way, to demonstrate need in a CON application. Typically, CON applications use some combination of historical use rates in a given geographic area for the service, equipment or facility the applicant proposes to develop, service area population growth, the aging of the service area population, growth in economic development and similar factors to develop a methodology that predicts future need for the service, equipment or facility being applied for in a proponent's CON application.

On or about 15 February 2022, Mission filed the Mission Application to develop a new FSED in Candler, Buncombe County, which the Agency identified as Project I.D. No. B-12192-22. Mission's Application was not in response to a need determination in the 2022 SMFP and was not a competitive review because no other provider filed a competing FSED application and the approval of Mission's Application would not result in the denial of another application. See 10A N.C.A.C. 14C.0202(3); see also Doc.Ex. 803-804. AdventHealth did not file a CON application to develop a FSED in Buncombe County and was not a competitive applicant in the CON Section's review of the Mission Application. The SMFP does not provide any binding restrictions on the number of FSEDs that can be developed in a single county.

The CON review period for the Mission Application began on 1 March 2022. During the review of the Mission Application, on 31 March 2022, AdventHealth filed extensive written comments pursuant to N.C. Gen. Stat. § 131E-185(a1)(1) opposing the Mission Application. Mission filed comments in response to the opposing comments of AdventHealth on 5 May 2022. Members of the public also filed comments both supporting and opposing the Mission Application.

N.C. Gen. Stat. § 131E-185(a1)(2) provides that:

no more than 20 days from the conclusion of the written comment period, the Department shall ensure that a public hearing is conducted at a place within the appropriate service area if one or more of several conditions apply, including that the proponent proposes to spend five million dollars (\$5,000,000) or more" or "a written request for a public hearing is received before the end of the written comment period from an affected party as defined in G.S. 131E-188(c).

It is undisputed that during the period from February of 2020 through September of 2022, the Agency did not hold public hearings with respect to any CON applications because of the COVID pandemic and out of concern for public safety. (Doc.Ex. 855). During that time period, the Agency conducted eightysix (86) CON application reviews which, pursuant to the provisions of N.C. Gen. Stat. § 131E-185(a)(2), would have required a public hearing because they were competitive reviews or involved projects costing more than five million dollars (\$5,000,000.00). (Doc.Ex. 353; 371-435). Those eighty-six (86) reviews involved a total of one hundred and fifty-two (152) applicants and proposed projects. The vast majority of those reviews resulted in at least one CON application being approved, including Mission's. The projects involved ranged from new hospitals to the acquisition of major medical equipment such as fixed cath labs, MRIs, PET Scanners, linear accelerators, new diagnostic centers, new facilities such as hospices and home health agencies, new hospitals, and a wide range of other services and facilities. Providers involved in those reviews include not only Mission, but Pardee Hospital; UNC Hospitals (with multiple projects approved including a new hospital in Durham County and new diagnostic centers); Duke University Health System; Novant Health; Cone Health; Wake Forest Baptist Hospital; Atrium Health; and others. *Id.*

It is undisputed that Mission proposed to expend more than \$5,000,000.00 to develop its proposed FSED in Candler. The proposed capital expenditure for the project was \$14,749,500.00. (Doc.Ex. 2; R.p. 620).

Mission's Application was filed on 15 February 2022. The Agency's review thereof commenced on 1 March 2022. As such, pursuant to N.C. Gen. Stat. § 131E-185(a1)(2), if the Agency had conducted a public hearing in connection with Mission's Application, that hearing would have been scheduled no later than 20 April 2022, which was twenty (20) days from the conclusion of the scheduled written comment period that ended on 31 March 2022. (Doc.Ex. 30).

At the time Mission's Application was filed and throughout the period from 1 March 2022, when the Agency's review began, to 20 April 2022, the date by which the Agency would have scheduled a public hearing, North Carolina and the entire United States were under an ongoing federal and state declared public health emergency due to the COVID pandemic. While conditions related to COVID were generally improving at that time, the pandemic was far from over. During the period from 1 March 2022 to 20 April 2022, COVID incidence rates in Buncombe County were steadily rising and the level of community transmission increased from moderate, to substantial, to high. (Doc.Ex. 348-49). Also, during that time period, numerous state and local county government functions were either cancelled or not being performed as usual.

Following the Agency's review of the Mission Application, the written comments, the response to comments, and the written comments in lieu of public hearing, the Agency issued its decision regarding the Mission Application (the "Agency Decision") and its Required State Agency Findings ("Agency Findings") on 24 May 2022, in which the Agency conditionally approved the Mission Application to develop a new FSED in Candler, Buncombe County.

On 23 June 2022, AdventHealth filed a Petition for Contested Case Hearing with the Office of Administrative Hearings ("OAH"), 22 DHR 02385, appealing the Agency's conditional approval of the Mission Application. On 15 February 2023, Mission, the Agency, and AdventHealth all filed Motions for Summary Judgment.

In their respective Motions for Summary Judgment, Mission and the Agency both argued that AdventHealth was not "substantially prejudiced" by the approval of Mission's Application as required by N.C. Gen. Stat. § 150B-23 because AdventHealth's claims of substantial prejudice were all allegations of either Agency error, which can never constitute substantial prejudice, or claims of market- and competition-based injury which, under our State's appellate precedent, also never can constitute substantial prejudice. In its competing Motion for Summary Judgment, AdventHealth, in addition to raising a series of "financial loss" and competition-based claims, alleged that the Agency's failure to hold a public hearing regarding the Mission Application during the COVID pandemic was Agency error which substantially prejudiced AdventHealth.

On 17 March 2023, ALJ David Sutton issued his Final Decision in which he granted the Motion for Summary Judgment by AdventHealth and denied the Motions for Summary Judgment filed by Mission and the Agency. The ALJ's Final Decision granting summary judgment to AdventHealth was based entirely on his conclusion that the Agency's failure to hold a public hearing in connection with its review of the Mission FSED Application was a violation of N.C. Gen. Stat. § 131E-185(a)(2) that substantially prejudiced the rights of

non-applicant AdventHealth and mandated reversal of the Agency's approval of the Mission noncompetitive CON application (R.p. 892-907).

STANDARD OF REVIEW AND APPLICABLE LAW

This Court reviews an ALJ's Final Decision and may reverse or modify that decision if:

[T]he substantial rights of the petitioners may have been prejudiced because the findings, inferences, conclusions, or decisions are:

- (1) In violation of constitutional provisions;
- (2) In excess of the statutory authority or jurisdiction of the agency or administrative law judge;
- (3) Made upon unlawful procedure;
- (4) Affected by other error of law;
- (5) Unsupported by substantial evidence admissible under G.S. 150B-29(a), 150B-30, or 150B-31 in view of the entire record as submitted; or
- (6) Arbitrary, capricious, or an abuse of discretion.

N.C. Gen. Stat. § 150B-51(b). *De novo* review is applied to alleged errors in categories one through four while categories five and six are reviewed under the "whole record test." In this appeal, Mission contends that the ALJ's Final Decision was in excess of is statutory authority, made upon unlawful procedure and/or affected by other error of law within the meaning of N.C. Gen. Stat. §

150B-51(b)(2)-(4). Thus, the *de novo* standard of appellate review applies to this appeal.

When reviewing a matter *do novo*, as here, this Court is not required to give deference to the lower court's ruling and is free to substitute its own judgment for that of the lower court. *Cumberland Cnty. Hosp. Sys., Inc. v. N.C. Dep't Health & Hum. Servs.*, 237 N.C. App. 113, 117, 764 S.E.2d 491, 494 (2014) (citations omitted).

In this case, the ALJ concluded as a matter of law that the Agency committed reversible error that substantially prejudiced AdventHealth and thus granted AdventHealth's motion for summary judgment. Resultingly, the ALJ denied Mission's competing motion for summary judgement alleging that AdventHealth failed to demonstrate Agency error that substantially prejudiced AdventHealth. Thus, the ALJs Final Decision is reviewable de novo. Craven Reg'l Med. Auth. v. N. Carolina Dep't of Health & Hum. Servs., 176 N.C. App. 46, 51, 625 S.E.2d 837, 840 (2006); Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs., 235 N.C. App. 620, 622, 762 S.E.2d 468, 470 (2014); Bio-Med. Applications of N. Carolina Inc. v. NC Dep't of Health & Hum. Servs., 282 N.C. App. 413, 415, 871 S.E.2d 555, 558 (2022);

Caldwell Mem'l Hosp., Inc. v. N. Carolina Dep't of Health & Hum. Servs., 264

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ARGUMENT

I. THE OAH ERRED IN REVERSING THE AGENCY'S APPROVAL
OF THE MISSION APPLICATION BY MISAPPLYING
APPLICABLE LAW AND IGNORING DECADES OF APPELLATE
PRECEDENT GOVERNING SUBSTANTIAL PREJUDICE

In reversing the Agency's approval of Mission's noncompetitive CON application to develop one of the first FSEDs in all of western North Carolina, the ALJ misapplied appellate precedent governing the requirement that a petitioner in a CON appeal demonstrate how it was substantially prejudiced by the decision at issue, ignored decades of appellate precedent governing the interplay of alleged Agency error and "substantial prejudice" in CON appeals and reversed a CON approval by the Agency based on claims of Mission's local competitor who did not and cannot demonstrate that it was substantially prejudiced by the Agency's approval of the Mission FSED CON application. The ALJ's denial of Mission's and the Agency's Motions for Summary Judgment, and his grant of AdventHealth's Motion for Summary Judgment, is wrong and constitutes reversible error.

- A. <u>The ALJ Erred in Denying Mission's and the Agency's Motions</u> for <u>Summary Judgment</u>
- 1. Summary Judgment was Appropriate in this Appeal of Mission's Noncompetitive CON Application Approval Because There is no Issue of Material Fact and AdventHealth has not and Cannot—Establish Substantial Prejudice, an Essential Element of its Case

A petitioner in a certificate of need appeal must show that (1) the agency substantially prejudiced its rights, and (2) the agency erred in one of the statutorily prescribed ways. See N.C. Gen. Stat. § 150B–23(a). Moreover, it is well established that "[t]hese showings must be <u>separately</u>" made. Caldwell Mem'l Hosp., Inc. v. N. Carolina Dep't of Health & Human Servs., Certificate of Need Section, No. COA18-586, 2019 WL 661559, at *2 (N.C. Ct. App. Feb. 19, 2019) (unpublished) (emphasis applied). To this end, Agency error—on its own—cannot supplant the need for a separate, distinct showing of substantial prejudice. See, e.g., CaroMont Health, Inc. v. N. Carolina Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Certificate of Need Section, 231 N.C. App. 1, 8, 751 S.E.2d 244, 249 (2013) (emphasis added).

AdventHealth in its Petition for Contested Case Hearing, its written discovery responses, its production of documents, and through deposition testimony taken as part of discovery has alleged that it was "substantially prejudiced" by the Agency's decision to approve the Mission Application, as

required by N.C. Gen. Stat. § 150B-23. Generally, AdventHealth has alleged that it was substantially prejudiced because: 1) the Agency committed various alleged errors in its application of the CON review criteria it applied to the Mission Application during its review thereof; 2) the decision by the Agency to grant Mission's application will erode AdventHealth's market share in Buncombe County, create unfair competition, and harm AdventHealth financially; 3) the Agency failed to consider the impact of the alleged "monopoly" that Mission has in Buncombe County and 4) the Agency failed to hold a public hearing and as a result AdventHealth was harmed.

AdventHealth's identified bases for claiming substantial prejudice as detailed by its designated Rule 30(b)(6) deposition witnesses, expert witness, pleadings, and discovery responses, taken together, all amount to either allegations of agency error, or speculative, non-specific claims of competition-based "harm" to AdventHealth. As discussed further herein, our appellate courts have held that these types of claims do not amount to substantial prejudice as a matter of law. See Bio-Medical Applications of N. C. Inc. v. N.C. Dep't of Health & Human Servs. 282 N.C. App. 413, 871 S.E.2d 555 (2022); Ridge Care, Inc., v. N. Carolina Dep't of Health & Hum. Servs., Div. of Facility Servcs., Certificate of Need Section, 214 N.C. App. 498, 716 S.E.2d 390 (2011);

Surgical Care Affiliates, LLC. v. N. Carolina Dep't of Health & Hum. Servs.,
Div. of Health Serv. Regul., Certificate of Need Section, 235 N.C. App. 620, 762
S.E.2d 468 (2014).

2. The North Carolina Appellate Courts Have Clearly Defined What Does and Does Not Constitute Substantial Prejudice

Over the past decade or longer, our State's appellate courts have set forth clear definitions of the phrase "substantial prejudice" as that term is used in N.C. Gen. Stat. § 150B-23. In so doing, our appellate courts have clearly defined what does, and what does not, constitute "substantial prejudice" in the context of a CON administrative appeal. As detailed below, that unbroken and consistent line of cases have stated, inter alia, that claims of lost patients, market share, revenue and/or profits never constitute substantial prejudice because all such claims are simply the outcomes of additional competition. Neither do claims of Agency error in the review and approval of a competitor's CON application. Finally, those cases have clearly prescribed a set of judicial rules and guidance for the lower courts to follow when evaluating claims of substantial prejudice in CON contested cases. Applying those appellate cases and holdings to the claims of AdventHealth in this case, it is clear that AdventHealth's claims of substantial prejudice are without merit and are each the type of substantial prejudice claims that our appellate courts have

consistently rejected over and over again. As such, AdventHealth's appeal was appropriate for disposition at OAH at the summary judgement stage and the ALJ's denial of Mission's and the Agency's Motions for Summary Judgment was an error of law.

a. <u>To Prevail in its CON Appeal, AdventHealth Was</u>
Required to Present Concrete Evidence of Substantial
Prejudice to Avoid Dismissal and Agency Error Does Not
Constitute Substantial Prejudice.

AdventHealth was required to demonstrate at OAH both material Agency error and that it, specifically, was substantially prejudiced by the alleged Agency error. If AdventHealth failed on either prong at OAH, then its appeal should have been dismissed on summary judgment. As our appellate courts have repeatedly held, where petitioners fail to meet the threshold of demonstrating substantial prejudice then any demonstration of Agency error is immaterial, and their case may not proceed to a contested case hearing. A mere showing of error by the Agency is not sufficient. Parkway Urology, P.A. v. N.C. Dep't of Health and Hum. Servs., 205 N.C. App. 529, 696 S.E.2d 187 (2010). The notion that a showing of Agency error establishes an automatic showing of substantial prejudice has been flatly rejected by our appellate courts. CaroMont Health, Inc., 231 N.C. App. 1, 751 S.E.2d 244. Even if AdventHealth could demonstrate material Agency error in this case—which it

cannot—it is well established that a showing of Agency error, standing alone, is not enough to overturn the Agency decision in a CON case. *Id*.

As OAH stated in its 9 July 2021, Final Decision in *The Charlotte-Mecklenburg Hospital Authority D/B/A Atrium Health Lake Norman v. NC Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need and Presbyterian Medical Care Corporation and Novant Health, Inc.,* 20 DHR 03986:

- 27. Thus we come to the second impassable obstacle Petitioners Lake Norman for Application: substantial prejudice, as set forth in N.C.G.S. 150B-"Novant's failure to establish substantial prejudice, standing alone, warrants a decision against Novant and upholding the CON Section's decision to approve NCBH's Application." Novant Health, Inc., Forsyth Memorial Hospital, Inc. D/b/a Forsyth Medical Center and Medical Park Hospital, Inc. v. N.C. Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section, 10 DHR 3788 2011 WL 2037599 (emphasis supplied).
- 28. Substantial prejudice is a necessary element of a contested CON case. N.C.G.S. § 150B-23(a); Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs., 235 N.C. App. 620, 633, 762 S.E.2d 468, 476 (2014).

(Doc.Ex. 776-777).

Under the plain and unambiguous language of N.C. Gen. Stat. § 150B-23(a), substantial prejudice must be established in all CON cases, even when the petitioner is an "affected person" for purposes of standing to file a petition under N.C. Gen. Stat. § 131E-188. See Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs., Nos. 12 DHR 12086, 12 DHR 12090, 12 DHR 12094, 2014 WL 5770252, at *3 (N.C. Ct. App. Oct. 21, 2014) (unpublished) disc. rev. denied, 368 N.C. 274, 772 S.E.2d 860 (2015); Parkway Urology, 205 N.C. App. at 539, 696 S.E.2d at 195; CaroMont Health, 231 N.C. App. at 5, 751 S.E.2d at 248; Wake Radiology Servs. LLC v. N.C. Dep't of Health & Human Servs., 215 N.C. App. 393, 716 S.E.2d 87, 2011 WL 3891026, at *5 (2011) (unpublished). These core obligations of a petitioner in a CON contested case to independently demonstrate substantial prejudice, apart from Agency error, which do not simply amount to allegations of harm from competition, were reaffirmed by the Court of Appeals as recently as April of last year in Bio-Medical Applications of N. C. Inc. v. N.C. Dep't of Health & Human Servs., 282 N.C. App. 413, 871 S.E.2d 555 (2022).

b. AdventHealth's Claims of Substantial Prejudice From Approval of the Mission Application Must be More Than Conjecture and Cannot be the Result of Additional Competition.

To avoid dismissal on summary judgment, a petitioner's evidence of substantial prejudice must meet certain criteria: (1) it must be more than conjectural or hypothetical, and (2) it must go beyond that which "necessarily resulted from additional . . . competition." Novant Health, Inc. v. N.C. Dep't of Health & Human Servs., 223 N.C. App. 362, 734 S.E.2d 138, 2012 WL 5397247, at *4 (2012) (unpublished); see also Blue Ridge Healthcare Hosps. Inc. v. North Carolina Dep't of Health & Hum. Servs., 255 N.C. App. 451, 464, 808 S.E.2d 271, 279 (2017); Ridge Care, Inc. v. N. Carolina Dep't of Health & Human Servs., 214 N.C. App. 498, 505–06, 716 S.E.2d 390, 395–96 (2011). To hold otherwise would "eviscerate the substantial prejudice requirement." Parkway Urology, 205 N.C. App. at 539, 696 S.E.2d at 195. Indeed, if generally alleging harm through increased competition satisfied the substantial prejudice requirement, that requirement would mean nothing. After all, an increase in market share by one health service provider will presumably always decrease the market share of a "pre-existing competing health service provider in the same geographic area." *Id*.

The decision in *Novant Health* illustrates this reality. There, Novant challenged the approval of North Carolina Baptist Hospital's application to construct a new facility in Forsyth County. Opposing this approval, Novant—which also operated in Forsyth County—argued that it would "suffer harm in the market" due to Baptist Hospital's "increased ability to provide health care services." *Novant Health*, 2012 WL 5397247, at *4. Rejecting this argument, the court noted that "mere competitive advantage is an insufficient basis upon which to argue prejudice." *Id*.

Similarly, in Surgical Care Affiliates, competition-based arguments fell short of establishing substantial prejudice. There, petitioners, Blue Ridge Day Surgery Center and Surgical Care Affiliates, challenged the approval of WakeMed's application to relocate two specialty ambulatory operating rooms from WakeMed's Southern Eye Surgery Center to WakeMed's Raleigh Campus. Surgical Care Affiliates, LLC, 235 N.C. App. at 620-21, 762 S.E.2d at 469. Since petitioners also operated a multispecialty ambulatory surgical facility in Raleigh, they were direct competitors of WakeMed. Id. Petitioners argued that the Agency's decision would "make it more difficult for Petitioners to acquire additional operating rooms in the future, giving WakeMed a competitive advantage." Id. at 632, 762 S.E.2d at 476. Rejecting this

argument, the court held that alleging the potential for future "competitive disadvantage" was insufficient to establish substantial prejudice. *Id*.

These decisions recognize an important principle: Because patients are not the "perpetual property of a health care system that provides them services," providers have "no right to be free of competition for patient services." (Doc.Ex. 186, Order on Summary Judgment, *Atrium Health Lake Norman v. Presbyterian Medical Care Corporation et al.*, 20-DHR-01836 ¶ 10(c) (Sept. 21, 2020)).

Therefore, in the instant case, to avoid summary judgment AdventHealth was required to establish a basis for substantial prejudice that was not "simply the result of normal competition." *CaroMont Health, Inc.*, 231 N.C. App. at 8, 751 S.E.2d at 249; *see also Novant Health*, 2012 WL 5397247, at *4. Further, AdventHealth's alleged harm cannot be "conjectural or hypothetical." *Surgical Care Affiliates, LLC*, 235 N.C. App. at 631, 762 S.E.2d at 476. It must be "concrete, particularized, and actual or imminent." *Id*.

c. AdventHealth's Allegations of Competition-Based Substantial Prejudice Failed to Establish That AdventHealth Has Alleged Concrete and Real Evidence of Harm.

AdventHealth's deponents and Rule 30(b)(6) designees made abundantly and irrefutably clear that AdventHealth's claims of substantial prejudice are

all competition-based claims of financial harm. They testified repeatedly that the Agency's approval of Mission's Application would cause AdventHealth to lose emergency department ("ED") market share and patients to Mission, and that AdventHealth would suffer financial harm which was derived from losing market share and patients to Mission. (Doc.Ex. 248; 2464; 2651-2659; 2754). AdventHealth witness Mark Murrill further testified that AdventHealth should be protected from the harmful unnecessary duplication of existing ED services—in Henderson County, not Buncombe County where the Candler FSED would be located—that would be caused by Mission's FSED. (Doc.Ex. Although couched in terms of a CON review criteria addressing "unnecessary duplication," this is just AdventHealth's way of saying that it should be protected from additional competition with Mission, a claim our appellate courts have flatly rejected, over and over again. CaroMont Health, *Inc.*, 231 N.C. App. at 8, 751 S.E.2d at 249.

Collectively, these theories posit that AdventHealth <u>might</u> "suffer harm in the market" because of Mission's "increased ability to provide health care services." Novant Health, 2012 WL 5397247, at *4. But harm that is "simply the result of normal competition" does not equate to substantial prejudice. CaroMont Health, Inc., 231 N.C. App. at 8, 751 S.E.2d at 249; see also Novant

Health, 2012 WL 5397247, at *4. Said another way, AdventHealth fell short of its burden. To be clear, publicly available documents that are exhibits in this case, including AdventHealth's annual hospital License Renewal Applications, prove that AdventHealth, located in Henderson County, serves a substantial number of emergency department patients who reside in Buncombe County. (Doc.Ex. 139-181). AdventHealth's complaint is that it "might" not be able to serve all of those patients in the future after Mission develops its FSED in Candler. Even assuming that claim was accurate, that's not sufficient to demonstrate substantial prejudice. It's just competition, plain and simple.

AdventHealth, in its Petition for a Contested Case Hearing, written discovery responses, and via its 30(b)(6) deposition designees, has iterated various and sundry versions of its alleged harm, all of which are just different ways of saying that it opposes competition with Mission. Our courts have roundly and consistently rejected competition-based claims of harm as insufficient to demonstrate substantial prejudice and have done so at the summary judgement stage. See CaroMont Health, Inc., 231 N.C. App. at 8, 751 S.E.2d at 249; see also Novant Health, 2012 WL 5397247, at *4. Finally, as discussed below, AdventHealth's claims are supported by unreliable data and

thus their harm is far from "concrete, particularized, actual or imminent" or anything other than faulty speculation. *Surgical Care*, 235 N.C. App. at 631, 762 S.E.2d at 476.

d. AdventHealth's Loss of Market Share Claims.

AdventHealth's Rule 30(b)(6) deposition designees testified that if Mission constructs a new FSED in Candler, that will increase Mission's market share in Buncombe County and harm AdventHealth. (Doc.Ex. 2590-2592). This is just another way of saying that AdventHealth will have to compete with Mission's FSED for patients who may previously have gone to AdventHealth for ED services. To be clear, Mission's CON Application clearly stated that it will serve a portion of patients already served at its own overcrowded main emergency department in Asheville and a small portion of future incremental growth (i.e., new patients). (Doc.Ex. 3-4). However, even assuming arguendo that AdventHealth's claims on this point are valid, its complaint is that patients who would normally come to AdventHealth's hospital-based ED in Henderson County may now come to Mission's new FSED facility, closer to their homes. That's competition. That's permitted. That's normal. And that's not substantial prejudice as our courts have defined it.

Patients do not become the perpetual property of a specific health care system that provides them services, nor may a health care system in effect purchase patients as if they were "parakeets or kittens at a pet shop." See CaroMont Health, Inc, 231 N.C. App. at 10, 751 S.E.2d at 251; see also (Doc.Ex. 182-189, Order on Summary Judgment, Atrium Health Lake Norman v. Presbyterian Medical Care Corporation et al., 20-DHR-01836 ¶ 7 (Sept. 21, 2020)). The fact that patients previously served by Petitioner may end up being served by another entity in the future does not substantially prejudice Petitioner as a matter of law, as Petitioner has no cognizable right to be free of competition for patient services. Id.

AdventHealth's Rule 30(b)(6) witnesses and expert witness in their depositions acknowledged those principles from our appellate courts. AdventHealth witness Mark Murrill agreed that, even if Mission was to build a FSED in Candler, patients living in the proposed service area could still go to another provider, such as AdventHealth. (Doc.Ex. 2621). Ms. Karin Sandlin, AdventHealth's expert witness, agreed that under the CON law of this state no provider is entitled to any specific group of patients. (Doc.Ex. 2314). Ms. Sandlin further stated that there was nothing that Mission could do to compel patients to come to its proposed facility. (Doc.Ex. 2315). Rather,

Ms. Sandlin stated it would be Mission's "expectation" that patients in a proposed service area would be treated at its facility. *Id*.

In an effort to drum up claims of substantial prejudice, AdventHealth's Mark Murrill and Brandon Nudd created a "harm exhibit" which purports to demonstrate that the opening of Mission's FSED in Candler will cause AdventHealth to lose approximately \$4,153,637.00. (Doc.Ex. 2272). As discussed herein, our appellate courts have roundly rejected the notion that loss of patients, market share or revenue *ever* constitute substantial prejudice because they are simply the result of additional competition. However, even assuming *arguendo* that such claims could ever amount to substantial prejudice, AdventHealth's claims, including as reflected on Doc.Ex. 2272, lack credibility based on the testimony of AdventHealth's own witnesses.

AdventHealth's Brandon Nudd testified that the premise behind AdventHealth's "harm exhibit" was that patients would choose where to obtain emergency department services based entirely on proximity to their homes. (Doc.Ex. 2270; 2785). However, when presented with data showing that patients currently served by AdventHealth bypass a closer emergency department operated by Mission, Mr. Nudd conceded that proximity was not a key factor in patient decision-making. (Doc.Ex. 2786-2787). In short, the

report compiled by Mr. Murrill is based on flawed assumptions and incomplete data. (Doc.Ex. 2783; 2649-2650; 2654-2658). Further, AdventHealth's expert witness, Karin Sandlin, confirmed that AdventHealth is acutely aware that AdventHealth is not entitled to serve any patient or that Mission had any ability to compel patients to come to its facility rather than to AdventHealth's. (Doc.Ex. 2314-2315). Finally, as noted above, Mr. Nudd admitted and fully accepted that AdventHealth's proximity argument was flawed since it relied on patient proximity to an ED when, in fact, that alone is not a key driver of how patients choose ED services. (Doc.Ex. 2786-2787). Taken together, the statements of Mr. Murrill, Mr. Nudd, and Ms. Sandlin clearly demonstrate that as a matter of law AdventHealth's attempts to demonstrate financial harm from the proposed Mission FSED are based on flawed assumptions and that AdventHealth cannot concretely demonstrate that it will be substantially prejudiced by Mission building a FSED in Candler.

There is no North Carolina OAH or appellate authority holding that a CON applicant is substantially prejudiced by being unable to service all additional demand in a given area.

The CON process does not ensure that [Petitioner] obtains sufficient capacity to care for all patients of its—or the patient's—choosing. Rather, the CON process addresses the needs of a given area as

determined by the SMFP. To hold otherwise would require DHHS to grant additional applications of an entity just because that entity created or wished to respond to more demand. This would unacceptably shackle or even eliminate Agency discretion. Accordingly, this claim is subject to summary judgment.

(Doc.Ex. 186, Order on Summary Judgment, Atrium Health Lake Norman v. Presbyterian Medical Care Corporation et al., 20-DHR-01836 (Sept. 21, 2020)).

The present CON Law expressly recognizes that competition among healthcare providers may benefit the public and negates any inference that the CON Law is designed to protect an existing provider's market share. It requires an applicant to "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" N.C. Gen. Stat. § 131E-183(a)(18a). Parkway Urology made clear that substantial prejudice requires more than increased competition: "[Petitioner's] argument, in essence, would have us treat any increase in competition resulting from the award of a CON as inherently and substantially prejudicial to any pre-existing competing health service provider in the same geographic area. This argument would eviscerate the substantial prejudice requirement contained in N.C. Gen. Stat.

§ 150B-23(a)." Parkway Urology, 205 N.C. App. at 539, 696 S.E.2d at 195. In Novant Health, the Court of Appeals again rejected the claim that even quantified, alleged harm a CON appeal petitioner claims it will suffer does not amount to substantial prejudice, as a matter of law. Novant Health, Inc., 2012 WL 5397247, at *3-4.

Though AdventHealth labeled its substantial prejudice theories in various ways, it is evident that AdventHealth is mainly concerned about the exposure to competition for ED services in and around Buncombe County—Mission's home county, not AdventHealth's home county which is Henderson County. In other words, AdventHealth will have to compete. AdventHealth has no right to be free from competition. This is the law in North Carolina. Bruton v. Smith, 225 N.C. 584, 586, 36 S.E.2d 9, 10 (1945) ("[T]he law does not protect one against competition."). This is not substantial prejudice and AdventHealth's arguments fail.

e. <u>Financial Harm From Loss of Market Share Does Not Constitute Substantial Prejudice.</u>

AdventHealth has claimed specifically that it will lose market share as a result of the development of Mission's FSED in Candler. (Doc.Ex. 2270). Neither the CON Law nor any of the statutory review criteria the Agency must apply during all CON reviews make any mention of "market share." Simply

put, the loss of market share or the preservation of existing or future market share is not a consideration in a CON review and this is plain from the language of the CON Law and the CON application form itself, factors of which this Court can take judicial notice.

Further, the annual SMFP, which guides the entire CON need determination and review process expressly states that preserving the market share or even the survival of any North Carolina hospital is, plain and simple, not a goal of the CON Law, contrary to the claims of AdventHealth. The 2022 SMFP at page 34 states the following:

Even so, it is not the policy of the state to guarantee the survival and continued operation of all the state's hospitals, or even any one of them. In a dynamic, fastchanging environment, which is moving away from hospital inpatient services, the survival and future activities of hospitals will be a function of many factors beyond the realm of public policy.

(Doc.Ex. 785). This text is contained in the Acute Care Services Chapter of the 2022 SMFP. It is beyond dispute that emergency department services are "acute care services," because FSEDs can only be developed by an existing acute care hospital in a county where that hospital is located and licensed. *See* N.C. Gen. Stat. § 131E-77(e1). Thus, this policy statement in the SMFP applies to services such as the proposed Mission FSED in Candler.

AdventHealth further claims that loss of market share and/or patients equates to loss of income and revenue. (Doc.Ex. 2270; 2648-2650). Economic loss from the approval or denial of a CON application does not amount to substantial prejudice, as it amounts to harm from additional competition. Cumberland Cty. Hosp. Sys., Inc., 237 N.C. App. at 123, 764 S.E.2d at 498; CaroMont Health, Inc. 231 N.C. App. at 10, 751 S.E.2d at 251. Nothing in AdventHealth's claims of "harm" from the approval of the Mission Application justifies divergence from multiple appellate cases holding that economic harm does not amount to substantial prejudice. "[Everyone has the] right to enjoy the fruits and advantages of his own enterprise, industry, skill[,] and credit. He has no right to be protected against competition." Coleman v. Whisnant, 225 N.C. 494, 506, 35 S.E.2d 647, 655 (1945).

In *CaroMont*, the petitioner alleged financial harm—\$463,000.00 to \$925,000.00 <u>net income per year</u>—and still the Court found that allegation of financial harm insufficient to constitute substantial prejudice. *CaroMont*, 231 N.C. App. at 11, 16-17, 751 S.E.2d at 251, 254-55 (finding that it is not enough that the non-applicant's witness attempts to quantify the projected harm because other factors such as causation, future marketing plans and reliability of the data are also relevant to the analysis). Even where a

disapproved applicant has quantified its projected losses, such losses do not constitute substantial prejudice. See Novant Health, 2012 WL 5397247, at *3-4; see also Blue Ridge Healthcare Hosp., 255 N.C. App. at 464, 808 S.E.2d at 279 (rejecting the loss of patients and profits as substantial prejudice); Ridge Care, 214 N.C. App. at 505-06, 716 S.E.2d at 395-96 (losing patients and suffering economic harm due to a competitor's approval did not constitute substantial prejudice).

Further, AdventHealth's assertions of financial harm stem from a deeply flawed analysis in its flawed harm exhibit, Doc.Ex. 2270-2276, and are unsupported by any credible documentation or other analysis. During discovery AdventHealth claimed that:

- Its harm exhibit reflects the analysis that demonstrates the alleged financial harm AdventHealth claims it will suffer as a result of the proposed Mission FSED in Candler (Doc.Ex. 2648-2649);
- In gathering data to create its harm exhibit, Mr. Murrill looked at the total number of historical ED visits for the year 2021 in only a portion of Mission's proposed Candler FSED service area by zip code; then looked at 2021 historical market share percentages for Mission and AdventHealth in those zip codes; and then assumed that in each of those

zip codes, AdventHealth would lose the vast majority of that market share and those patients to the Mission Candler FSED (Doc.Ex. 2649; 2270);

- Mr. Murrill took those alleged "lost patients" and that lost market share and calculated how much money AdventHealth claims it would lose if the Mission FSED in Candler is developed by building out a product line analysis to determine what the revenue and market loss would be if Mission's FSED in Candler is built (Doc.Ex. 2650);
- Using that data and those assumptions, Mr. Murrill attempted to quantify AdventHealth's losses in dollars in terms of gross revenue, net revenue, and the contribution margin impact (Doc.Ex. 2272); and
- AdventHealth's expert witness, Ms. Sandlin, testified at deposition that Mr. Murrill's analysis supports her claims of substantial prejudice because it illustrates the number of patients she alleges AdventHealth will lose if Mission's FSED in Candler is built and financial losses to AdventHealth as a result. (Doc.Ex. 2316).

However, regarding the alleged financial harm AdventHealth claims it will incur if Mission's FSED is developed in Candler, AdventHealth witnesses admitted that:

- The data compiled by Mr. Murrill failed to include nine (9) of the zip codes Mission proposed to serve in its application (Doc.Ex. 2783);
- Mr. Murrill failed to include any data regarding labor and delivery which
 is a service that AdventHealth provides. (Doc.Ex. 2650-2651). In other
 words, Mr. Murrill only selected certain types of ED services to include
 in his harm analysis;
- That even if this FSED is constructed by Mission in Candler, patients could still choose to go to AdventHealth for ED services (Doc.Ex. 2787);
- That Mr. Murrill calculated these alleged losses by looking at how close patients in certain zip codes were to the proposed Mission FSED in Candler but that in calculating that distance, Mr. Murrill used the center point of each zip code despite freely admitting that the center point of any given zip code is not reflective of the distance from all points contained in a zip code. (Doc.Ex. 2654-2658). In other words, Mr. Murrill's primary assumption underlying these claims of lost market share, patients and revenue was that all patients who live closer to the Mission Candler FSED location than to AdventHealth would always choose to seek ED services at the Mission Candler FSED, despite

admitting that does not reflect reality or how patients choose ED services;

- That there is nothing wrong with an applicant achieving an increased market share capture when it develops a new facility (Doc.Ex. 2474); and
- That proximity of an ED to a patient's home was the key assumption underlying AdventHealth's proposed harm exhibit (Doc.Ex. 2270), yet proximity did not appear to be a key factor for patients when deciding where to seek ED services. (Doc.Ex. 2785-2787).

In addition to these admissions by AdventHealth's own witnesses, the credibility and accuracy of AdventHealth's alleged harm exhibit is further undercut by its flawed assumption that Mission would serve a larger percentage of patients in certain zip codes located in its proposed service area than Mission proposed to serve in those zip codes in its application. (Doc.Ex. 5-17; 2270).

Finally, Mission's expert witness, Kathy Platt, opined in her expert report and testified unequivocally at deposition that AdventHealth has only a 6.6% market share in the zip codes from Mission's proposed Candler service area that it relied upon for its harm analysis and that she disagreed with AdventHealth's harm analysis and found it unreliable and speculative at best.

Further, she opined that AdventHealth will serve more patients in year 3 of the Candler FSED operation than it does today and so will not "lose" patients. (Doc.Ex. 134-137). These statements of Ms. Platt were not refuted by any AdventHealth evidence.

AdventHealth's argument is that the Agency should have put AdventHealth's bottom line first and the people of Buncombe County's access to emergency medical services second. AdventHealth has done nothing more than theorize, without any concrete proof, that it *might* lose some future ED market share in Henderson County and Buncombe County. Further, AdventHealth's purported "harm analysis" in Doc.Ex. 2270, based on the deposition admissions of AdventHealth's own witnesses, is based on flawed assumptions and flawed data and thus is both unreliable and conjectural, at It's clear that AdventHealth's "harm exhibit" attempts to portray a worst-case, "the sky is falling" scenario unrelated to reality, or to Mission's actual CON application service area or utilization projections and is based on admittedly flawed assumptions. However, even accepting AdventHealth's claims of financial harm at face value (which Mission disputes), they amount to nothing more than the results of additional competition. Even where a petitioner in a CON appeal has quantified its projected losses, such losses do not constitute substantial prejudice. See Novant Health, 2012 WL 5397247, at *3-4; see also Blue Ridge Healthcare Hosp., 255 N.C. App. at 464, 808 S.E.2d at 279 (rejecting the loss of patients and profits as substantial prejudice); Ridge Care, 214 N.C. App. at 505-06, 716 S.E.2d at 395-96 (losing patients and suffering economic harm due to a competitor's approval did not constitute substantial prejudice).

f. Mission's Arden FSED Decision by ALJ Sutton

A few short months before Judge Sutton issued his Final Decision in the instant case, he presided over another similar case in which Mission proposed a FSED in a different part of Buncombe County, in Arden. In that review, the Agency also failed to hold a public hearing. The Agency approved Mission's Arden FSED CON application and AdventHealth appealed that one also. In 2022, Judge Sutton heard motions for summary judgment by Mission, the Agency and AdventHealth that raised nearly identical arguments as the instant case. In the Arden appeal, Judge Sutton denied *all parties*' motions for summary judgment.

In November of 2022 and January of 2023, Judge Sutton presided over a three-week trial of the Arden case. On 22 June 2023, Judge Sutton issued his Final Decision in the Arden case in which he again reversed the Agency's

approval of the Mission application solely because the Agency failed to hold a public hearing regarding that application. However, in his Final Decision Judge Sutton agreed with each and every argument of Mission and the Agency that none of AdventHealth's other claims—not loss of money, loss of market share, the inability to serve all of its intended patients or any competitive disadvantage—constituted substantial prejudice to AdventHealth. See Appendix A, Final Decision 23 DHR 01286/01294, Henderson County Hospital Corporation d/b/a Pardee Hospital & Fletcher Hospital Inc. d/b/a AdventHealth Hendersonville v. N.C. Dep't of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need Section & MH Mission Hospital, LLLP.

That decision demonstrates that even Judge Sutton recognized that AdventHealth was not prejudiced by the Agency's approval of the Arden decision, unless this Court adopts Judge Sutton's ruling on the public hearing issues, discussed *supra*, and in a related brief filed in this case by the Agency. Likewise, AdventHealth is not substantially prejudiced by the approval of the Candler application, which is the subject of this appeal.

B. AdventHealth's Public Hearing Argument

In its Motion for Summary Judgment at OAH, AdventHealth argued that the Agency's failure to hold a public hearing on the Mission FSED West CON Application during the COVID pandemic was Agency error that substantially prejudiced AdventHealth. That argument was accepted by ALJ David Sutton and became the exclusive basis for his grant of Summary Judgment to AdventHealth in this case. That argument is wrong, and that decision is wrong.

The Agency has briefed this issue extensively in the brief it is filing with this Court in this matter. Mission adopts and joins in the Agency's brief and arguments regarding the public hearing issue. In addition, Mission makes the following argument to this Court on the public hearing issue, in addition to those presented in the Agency's brief.

1. AdventHealth's Suggested Remedy is Wrong.

AdventHealth argues in its pleadings in this case that the Agency's failure to hold a public hearing regarding the Mission FSED West Application must result in a reversal of the Agency's approval of that application. That argument is just plain wrong. In fact, under applicable North Carolina precedent, if this Court disagrees with Mission that the Agency's failure to hold

a public hearing in this case during the COVID pandemic was not error or, at worst, was harmless error given the ongoing COVID pandemic at the time, then the outcome of that ruling would result in the automatic approval of the Mission Application. Our appellate courts faced an analogous issue in 1990 in the case of HCA Crossroads Residential Center v. N.C. Dept. of Human Resources, Division of Facility Services, Certificate of Need Section, 327 N.C. 573, 398 S.E.2d 466 (1990).

In that case, the Agency failed to issue a decision on petitioner's CON application within the one-hundred-and-fifty (150) days prescribed for it to render decisions in N.C. Gen. Stat. § 131E-185. Our Supreme Court held that the CON process is a statutorily-authorized limitation on a provider's fundamental right to engage in an otherwise lawful business and, as such, the Agency must follow the procedures governing its reviews set forth in statute. Where the Agency fails to do so, it loses jurisdiction to deny an affected applicant's CON application and the Agency is then deemed to have approved the application as a matter of law. Id. at 579, 398 S.E.2d at 470. While Crossroads deals with the timeframe within which the Agency must act on applications, the principle that drove the Supreme Court's decision applies equally here—where the Agency fails to follow its statutorily-

prescribed mandates, it loses its authority to preclude an affected CON applicant from engaging in the fundamental right to engage in a lawful business, and it's right to deny a CON application. The statutory timeframe the Court considered in *Crossroads* is located in the precise section of the CON Statute that contains the Agency's obligation to conduct public hearings in certain CON reviews. *See* N.C. Gen. Stat. § 131E-185.

To be clear, Mission does not agree with AdventHealth's position that the Agency's failure to hold a public hearing during the COVID pandemic was error. And, even if it was a technical error for the Agency not to hold public hearings during the COVID pandemic, that was a reasonable decision designed to protect the public's health and AdventHealth had ample notice that the Agency was allowing (not demanding) written comments in lieu of a public hearing. It cannot be stated more clearly: <u>AdventHealth never complained about that issue until it chose to challenge Mission's approved application</u>. AdventHealth fully participated in the alternative written comment period the Agency provided without complaint or objection until AdventHealth did not get the result it wants—denial of Mission's FSED Application. Further, AdventHealth engaged in coordinated, calculated efforts to ensure that the narrative it wanted the Agency to hear was communicated

in the form of letters from purported "members of the public." AdventHealth worked tirelessly to make sure it got the letters from "the public" it wanted in front of the Agency. AdventHealth elicited its employees and their family members to use language provided by AdventHealth to submit letters to the Agency. (Doc.Ex. 2228-69). AdventHealth is upset that the Agency did not agree with the letters and comments and approved Mission's Application. However, should this Court agree with AdventHealth that the failure to hold a public hearing constitutes substantial prejudice, then the result is not the disapproval of the Mission Application. To the contrary, under *Crossroads*, Mission's Application would be deemed approved as a matter of law.

CONCLUSION

The Agency's ultimate decision to approve the Mission Application is both sound and proper. The Agency committed no reversible error in its review nor in its determination that Mission's Application to establish a new FSED in Candler was adequately supported by the information contained in Mission's Application. For the foregoing reasons and those stated in the brief of the Agency, the Final Decision of the ALJ should be reversed.

Respectfully submitted, this the 9th day of October, 2023.

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CERTIFICATION OF COMPLIANCE

Pursuant to Rule 28(j) of the North Carolina Rules of Appellate Procedure, counsel for Respondent-Intervenor Appellant Mission certifies that the foregoing brief, which—pursuant to Rule 26(g)(1) of the North Carolina Rules of Appellate Procedure—is prepared using the mono-spaced Century Schoolbook font with 13 point size, is less than 8,750 words (excluding cover, indexes, tables of authorities, certificates of service, this certificate of compliance and appendixes) as reported by the word-processing software utilized by the undersigned.

This the 9thth day of October, 2023.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing document was served upon counsel of record by depositing a copy thereof in the U.S. mail, first class, postage prepaid, addressed as follows:

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NORTH CAROLINA C	OURT OF APPEALS
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HENDERSONVILLE,	,)
Petitioner-Appellee,	,)
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SERVICE REGULATION,) Contested Case No.
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STATE OF NORTH CAROLINA COUNTY OF BUNCOMBE

IN THE OFFICE OF ADMINISTRATIVE HEARINGS

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FINAL DECISION

This matter came on for hearing before David F. Sutton, Administrative Law Judge (the "ALJ"), on November 7-10, 14-17, 2022, January 23-27, and February 1-3, 2023, in Waynesville, North Carolina to hear Petitioners' contested case petitions, filed pursuant to N.C. Gen. Stat. §§ 150B-23 and 131E-188, appealing Respondent's May 24, 2022, Agency Decision and Required State Agency Findings, to conditionally approve a Certificate of Need Application by Respondent-Intervenor to construct a new freestanding emergency department in Arden, North Carolina.

Having heard all the evidence presented in the contested case hearing, and considered the testimony, admitted exhibits, the arguments of the parties, and the relevant law, the Undersigned finds by the preponderance of the evidence the following Findings of Fact, enters Conclusions of Law based thereon, and issues this Final Decision pursuant to N.C. Gen. Stat. §§ 150B-34 and 131E-188.

As set forth below, the May 24, 2022 Decisions and Required State Agency Findings approving the Mission Application is REVERSED because the Agency acted erroneously, failed to use proper procedure, and failed to act as required by law or rule when the Agency approved Mission's Application without having held a statutorily mandated public hearing, and AdventHealth and Pardee having been substantially prejudiced thereby. While the findings of fact and conclusions of law related solely to the Agency's failure to conduct a public hearing are sufficient to dispose of this contested case, the Undersigned has determined in the interest of judicial economy, to find facts and make conclusions of law related to all other outstanding issues.

The findings of fact and conclusions of law relative to the issues other than the Agency's failure to conduct a public hearing, are based on the evidence presented to the Undersigned during the hearing of this contested case and the information before the Agency during its review of the Mission Application. A properly conducted public hearing would most likely have changed the information available to the Agency during its review and the evidence presented to the Undersigned during the contested case hearing and may have affected the Undersigned's findings of fact and conclusions of law relative to the issues other than the Agency's failure to conduct a public hearing.

APPEARANCES

For Henderson County Hospital Corporation d/b/a Pardee Hospital ("Pardee")

Maureen D. Murray
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For Petitioner Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville ("AdventHealth")

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Raleigh, North Carolina 27607

For Respondent North Carolina Department of Health and Human Services,

Division of Health Service Regulation,

Healthcare Planning and Certificate of Need Section (the "CON Section" or "Agency"):

Kimberly M. Randolph Chris D. Agosto Carreiro North Carolina Department of Justice P.O. Box 629 Raleigh, North Carolina 27602

For Respondent-Intervenor MH Mission Hospital LLLP ("Mission"):

Kenneth L. Burgess
Matthew A. Fisher
Iain M. Stauffer
William F. Maddrey
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ISSUES PRESENTED

AdventHealth

- 1. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule when it failed to conduct a public hearing as required by N.C. Gen. Stat. § 131E-185(a1)(2)?
- 2. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Mission Application was conforming with respect to N.C. Gen. Stat. § 131E-183(a)(3) ("Criterion 3")?
- 3. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule

in finding that the Mission Application was conforming with respect to N.C. Gen. Stat. § 131E-183(a)(4) ("Criterion 4")?

- 4. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Mission Application was conforming with respect to N.C. Gen. Stat. § 131E-183(a)(5) ("Criterion 5")?
- 5. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Mission Application was conforming with respect to N.C. Gen. Stat. § 131E-183(a)(6) ("Criterion 6")?
- 6. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in failing to apply N.C. Gen. Stat. § 131E-183(a)(18a) ("Criterion 18a") as a part of its review of the Mission Application?
- 7. In the alternative, if it is determined that the Agency applied Criterion 6 as a part of its review of the Mission Application, whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Mission Application was conforming with respect to Criterion 18a?
- 8. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Missions Application was conforming with respect to N.C. Gen. Stat. § 131E-183(a)(20) ("Criterion 20")?
- 9. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in conditionally approving a certificate of need to Mission?
- 10. Whether AdventHealth was substantially prejudiced in its rights as a result of the Agency's exceeding its authority or jurisdiction, acting erroneously, failing to use proper procedure, acting arbitrarily or capriciously, or failing to act as required by law?
- 11. Whether the Mission Application contained such material errors, misrepresentations and/or omissions such that the Agency decision to conditionally approve a certificate of need to Mission should be overturned as a matter of law?

Pardee

- 12. Whether Mission misrepresented information in its Arden FSED Application contrary to its signed certification such that its Application should not be approved and the Agency's approval of the Application should be reversed?
- 13. Whether the Agency has substantially prejudiced Pardee's rights and: (1) exceeded its authority or jurisdiction; (2) acted erroneously; (3) failed to use proper procedure; (4) acted arbitrarily or capriciously; and/or (5) failed to act as required by law or rule?

Agency

14. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule and otherwise substantially prejudiced Petitioners' right when it approved the application of MH Mission Hospital, LLLP to develop a freestanding emergency department in Arden, NC licensed under Mission Hospital?

Mission

- 15. Whether the Respondent Agency exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule, in its 24 May 2022 Decision and Required State Agency Findings conditionally approving Mission's Certificate of Need Application (Project ID # B-12191-22) to develop a freestanding emergency department in Arden, Buncombe County, North Carolina (the "Mission Application")?
- 16. Whether the Respondent Agency's 24 May 2022 Decisions and Required State Agency Findings approving the Mission Application substantially prejudiced Petitioners' rights pursuant to N.C. Gen. Stat. § 150B-23 and applicable decisional case law?

APPLICABLE LAW

- 1. The procedural law applicable to this contested case hearing is the North Carolina Administrative Procedure Act ("APA"), N.C. Gen. Stat. § 150B-1 *et seq.*, to the extent not inconsistent with the Certificate of Need Law, N.C. Gen. Stat. § 131E-175 *et seq.*
- 2. The substantive law applicable to this contested case is the Certificate of Need ("CON") law, N.C. Gen. Stat. § 131E-175 et seq.
- 3. The administrative regulations applicable to this contested case hearing are the North Carolina Certificate of Need Program Administrative Regulations, 10A N.C.A.C. 14C .0101 *et seq.*, and the Office of Administrative Hearings Regulations, 26 N.C.AC. 3 .0101 *et seq.*

BURDEN OF PROOF

- 1. The petitioner in a contested case hearing before the Office of Administrative Hearings ("OAH") must establish by a preponderance of the evidence that the state agency named as respondent has deprived the petitioner of property, has ordered the petitioner to pay a fine or civil penalty, or has otherwise substantially prejudiced the petitioner's rights and that the state agency named as respondent has:
 - (1) Exceeded its authority or jurisdiction.
 - (2) Acted erroneously.
 - (3) Failed to use proper procedure.
 - (4) Acted arbitrarily or capriciously; or
 - (5) Failed to act as required by law or rule.

N.C. Gen. Stat. §§ 150B-23(a); 150B-25.1(a); 150B-29(a); 150B-34(a).

- 2. As Petitioners, AdventHealth and Pardee bear the burden of proof in this contested case. N.C. Gen. Stat. § 150B-25.1(a); N.C. Gen. Stat. § 150B-29(a).
- 3. A CON petitioner must show both agency error and substantial prejudice; lack of one or the other is fatal to a petitioner's case. *Britthaven, Inc. v. N.C. Dep't of Human Res.*, 118 N.C. App. 379, 382, 455 S.E.2d 455, 459 (1995).

WITNESSES

- 1. The following witnesses were called by AdventHealth and Pardee in their case in chief and such witnesses' testimony appears as follows in the certified transcript from the contested case hearing:
 - a. Michael John McKillip, Team Leader, the CON Section, (Vol. 1, Tr. at 53–167; Vol. 2, Tr. at 177–282);
 - b. Johnna Suzanne Reed, Chief Administrative Officer, Pardee Hospital, (Vol. 2, Tr. at 282–361);
 - c. James Kirby, President and Chief Executive Officer, Pardee Hospital, (Vol. 6, Tr. at 956–1021);
 - d. Dawn Carter, Senior Partner, Ascendient Health Planning, (Vol. 6, Tr. at 1021–1112; Vol. 7, Tr. at 1122–1310; Vol. 8, Tr. at 1318–1495; Vol. 12, Tr. at 1839–1875);
 - e. Brandon Mitchell Nudd, President and Chief Executive Officer, AdventHealth, (Vol. 2, Tr. at 361–77; Vol. 3, Tr. at 382–453);
 - f. Graham Redmond Fields, Assistant to the President, AdventHealth, (Vol. 3, Tr. at 453–544);
 - g. Mark William Murrill, Administrative Director of Business Development and Strategy, AdventHealth, (Vol. 3, Tr. at 544–615; Vol. 4, Tr. at 620–626):

- h. Lisa Pittman, Assistant Chief, the CON Section, (Vol. 4, Tr. at 626–774; Vol. 5, Tr. at 783–951);
- i. Karin Lastowski Sandlin, AdventHealth's expert witness, (Vol. 9, Tr. at 1536–1591; Vol. 10, Tr. at 1603, 1612–1736; Vol. 11, Tr. at 1781–1806);
- 2. The following witnesses were called by Mission in its case in chief and their testimony appears as follows in the certified transcript from the contested case hearing:
 - a. Sondra Smith, Vice President of Strategy and Planning, Mission Health System, (Vol. 13, Tr. at 1998–2133, 2155–2162; Vol. 14, Tr. at 2178–2241);
 - b. Samuel Wyatt Chocklett, Chief Operating Officer, Mission Hospital, (Vol. 14, Tr. at 2241–2317);
 - c. Katherine M.T. Platt, Mission's expert witness, (Vol. 14, Tr. at 2317–2391; Vol. 15, Tr. at 2396–2602; Vol. 16, Tr. at 2607–2662);
- 3. The Agency did not offer any witnesses other than Michael John McKillip and Lisa Pittman, who were called during the case in chief of AdventHealth and Pardee.

EXHIBITS ADMITTED INTO EVIDENCE

Joint Exhibits ("Jt. Ex.")

- 1. Mission/HCA 2022 Arden FSED Application
- 2. Agency File on the Mission/HCA 2022 Arden FSED Application
- 5. Agency's Application Log that includes the Mission 2022 FSED Application
- 6. November 19, 2021 Public Notice from the CON Section Regarding No Public Hearings.
- 7. Virtual Public Hearing Notice and WebEx Instructions 2023 SMFP
- 8. Mission/HCA 2021 Arden FSED Application
- 9. Agency File on the Mission/HCA 2021 Arden FSED Application
- 23. Article -Lawsuit targets HCA's hospital monopoly in Western NC 9.1.2021
- 31. License Renewal Application of Pardee Effective January 1, 2022
- 36a. ATTORNEY EYES ONLY Spreadsheet (Dep. Ex 36)
- 38. Charles Burgin Quotes 3.9.12
- 46. CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER CON Section Preapplication Conference Topics to Address
- 69. ATTORNEY EYES ONLY HC Healthcare CAMS FSER Investment Model-Mission Hospital
- 75. ATTORNEY EYES ONLY- 3.21.21 CAMS Memo re: Approval for Arden FSED
- 91. 1.11.2022 Email from T. Vincent Regarding ACEP Standards Questionnaire and Sample Response Table
- 92. Spreadsheet Containing ACEP Standards, Dedicated Spaces, and Table 2A1
- 96. 8.17.22 Email from Rachel Coleman Regarding HVA North Carolina FSEDs
- 97. 4.28.21 Email from Catherine Durham Regarding EMR Package- Mission FSER
- 115. Dawn Carter CV
- 116. Dawn Carter Expert Report dated 9.30.2022

- 117. Dawn Carter Expert Report Attachments
- 119. Findings 2019 Bone & Joint Surgery Clinic
- 135. Application Atrium Health Concord ED CON Application
- 139. Application 2021 Atrium Ballantyne ED CON Application
- 140. Findings 2021 Mecklenburg F-12088-21 Atrium Health Ballantyne Emergency Department 210484 Findings
- 141. Findings 2022 Cabarrus F-12186-22 Atrium Health Concord Emergency Department 220167
- 143. Karin Sandlin CV
- 144. Karin Sandlin Expert Opinion Summary
- 145. Karin Sandlin Report Attachments for Expert Opinion Summary
- 159. Kathy Platt CV
- 160. Kathy Platt Expert Report for Deposition 9.23.2022
- 161. Kathy Platt Deposition Exhibits 9.23.2022
- 162. Kathy Platt Additional Deposition Exhibits 10-7-C
- 163. MH Mission FSER Arden CON Application- Changes from 2021 to 2022
- 170. ACEP Standards (pp. 109-119)
- 177a. Deposition Transcript of Lisa Pittman Volume 1
- 177b. Deposition Transcript of Lisa Pittman Volume 2
- 178a. Deposition Transcript of Mike McKillip Volume 1
- 178b. Deposition Transcript of Mike McKillip Volume 2
- 184a. Deposition Transcript of Catherine Durham Volume 1
- 184b. Deposition Transcript of Catherine Durham Volume 2
- 188a. Deposition Transcript of Terence Van Arkel- CONFIDENTIAL UNREDACTED
- 188b. Deposition Transcript of Terence Van Arkel- ATTORNEY EYES ONLY
- 190a. Deposition Transcript of Dawn Carter- CONFIDENTIAL UNREDACTED
- 190b. Deposition Transcript of Dawn Carter- ATTORNEY EYES ONLY

AdventHealth Exhibits ("AdventHealth Ex.")

- 200. Article: "A Concerning Number,' Attorney General Describes Recent Mission Health Complaints Filed." WLOS News 13, 6-8-2021
- 203. Article: Attorney General's Office Had 'Great Concerns' Mission HCA Deal Was Rigged 'From the Beginning', Asheville Watchdog, 3-15-2022
- 206. Article: Group of NC Residents Files Antitrust Lawsuit Against HCA Healthcare, WLOS Channel 13, 8-10-2021
- 209. Article: How Many Doctors Have Left Mission, Asheville Watchdog, 3-24-2022
- 210. Article: Irate Crowd Voices Frustrations with Medical Services in Cashiers, Carolina Public Press, 1-29-2020
- 220. Findings: 2021 Mecklenburg Satellite ED Review
- 241. Ex. 7 to MSJ Response- FTC Policy Perspectives on Certificates of Public Advantage, FTC Staff Policy Paper, 8-15-22
- 242. Ex. 10 to MSJ Response- Letter from Attorney General Josh Stein Regarding Mission's 2022 Acute Care Bed CON Application
- 251. Letter: 2-25-2020 Letter from Attorney General Josh Stein to Greg Lowe, President of the North Carolina Division of HCA Healthcare Regarding Complaints about Quality of Care, Charity Care, Patient Charges, etc.

- 252. N.C. Gen. Stat. § 131E-192.1 *et seq.* (pre 9-29-2016 COPA statute)
- 257. 10A NCAC 14C .0202- Certificate of Need Regulations- Definitions

Pardee Exhibits ("Pardee Ex.")

- 400. Area Map with Zip Codes
- 401. Drive Time Analysis Chart
- 402.A. Chart: Mission Volume/Capacity Under ACEP Guidelines
- 403. Chart: Incremental Market Share Gains in Mission 2021 and 2022 Applications
- 404. Chart: Service Area Inpatients Traveling to Other Level I or II Trauma Centers
- 405.A1Dawn Carter Rebuttal Opinion
- 405.B. Dawn Carter Rebuttal Opinion
- 406.B. Opinion Dawn Carter Supplemental Attachments to Rebuttal Opinions
- 407. Chart: Mission FSER Zip Code Service Area Population Comparison
- 408. Map Hospitals (admitted for illustrative purposes only)
- 409. Map From 405a, p. 8
- 410. Chart From 405a, p. 10
- 411. Chart from 405b, p. 9

Mission Exhibits ("Mission Ex.")

- 604. 2022 SMFP (Excerpts)
- 635. Findings- 2009- Gaston Emergency Department Review and Findings
- 636. Pittman Affidavit Attachment 1
- 637. Pittman Affidavit Attachment 2
- 638. Pittman Affidavit Attachment 3
- 639. Pittman Affidavit Attachment 4
- 640. Pittman Affidavit Attachment 7
- 641. Pittman Affidavit Attachment 8
- 642. Green Level Application (Excerpts)
- 643. Buncombe Hospital Advent Application (Excerpts)
- 644. Chart: Visits by Emergency Bay by Type and Use
- 645. Chart: Visits per Emergency Bay with Holds

Agency Exhibits ("Agency Ex.")

800. Map

EXHIBITS ADMITTED UNDER AN OFFER OF PROOF

Joint Exhibits

- 10. Mission/HCA 2022 FSED Candler Application
- 36.b ATTORNEY EYES ONLY Spreadsheet (Dep. Ex 36)

AdventHealth Exhibits

- 249. 2021 Arden Settlement Agreement
- 265. Mission 2754
- 266. Mission 0740
- 267. Email Mission West 2845
- 268. Map Candler Mission West 2846
- 269. Map Candler Mission West 2847
- 270. Transcript 2022 Acute Care Beds Buncombe Public Hearing

Pardee Exhibits

- 402.B. Chart: Mission Volume/Capacity under ACEP Guidelines
- 405.A2Opinion: Dawn Carter Rebuttal Opinions
- 406.A. Opinion: Dawn Carter Supplemental Attachments to Rebuttal Opinions
- 412. Map 20 Minute Drive Time
- 413. Spreadsheet Mission-West 01506

STIPULATED FACTS

In the Joint Prehearing Order, the parties stipulated to the following facts:

- 1. These contested cases arise from the May 24, 2022, decision ("Decision") of the Agency to conditionally approve the Certificate of Need ("CON") application filed by Mission on February 15, 2022, to develop a freestanding emergency department ("FSED") in Arden, Buncombe County, North Carolina and identified by Project ID B-12191-22 (the "Mission Application").
- 2. After the decision to conditionally approve the Mission Application, AdventHealth filed its Petition for Contested Case hearing with the Office of Administrative Hearings ("OAH") on June 23, 2022 and was assigned file number 22 DHR 2369.
- 3. Pardee also filed a contested case hearing on June 23, 2022, with OAH and was assigned file number 22 DHR 2387.
 - 4. Cases 22 DHR 2369 and 22 DHR 2387 have been consolidated for hearing in OAH.
- 5. All parties are properly before OAH, and OAH has jurisdiction of the parties and of the subject matter.
- 6. All parties have been correctly designated, and there is no question as to misjoinder or nonjoinder of parties.
- 7. The Parties stipulate that each party is represented by competent counsel and stands ready to proceed with the contested case hearing in this matter.

- 8. The Parties stipulate that there are no outstanding issues pertaining to discovery that would prevent, interfere, or otherwise necessitate the delay of the contested case hearing in this matter
- 9. Ms. Karin Sandlin, a witness proffered as an expert by AdventHealth, is accepted by the Office of Administrative Hearings without objection as an expert in:
 - a. The field of healthcare planning; and
 - b. The preparation and analysis of Certificate of Need applications.
- 10. Ms. Dawn Carter, a witness proffered as an expert by Pardee, is accepted by the Office of Administrative Hearings without objection as an expert in:
 - a. The field of healthcare planning; and
 - b. The preparation and analysis of Certificate of Need applications.
- 11. Ms. Kathryn MT Platt, a witness proffered as an expert by Mission, is accepted by the Office of Administrative Hearings without objection as an expert in:
 - a. The field of healthcare planning; and
 - b. The preparation and analysis of Certificate of Need applications.
- 12. Mr. Daniel Sullivan, a witness proffered as an expert by Mission, is accepted by the Office of Administrative Hearings without objection as an expert in:
 - a. The field of healthcare planning; and
 - b. The preparation and analysis of Certificate of Need applications.

In a stipulation agreed to by counsel for AdventHealth and Mission and read into the record on January 25, 2023, and subsequently filed with the Tribunal on February 17, 2023, the counsel for AdventHealth and the counsel for Mission agreed and stipulated to the following:

- 1. If called Mr. Van Arkel would testify to the following:
 - a. That Mission witness Sondra Smith is the Vice President of Planning and Strategy for HCA Mission:
 - b. In that role she has overall responsibility for certificate of need planning and projects;
 - c. Mr. Van Arkel believes Ms. Smith is good at her job;
 - d. Mr. Van Arkel finds Ms. Smith to be reliable;
 - e. Mr. Van Arkel trusts Ms. Smith's assessments regarding planning for new projects; and
 - f. Mr. Van Arkel believes Ms. Smith knows what she is doing when planning for new projects.

(Tr. Vol. 11, pp. 1812-13).

MOTIONS

On November 7, 2022, at the outset of the contested case hearing, the undersigned heard Respondent-Intervenor's Motion *in Limine* ("Motion"). (Tr. Vol. 1, pp. 8-28)

- 1. Respondent-Intervenor moved the Court for an order prohibiting counsel for all parties, the parties themselves, and all witnesses from testifying about, introducing any evidence relating to, or referring in any way to the following subjects on the grounds that the subjects are not relevant to or admissible in this contested case:
 - a. Evidence and testimony regarding Mission's FSED West Project;
 - b. Mission's 2021 Executive Management Review or Capital Project Improvement Memorandum;
 - c. Any and all information that post-dates the Agency's May 24, 2022, Decision conditionally approving the Mission FSED South Con Application; and
 - d. Claims by Petitioners that Mission had or has a monopoly in Buncombe County, North Carolina.
 - 2. The Respondent CON Section supported the Motion and Petitioners opposed.
 - 3. After hearing argument from all parties, the undersigned:
 - a. Granted Mission's Motion regarding evidence and testimony regarding Mission's FSED West Project;
 - b. Denied Mission's Motion regarding Mission's 2021 Executive Management Review or Capital Project Improvement Memorandum;
 - c. Took under advisement the issue related to any and all information that post-dates the Agency's May 24, 2022, Decision conditionally approving the Mission FSED South Application; and
 - d. Took under advisement the issue related to claims by Petitioners that Mission had or has a monopoly in Buncombe County, North Carolina.

(Tr. Vol. 1, p. 28)

FINDINGS OF FACT

Upon consideration of the sworn testimony of the witnesses presented at the hearing, the documents and exhibits received and admitted into evidence, and the entire record in this proceeding, the Undersigned makes the following Findings of Fact. In making the Findings of Fact, the Undersigned has weighed all the evidence and has assessed the credibility of each witness, including but not limited to, the demeanor of the witnesses; any interest, bias, or prejudice the witnesses may have; the opportunity of the witness to see, hear, know, or remember the facts or occurrences about which the witness testified; whether the testimony of the witnesses is reasonable; and whether the testimony is consistent with all other credible evidence in the case:

PARTIES

- 1. AdventHealth is a non-profit hospital located in Hendersonville, North Carolina, and provides emergency services in the service area proposed for the FSED at issue in this contested case. (See Vol. 2, Tr. at 361:23-362:25, 368:20-369:18; Ex. 1, MH-097).
- 2. Pardee is a non-profit, community hospital that offers acute and critical care services, including emergency services, in the service area proposed for the FSED at issue in this contested case. (See Vol. 2, Tr. at 285:24-286:8; Ex. 1, MH-097).
- 3. Respondent CON Section is the agency of the State of North Carolina authorized and required to review CON applications under Article 9 of Chapter 131E of the North Carolina General Statutes (the "CON law"). (Joint Prehearing Order, ¶ 2(a)).
- 4. Respondent-Intervenor Mission Hospital is a health service provider located in Buncombe County, North Carolina and is licensed to provide acute care hospital services, including emergency department services, pursuant to Article 9, Chapter 131E of the North Carolina General Statutes. Mission provides health care services to patients in Buncombe County and eighteen (18) surrounding counties. (Jt. Ex. 1, MH 25).

BACKGROUND

- 5. A Certificate of Need ("CON") is required for certain "new institutional health services" as that term is defined by N.C. Gen. Stat. § 131E-176(16).
- 6. The State Medical Facilities Plan ("SMFP") is the official plan developed and published each year which inventories certain services, facilities, and equipment that are subject to CON regulation as well as the utilization of those services, facilities, and equipment. The SMFP includes "need determinations" which are determinations that certain additional services, facilities, and equipment are needed in certain service areas. The SMFP does not have a need determination requirement for the development of a new FSED. (Jt. Ex. 2, Agency File AF-499)
- 7. A freestanding emergency department ("FSED") for purposes of the CON law is a new institutional health service that requires a certificate of need if the proposed capital expenditure for the project exceeds Four Million Dollars (\$4,000,000) because it is an "obligation by any person of a capital expenditure exceeding four million dollars (\$4,000,000) to . . . expand a health service or health service facility, or which relates to the provision of a health service" as the terms "health service" or "health service facility" are defined in the CON Statute. N.C. Gen. Stat. §§ 131E-176 (9a), (9b) (16)b and 178(a).
- 8. Free standing emergency departments are not included in the list of facilities for which the State Medical Facilities Plan ("SMFP") provides a projection of need. Accordingly, an applicant for such is not required to show that there is a need determination for the facility in the SMFP. However, the applicant is still required to show that there is a need for the project proposed in the application. N.C. Gen. Stat. § 131E-183. (Tr. Vol. 14, Platt, p. 2332).

- 9. On or about February 15, 2022, Mission filed an application for a CON to establish a new FSED in Arden, Buncombe County, North Carolina, Project I.D. No. B-12191-22. Mission was required to apply for a CON for the proposed FSED because the proposed capital expenditure for the FSED was projected to be Thirteen Million, Three Hundred and Twenty Thousand, Five Hundred Dollars (\$13,320,500), (Jt. Ex. 1, Mission Application MH 088), and because the proposed FSED would be licensed as part of Mission Hospital. (Jt. Ex. 1, Mission Application MH 034).
- 10. In accordance with N.C. Gen. Stat. § 131E-185(a1)(1), written comments may be filed by any person in response to applications under review by the Agency. AdventHealth and Pardee each filed separate written comments in opposition to the Mission Application on March 31, 2022. (Jt. Ex. 2, Agency File AF 65-199) In addition, numerous members of the public filed written comments both in opposition to and in support of the Mission Application. (Jt. Ex. 2, Agency File AF 200-03, 262-98)
- 11. In accordance with N.C. Gen. Stat. § 131E-185(a1)(2), the Agency is required to hold in-person public hearing in connection with CON applications, like the Mission Application. However, due to the ongoing COVID public health emergency, in this case, contrary to the statutory mandate, the Agency issued notices to both the public and interested parties asking the public not to request a public hearing because of the pandemic. The Agency specifically published a notice in the Asheville Citizen Times on March 2, 2022, stating: the Agency would not be holding a public hearing in the review of the Mission Application, the Laurels at Summit Ridge Application, a second Mission Application for a new health service facility in Western Buncombe County, and the Deerfield Episcopal Retirement Community Application. Other notices informed the public that the Agency would accept written remarks or comments in lieu of the public hearing. (Mission Ex. 636, 637, 638, 639; Jt. Ex. 2, Agency File AF 210).
- 12. The Agency accepted written comments in lieu of holding a public hearing in the review of the Mission Application. (Jt. Ex. 2, Agency File, AF 262-98).
- 13. On May 5, 2022, Mission filed comments in response to both the AdventHealth comments and Pardee comments. (Jt. Ex. 2, Agency File AF 213-60).
- 14. On May 24, 2022, by letter and Required State Agency Findings, CON Section Project Analyst Mike McKillip and Assistant Chief Lisa Pittman informed Mission that the Mission Application had been conditionally approved. (Jt. Ex. 2, Agency File AF 499-524).
- 15. On June 23, 2022, AdventHealth filed a Petition for Contested Case Hearing ("AdventHealth Petition") with the Office of Administrative Hearings, appealing the Agency's Decision. The AdventHealth Petition was assigned case number 22 DHR 02369.
- 16. Also on June 23, 2022, Pardee filed a Petition for Contested Case hearing ("Pardee Petition") with the Office of Administrative Hearings, appealing the same Agency Decision. The Pardee Petition was assigned case number 22 DHR 02387.

- 17. On July 12, 2022, Mission filed a Joint Motion to Intervene in contested cases 22 DHR 02369 and 22 DHR 02387 as a Respondent-Intervenor and a Stipulation to Consolidate the contested cases (22 DHR 02369 and 22 DHR 02387) with consent of AdventHealth, Pardee, and the Agency.
- 18. The order allowing intervention was issued on July 14, 2022, and order for consolidation was issued on July 15, 2022.
- 19. On March 14, 2023, this Tribunal entered an Order for Voluntary Dismissal Without Prejudice, to allow the Petitioners to refile their respective Petitions for Contested Case Hearing for the purpose of initiating a new 270-day deadline by which the undersigned ALJ must render a decision.
- 20. AdventHealth refiled its Petition for Contested Case Hearing on March 16, 2023, which was assigned docket number 23 DHR 01294. Pardee refiled its Petition for Contested Case Hearing on March 16, 2023, which was assigned docket number 23 DHR 01286.
- 21. Mission filed a CON Application to develop a FSED in Arden in <u>2021</u>. That Application was denied by the Agency and appealed by Mission. Upon approval of Mission's 2022 CON application to develop a FSED in Arden, which is the subject of this contested case hearing, Mission dismissed that appeal. The relevance of Mission's <u>2021</u> Application will be addressed in subsequent portions of this Final Decision.

EXPERT WITNESSES

- 22. Ms. Dawn Carter is employed by Ascendient Healthcare Advisors. Ms. Carter has worked for Ascendient for over 25 years. Ms. Carter has an undergraduate degree in Business Administration and a master's degree in healthcare administration. Ms. Carter was retained by Pardee to assist with its response, comments, and opposition to the Mission Application. (Tr. Vol. 6, Carter, pp. 1023-27) (Jt. Ex. 115)
- 23. Ms. Karin Lastowski Sandlin is employed by Clarity Strategic Services. Ms. Sandlin is the President/owner of Clarity. Ms. Sandlin has an undergraduate degree in Public Health with a concentration in Health Policy Administration. Ms. Sandlin does not hold any advanced degrees. Ms. Sandlin was retained by AdventHealth to assist with its response, comments, and opposition to the Mission Application. (Tr. Vol. 9, Sandlin, pp. 1536-42) (Jt. Ex. 143)
- 24. Ms. Kathy Platt is President of Platt HMC Consulting, Inc. Ms. Platt has a undergraduate degree in Psychology and a Master of Business Administration focusing on healthcare management and finance. Ms. Platt has worked in healthcare consulting for over 32 years focused on the preparation of CON applications. She has also provided litigation support and testimony during that time and has been qualified as an expert witness in health planning and finance, including in the states of North Carolina, South Carolina, Georgia, Florida, Alabama, Tennessee, and Kentucky. She has testified in CON hearings or depositions approximately 100

times and has prepared many hundreds of CON applications in numerous states. (Tr. Vol. 14, Platt, p. 2318-23) (Jt. Ex. 159).

25. Each of the three proffered expert witnesses were accepted by this Tribunal as experts in the field of health care planning and the preparation of certificate of need applications in the prehearing order entered in this case. (Pre-Trial Order, $\P\P$ 3(i), (j) and (k)) (Tr. Vol. 6, Cater, p. 1027) (Tr. Vol. 9, Sandlin, p. 1542) (Tr. Vol. 14, Platt, p. 2323)

THE CON REVIEW PROCESS AND THE MISSION APPLICATION

Overview

- 26. The CON review criteria are both statutory and regulatory. The statutory review criteria are found in N.C. Gen. Stat. § 131E-183(a). There are 15 statutory review criteria (excluding subparts of Criterion 13). N.C. Gen. Stat. § 131E-183(b) authorizes the Agency "to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a)."
- 27. N.C. Gen. Stat. § 131E-182(b) states in part: "an applicant shall be required to furnish only that information that is necessary to determine whether the proposed new institutional health service is consistent with the review criteria . . . and with duly adopted standards, plans and criteria."
- 28. N.C. Gen. Stat. § 131E-182(b) instructs the Agency to provide application forms for the various types of CON proposals in order to obtain the information necessary to conduct its review of proposed applications.
- 29. The Agency File is a compilation of everything, other than the application itself, produced by or considered by an analyst during the review of the application. Mr. McKillip prepared the Agency File in this case. In this matter, it included seven sections: General Correspondence; Written Comments; Letters of Support; Public Hearing Documents; Project Analyst's Notes and Reference Materials; Other Agency Findings; and the Agency Findings for this review. (McKillip, Vol. 1, p. 57) (Jt. Ex. 2, Agency File AF 1-524).
- 30. N.C. Gen. Stat. § 131E-186(b) states: "Within five business days after it makes a decision on an application, the Department shall provide written notice of all the findings and conclusions upon which it based its decision, including the criteria used by the Department in making its decision, to the applicant."

Mission's Application

31. Ms. Sondra Smith is the Vice President of Strategy and Planning for Mission Health. (Tr. Vol. 13, Smith, p. 1998-99). In her role at Mission, Ms. Smith is responsible for the general oversight of the process of developing a certificate of need for Mission Hospital. (Tr. Vol. 13, Smith, p. 2019).

- 32. Ms. Smith is part of a team that includes some internal staff members as well as some outside consultants that help Mission during the CON application process. (Tr. Vol. 13, Smith, p. 2019).
- 33. Ms. Smith oversees the overall collection of data for Mission's CON applications. Ms. Smith also reviews the narratives contained in the CON applications before an application is submitted. (Tr. Vol. 13, Smith, p. 2019).
- 34. Ms. Smith testified that for CON applications submitted by Mission, "while I don't see every single Excel file that is produced by the -- by our consultant, I do read everything before it goes out the door. And I do make sure that we're comfortable, that it's truthful, and that it represents what we're trying to accomplish." (Tr. Vol. 13, Smith, pp. 2019-20).
- 35. When considering applying for a CON for a CON regulated service, Mission reviews the SMFP issued by the State to determine if there is a need in its community it feels it can meet. (Tr. Vol. 13, Smith, p. 2020).
- 36. Ms. Smith stated that, if Mission determines that there is a need it feels it can meet, "leadership in our hospitals, both at the hospital level and the division level, meet and talk about how we might meet that need. And then we assemble our team to start the process of completing the certificate of need." (Tr. Vol. 13, Smith, p. 2020).
- 37. Mission submitted an application to establish a FSED in Arden to help decompress congestion at Mission Hospital's main ER. (Tr. Vol. 13, Smith, p. 2022).
- 38. Ms. Smith stated, "[Mission is] not serving the patients in that ER in the way that we find acceptable in terms of the length of time they have to spend there, the length of time they have to wait. And so we've looked at many strategies to alleviate this." (Tr. Vol. 13, Smith, p. 2022-23).
- 39. Mission determined that the best way to continue to serve patients was to develop a freestanding ER in a location that would be closer to their home and develop a freestanding ER where patients didn't have to drive into Mission main and where patients could be served in a more efficient fashion which would help the patient experience. (Tr. Vol. 13, Smith, p. 2023).
- 40. Mission believes that developing a FSED in Arden will allow patients to obtain the same high level emergency care from board certified emergency medicine physicians without having to spend time driving to Mission and experiencing the long wait times. (Tr. Vol. 13, Smith, pp. 2023).
- 41. Mission retained Kathy Platt as a consultant to assist with the Mission Application. (Tr. Vol. 13, Smith, p. 2021).
- 42. Ms. Platt, Mission's CON Consultant, and her firm primarily focused on Section C of the Mission Application which involves the project need and the utilization projections and

accessibility in Section L. However, Ms. Platt reviewed all aspects of the Mission Application before it was submitted to the Agency. (Tr. Vol. 14, Platt, p, 2326).

The Agency's Review of the Mission Application

- 43. Mike McKillip is an analyst that works in the CON Section. Mr. McKillip is a team leader and oversees several other analysts. (Tr. Vol. 1, McKillip, p. 54). Mr. McKillip completes around 20 to 30 reviews of CON applications a year. (Tr. Vol. 2, McKillip, p. 221).
- 44. Mr. McKillip is the analyst who reviewed the Mission Application to establish a FSED in Arden, Buncombe County, North Carolina. (Tr. Vol. 1, McKillip, p. 54).
- 45. Mr. McKillip in his role as an analyst reviewed the Mission Application, reviewed the written comments in opposition to the Mission Application submitted by AdventHealth and Pardee, and reviewed Mission's responses to the comments in opposition. (Tr. Vol. 2, McKillip, p. 217).
- 46. When the Agency reviews an application, it reviews the application that is before it, standing alone, which in this case, included the most recent information contained in the 2022 Mission Arden Application. (Tr. Vol. 2, McKillip, p. 184).
- 47. Mr. McKillip in his review of the written comments in opposition to Mission's Application stated, "Well, like all written comments, they raise concerns or critiques or criticisms of ways that the applicant has supported their argument or their projections, things they could have done differently or done better in the view of the commenters and then the applicant responds to those criticisms and critiques." (Tr. Vol. 2, McKillip, p. 259).
- 48. However, in this review, Mr. McKillip found that the responses by Mission in its response to comments were adequate, "such that they addressed the concerns, critiques by the commenters and the applicant could be found conforming under the statutory criteria." (Tr. Vol. 2, McKillip, p. 259).
- 49. Mr. McKillip was asked if he considered any of the points raised in the comments to be true. Mr. McKillip stated, "I don't remember making a determination of, this is certainly true, this is certainly not true. That's not important for this process. These are assertions made by the commenters and then counter assertions made by the applicant. I make some judgment about the reasonableness and how well it's supported, and then I determine or make a judgment, or the agency makes a judgment about whether or not they rise to the level of concern where they would change the finding." (Tr. Vol. 2, McKillip, pp. 259-60)
- 50. After Mr. McKillip reviewed all the information regarding the Mission Application, he drafted a copy of the Required State Agency Findings and sent it to Lisa Pittman for review. (Tr. Vol. 2, McKillip, p. 217).

- 51. Lisa Pittman is the Assistant Chief of the CON Section. She has served in that role for 5 years. Ms. Pittman's duties include guiding and managing two team leaders and supervising their work. (Tr. Vol. 4, Pittman, pp. 627-28).
- 52. Prior to her current role, Ms. Pittman was a team leader for approximately five years. In that role, she supervised five project analysts, conducted training and reporting for the project analysts, cosigned findings, and cosigned administrative decisions. Ms. Pittman was also a project analyst for two years before becoming a team leader. (Tr. Vol. 5, Pittman, pp. 899-900)
- 53. Ms. Pittman participates in about 50 to 80 reviews a year. (Tr. Vol. 5, Pittman, p. 884).
- 54. Ms. Pittman receives initial CON applications and assigns them for review. (Tr. Vol. 4, Pittman, p. 629).
- 55. Ms. Pittman's duties as a cosigner are to review the draft of the proposed findings that the analyst has provided for both compliance and accuracy regarding what is presented to the Agency in the application. (Tr. Vol. 5, Pittman, p. 884).
- 56. Ms. Pittman also reviews the draft findings to make sure the findings are consistent with how the CON Section interprets the law. (Tr. Vol. 5, Pittman, p. 884).
- 57. Once Mr. McKillip and Ms. Pittman reviewed and incorporated any changes or edits, they drafted the Agency's final findings and issued a decision in this case. (Tr. Vol. 2, McKillip, p. 217).

Non-Competitive Applications

- 58. Upon receipt of an application, the Agency will make an initial determination as to whether the application is competitive or not competitive. (Tr. Vol. 4, Pittman, p. 629). After the applications are received, the Agency enters the applicable information into its database, assigns the applications to a workload, assigns a review analyst and a co-signer for each project, and puts them on a calendar for review. The Agency then makes a determination as to whether the applications are competitive or not competitive. (Tr. Vol. 2, McKillip, p. 221)
- 59. In determining if an application is competitive or not competitive in the CON application process, the Agency considers whether the approval of one application will necessarily lead to the denial of another application in the review. If it does not, then the applications will be deemed noncompetitive. (Tr. Vol. 2, McKillip, pp. 218-19).
 - 60. Specifically, the Agency applies 10A NCAC 14C .0202(3) which states:

"Competitive review" means two or more applications submitted to begin review in the same review period proposing the same new institutional health service in the same service area and the CON Section determines that approval of one application may require denial of another application included in the same review period."

- 61. It is undisputed that neither Pardee nor AdventHealth submitted a CON application to develop a FSED in Buncombe County during this review. In fact, both Pardee and AdventHealth were prohibited from developing a FSED in Buncombe at the time of this review because neither are licensed to operate a hospital in Buncombe County. The North Carolina Hospital Licensure Act and rules provide that a hospital license will include only facilities operated by the hospital within a single county where the hospital is located. (Tr. Vol. 10, Sandlin, p. 1739); see also N.C. Gen. Stat. 131E-79(e1) and 10A NCAC 13B .3101(f).
- 62. The Mission Application was not part of a competitive review. (Tr. Vol. 2, McKillip, p. 218).
- 63. In addition to the Mission Application at issue in this appeal, Mission also submitted a separate CON application to develop a FSED in Candler, in a separate and distinct area of Buncombe County. (Jt. Ex. 1, Mission Application MH 36).
- 64. The Agency determined that the Mission Application for the Arden location and the application for the Candler location were non-competitive. (Tr. Vol. 2, McKillip, p. 218).
- 65. Both Petitioners attempted to present evidence that the Arden and Candler Applications should have been reviewed competitively. ¹
- 66. This Tribunal ruled that the Arden Application and the Candler Application were separate and non-competitive and entered a protective order prior to trial and granted Mission's Motion in Limine at the start of the trial ruling that the Arden and Candler contested cases were not competitive applications. As a result, evidence of Mission's Candler Application was excluded from this trial. (Tr. Vol. 1, Motion in Limine, pp. 1-37)

The Agency's Decision

- 67. On May 24, 2022, the Agency issued its Required State Agency Findings. (Jt. Ex. 2, Agency File AF 497-524).
- 68. N.C. Gen. Stat. § 131E-183(a) states, "The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued."
- 69. In its Required State Agency Findings, the Agency found the Mission Application conforming to each statutorily required Review Criteria.

AdventHealth made an offer of proof regarding the Mission Application being reviewed as non-competitive. (Pittman Vol. 4, pp. 632-42, 44-50, 58-62). Pardee made an offer of proof regarding the Mission Application being reviewed as non-competitive. (Pittman Vol. 5, pp. 853-59).

- 70. AdventHealth expert witness Karin Sandlin testified that in her opinion the Agency erred in finding the Mission Application conforming to Statutory Review Criteria 3, 4, 5, 6, 13, 18a, and 20. (Tr. Vol. 9, Sandlin, p. 1545).
- 71. Pardee expert witness Dawn Carter testified that in her opinion the Agency erred in finding the Mission Application conforming to Statutory Review Criteria 3, 4, 5, 6, and 18a. (Tr. Vol. 6, Carter, p. 1030). Ms. Carter confirmed that these are the only criteria that Pardee contends the Agency erred in assessing. (Tr. Vol. 8, Carter, p. 1322 -23).

PUBLIC HEARING

- 72. Under N.C. Gen. Stat. § 131E-185(a1)(2), "the Department shall ensure that a public hearing is conducted at a place within the appropriate service area if one or more of the following circumstances apply; the review to be conducted is competitive; the proponent proposes to spend five million dollar (\$5,000,000) or more; a written request for a public hearing is received before the end of the written comment period from an affected party as defined in G.S. 131E-188(c); or the agency determines that a hearing is in the public interest."
- 73. Mr. McKillip and Ms. Pittman acknowledged that N.C. Gen. Stat. § 131E-185 requires a public hearing whenever the proponent of a project spends five million dollars or more, and in that event, the statute does not require anyone to request a public hearing. (Tr. Vol. 1, McKillip, p. 59; Tr. Vol. 4, Pittman, p. 674).
- 74. The total projected capital expenditure for Mission's Project is \$13,320,500. (Jt. Ex. 1, Mission Application MH 02, MH 173). This amount exceeds the statutory threshold of \$5,000,000 that automatically triggers the requirement for a public hearing under N.C. Gen. Stat. § 131E-185(a1)(2).
- 75. The Agency did not hold a public hearing with respect to the Mission Application. (Tr. Vol. 1, McKillip, p. 61; Tr. Vol. 4, Pittman, p. 670).
- 76. The intake form for Mission's Application indicated that: "If a public hearing is required by law, during the COVID-19 state of emergency, no public hearings will be scheduled." (Jt. Ex. 2, Agency File AF 06). The intake form specifically indicated that a public hearing was required by law. (Jt. Ex. 2, Agency File AF 06).
- 77. On February 17, 2022, Mr. McKillip wrote Mission's representative, Catherine Durham, informing her that, "[d]ue to the COVID-19 State of Emergency, no public hearings were being scheduled. Please see the Public Notice at https://info.ncdhhs.gov/dhsr/coneed/press_release/2020/PublicHearings-during-COVID.pdf" (Tr. Vol. 1, McKillip, p. 57; Jt. Ex. 2, Agency File AF 07; Jt. Ex. 6).
- 78. The above link was to a Public Notice dated November 19, 2021, entitled Scheduling of Public Hearings for Certificate of Need Applications During the COVID-19

Pandemic. (*See* https://info.ncdhhs.gov/dhsr/coneed/press_release/2020/PublicHearings-during-COVID.pdf; Jt. Ex. 6).

79. The Public Notice provided in pertinent part:

Public hearings for certificate of need applications are scheduled only if they are required by law. The law requires a public hearing be held if the capital cost of a project proposed in a certificate of need application is \$5,000,000 or more, the review is competitive, or a written request to hold a public hearing is received by the Healthcare Planning and Certificate of Need Section during the 30-day public comment period for the review.

During the COVID-19 pandemic, the Healthcare Planning and Certificate of Need Section asks that no one request a public hearing be held due to social distancing guidelines and potential restrictions on locations to hold public hearings.

If a public hearing was required by law, members of the public will be given an opportunity to submit remarks in lieu of a public hearing in writing

Remarks from members of the public must be received no later than 5:00 p.m. on the 20th day of the month after the last day to submit written comments. If the 20th day falls on a weekend or holiday, the last day to submit remarks is the last business day **before** the weekend or holiday

The applicant will have an opportunity to respond to any written comments received during the 30-day public comment period and any written remarks from members of the public submitted in lieu of a public hearing. Within three business days of receipt of the remarks, the project analyst will notify the applicant that comments and/or remarks were received and request that the applicant provide a response within 10 business days of the analyst's notice.

(See https://info.ncdhhs.gov/dhsr/coneed/press_release/2020/PublicHearings-during-COVID.pdf; Jt. Ex. 6) (emphasis in original).

- 80. The CON Section of the Agency did not conduct public hearings between March 2020 and August 11, 2022, until a public hearing took place on August 12, 2022. (Tr. Vol. 4, Pittman, pp. 699-700, 704).
- 81. The Agency was aware that as of July 30, 2021, there were no restrictions on gathering in public pursuant to any Executive Order, as such restrictions had been lifted by the Governor. Such restrictions were not in place in March or April of 2022, and Ms. Pittman acknowledged that the Agency's decision to continue not having public hearings was not based on

the public gathering restrictions, as they had been lifted. (Tr. Vol. 4, Pittman, pp. 696-699); Tr. Vol. 5, Pittman, pp. 847-848).

- 82. The Tribunal takes Official Notice of the fact that, on May 14, 2021, North Carolina Governor Roy Cooper issued Executive Order No. 215, in which he determined that, based on the data available at that time: "the Face Covering requirement should be lifted in most settings, and the capacity restrictions, and social distancing requirements should be lifted for all settings." https://governor.nc.gov/media/2406/open.
- 83. Specifically, Executive Order No. 215 provided: "This Executive Order fully lifts the capacity limitations and social distancing requirements on businesses in Executive Order No. 209, and lifts the indoor Face Covering requirement on most businesses and operations." https://governor.nc.gov/media/2406/open.
- 84. Ms. Pittman nevertheless testified that, even though the public gathering restrictions had been lifted, the State of Emergency remained in place, which justified still not having public hearings. She acknowledged that the State of Emergency was lifted on August 15, 2022, and yet the Agency had a public hearing three days earlier on August 12, 2022, which she justified by saying that the Agency had heard in July that the State of Emergency was going to be lifted and because the Agency thought it was "the right thing to do." (Tr. Vol. 4, Pittman, pp. 696, 699-700).
- 85. The Tribunal takes Official Notice that the COVID-19 State of Emergency in Executive Order 116 contained no restrictions on public gatherings. https://governor.nc.gov/media/1750/open.
- 86. During her testimony, Ms. Pittman identified additional reasons that she felt the Agency was justified in not having public hearings, including that COVID-19 was not gone, spikes with new variants were unpredictable, and Agency employees were still working from home. (*See, e.g.*, Tr. Vol. 4, Pittman, pp. 695, 698).
- 87. The agency determined that, after July 30, 2021, "despite the fact that there were no restrictions or measures imposed by executive order for the general public, . . . it was still appropriate not to have hearings that the statutes of North Carolina required[.]" (Tr. Vol. 4, Pittman, p. 697).
- 88. In 2021 and early 2022, the Agency held public hearings via WebEx related to the development of the Proposed 2022 State Medical Facilities Plan ("SMFP") and the Proposed 2023 SMFP. Specifically, the Agency held public hearings on March 3, 2021, July 8, 2021, July 12, 2021, July 14, 2021, July 20, 2021, July 26, 2021, July 28, 2021 and March 2, 2022. (Tr. Vol. 4, Pittman, pp. 714-716; Jt. Ex. 144 at 4-5).
- 89. Ms. Pittman stated that holding a WebEx hearing for Mission's 2022 Arden Application was not feasible because: (1) hearings for CON applications are required to be in the service area by statute; (2) only two members of the CON Section have WebEx accounts, which are email specific; (3) it would not be possible for those individuals to host all public hearings

from their accounts; and (4) it would have been difficult to get budget approval for additional WebEx accounts. (Tr. Vol. 4, Pittman, pp. 716-717).

- 90. In March 2022, the CON Section held planning meetings regarding the SMFP virtually via WebEx and provided information for members of the public to participate. (Tr. Vol. 1, McKillip, p. 66; Jt. Ex. 7).
- 91. The Agency did not offer any virtual public hearing opportunity in the review of Mission's Application. (Tr. Vol. 1, McKillip, p. 66).
- 92. The Agency indicated that if someone had requested a public hearing that it would have been taken up with Agency counsel or the then–Agency Chief, Martha Frisone. (Tr. Vol. 4, Pittman, pp. 692-693).
- 93. Despite this statement, Ms. Pittman acknowledged that in an earlier matter involving WR Imaging in 2021, WR Imaging, which was represented by the same counsel as AdventHealth in the current matter, requested a public hearing but that request was not granted, and no public hearing occurred. (Tr. Vol. 4, Pittman, pp. 702, 706-707).
- 94. Ms. Pittman agreed that she could not point to anything that would require AdventHealth to ask for a public hearing when its lawyers were aware that a prior request for a public hearing had not been granted, (Tr. Vol. 4, Pittman, p. 709), and Mr. McKillip agreed that under the applicable statute there was not a requirement to ask for a public hearing if the project amount exceeded \$5,000,000, (Tr. Vol. 1, McKillip, p. 59).
- 95. On February 17, 2022, Mr. McKillip sent Ms. Durham a separate letter via e-mail entitled "**Notice Regarding Public Hearings during COVID-19**." (Jt. Ex. 2, Agency File AF 211–AF 212).
- 96. The letter provided that: "the applicant will have an opportunity to respond to any comments received during the 30-day public comment period and any written remarks from members of the public submitted in lieu of a public hearing. Within three business days of receipt of the remarks, the project analyst will notify the applicant that comments or remarks were received and request that the applicant provide a response within 10 business days of the analyst's notice." (Jt. Ex. 2, Agency File AF 212).
- 97. By statute, if there had been a public hearing, Mission would have had to respond to comments at the hearing, whereas the Agency gave Mission extra time to respond to public comments and remarks in writing with respect to its Application. (Tr. Vol. 4, Pittman, pp. 723-724).
 - 98. With respect to public hearings, N.C. Gen. Stat. § 131E-185(a1)(2), provides:

At such public hearing oral arguments may be made regarding the application or applications under review; and this public hearing shall include the following:

- a. An opportunity for the proponent of each application under review to respond to the written comments submitted to the Department about its application;
- b. An opportunity for any person, except one of the proponents, to comment on the applications under review;
- c. An opportunity for a representative of the Department, or such other person or persons who are designated by the Department to conduct the hearing, to question each proponent of applications under review with regard to the contents of the application.
- 99. Ms. Pittman acknowledged that the opportunity to ask questions in person and hear oral argument was not present in the written comment process for Mission's 2022 Arden Application. (Tr. Vol. 4, Pittman, p. 727).
- 100. Mr. McKillip also acknowledged that, in his experience, people attend and speak at public hearings that have not submitted written comments. (Tr. Vol. 1, McKillip, p. 60).
- 101. Ms. Pittman stated that the CON Section does not necessarily know what will be said at a public hearing if one is held. (Tr. Vol. 4, Pittman, pp. 709-710).
- 102. There is no statutory time limit on the length of the public hearing or on the number of people who may speak. (Tr. Vol. 1, McKillip, p. 60).
- 103. At a public hearing, the representative of the Agency may ask questions of the applicant, whereas the statute only provides that the Agency may ask the applicant questions in writing if the review is expedited. (*Id.* at 60-61).
- 104. Ms. Pittman was not aware of any attempt by the CON Section to find a substitute process for an Agency representative to ask the proponent of an application questions as they would have had the opportunity to do if a public hearing had been held. (Tr. Vol. 4, Pittman, p. 727).
- 105. While it is undisputed that AdventHealth and Pardee did not request a public hearing nor did it mention in its written comments the lack of a public hearing, (see Tr. Vol. 2, McKillip, p. 233; Tr. Vol. 5, Pittman, p. 888), neither the Agency nor Mission points to any evidence or legal authority of any kind indicating that AdventHealth or Pardee were required to do either.
- 106. Rather, the North Carolina General Statutes explicitly state that it was the Agency that was required to ensure that a public hearing was conducted. N.C. Gen. Stat. § 131E-185(a1)(2). Additionally, N.C. Gen. Stat. § 131E-185 mandates public hearings in prescribed circumstances *in addition to* the right to submit written comments. (See N.C. Gen. Stat. § 131E-

- 185(a1)(1) (entitling "[a]ny person [to] . . . file written comments and exhibits concerning a proposal under review with the Department").
- 107. The Agency relies on numerous notices that it sent out at various times that would have been received by AdventHealth and Pardee or their representatives in addition to the November 19, 2021, notice, (Jt. Ex. 6), regarding the fact that the Agency would not be conducting public hearings due to public safety concerns (*See*, *e.g.*, Tr. Vol. 5, Pittman, pp. 909-913; Mission Exs. 636, 637, 638, 639, 640). Ms. Pittman contends, and AdventHealth and Pardee did not offer any evidence disputing, that each of these notices would have been provided to AdventHealth and Pardee or someone acting on their behalf. (Tr. Vol. 5, Pittman, pp. 909-913).
- 108. The Agency and Mission also rely on newly developed procedures to submit written comments, in lieu of a public hearing, that were afforded to AdventHealth, Pardee, and others to support its contention that AdventHealth and Pardee had adequate opportunities to make their position known regarding Mission's 2022 Arden Application. (*See, e.g.*, Tr. Vol. 4, Pittman, pp. 671, 688). Neither the Agency nor Mission points to any statute, rule, regulation, or case law that would allow the Agency to develop a substitute for the public hearing required under N.C. Gen. Stat. § 131E-185(a1)(2), and this Tribunal is not aware of any.
- 109. Lastly, both Mission and the Agency contend that if the Agency erred by not conducting a public hearing and that AdventHealth and Pardee were substantially prejudiced as a matter of law as a result, that 86 separate reviews where a public hearing was required but not held, would be nullified. (Tr. Vol. 5, Pittman, pp. 916-918).
- 110. Neither Mission nor the Agency point to any statute, rule, regulation, or case law that would support the position that if the Agency does not comply with N.C. Gen. Stat. § 131E-185 on numerous occasions, it excuses the Agency's failure to comply with the statute on every occasion, and this Tribunal is not aware of any statute, rule, regulation, or case law that would do so.

AGENCY REVIEW OF STATUTORY REVIEW CRITERION 1

- 111. Criterion 1 applied to the Mission Application. Statutory Review Criterion 1 requires that the proposed project be consistent with applicable polices regarding need determinations in the State Medical Facilities Plan, the need determinations of which constitute 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. (Jt. Ex. 2, Agency File AF 499; see also N.C. Gen. Stat. §131E-183(a)(1)).
- 112. Pursuant to Review Criterion 1, SMFP Policy GEN-4 applied to the Mission Application. The Agency determined that Policy GEN-4 was applicable. Policy GEN-4 provides:

Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.

(Policy GEN-4, 2022 SMFP) (Jt. Ex. 2, Agency File AF 500)

- 113. There is no need determination in the 2022 SMFP that is applicable to this proposed project. (Jt. Ex. 2, Agency File AF 499).
- Application to be conforming to Statutory Review Criterion 1 because Mission did not propose to develop any beds, services, or equipment for which there was a need determination in the 2022 SMFP. Further, the Agency determined that Mission adequately demonstrated that its proposed FSED was consistent with Policy GEN-4 based on its representations that the proposed project included a plan for energy efficiency and water conservation. (Jt. Ex. 2, Agency File AF 501). The Agency reviewed the application, the exhibits to the application, the written comments, the remarks made in lieu of the public hearing, and the responses to comments before determining that Mission's Application was conforming to Statutory Review Criterion 1. (Jt. Ex. 2, Agency File AF 500-01).
- 115. There is no SMFP chapter or section relevant to Freestanding Emergency Departments. There are also no specific standards relating to FSEDs. Policy GEN-4 is the only policy that applies in this review. (Tr. Vol. 14, Platt, p. 2332).
- 116. The Mission Application met all the relevant policies contained in Statutory Review Criterion 1. Further, the information provided in the Mission Application specific to Policy GEN-4 demonstrated how the design and construction of the FSED would maximize energy efficiency

and water conservation from a design and implementation standpoint. (Tr. Vol. 14, Platt, pp. 2332-33) (Jt. Ex. 160, p. 4).

- 117. Ms. Platt opined that the Agency was correct in finding the Mission Application conforming to Statutory Review Criterion 1. (Tr. Vol. 14, Platt, p. 2334) (Jt. Ex. 160, p. 4).
- 118. This Tribunal finds that Ms. Platt's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 1 to be credible, reliable and persuasive.
- 119. Neither AdventHealth nor Pardee presented any testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 1.

- 120. Statutory Review Criterion 3 applied to the Mission Application. Statutory Review Criterion 3 requires that the applicant identify the population to be served by the proposed project and demonstrate the need that the proposed population to be served has for the proposed services. Further, the applicant must demonstrate how underserved populations including low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed. (Jt. Ex. 2, Agency File AF 501-06, *see also* N.C. Gen. Stat. §131E-183(a)(3)) (Tr. Vol. 14, Platt, p. 2334) (Tr. Vol. 15, Platt, pp. 2402-03).
- 121. There is nothing in the SMFP that sets forth any criteria or standards applicable to FSEDs in terms of how an applicant must demonstrate the need for a proposed FSED or any utilization or other metrics an applicant must meet. (Jt. Ex. 2, Agency File AF 501-06). Therefore, the applicant can present whatever information or justification it wants, in whichever manner it chooses. (Tr. Vol. 8, Carter, p. 1365). Then the agency reviews that information and determines whether it's reasonable or not. (Tr. Vol. 14, Platt, pp. 2354-55).
- 122. The Agency determined that the Mission Application was conforming with Statutory Review Criterion 3. (Jt. Ex. 2, Agency File AF 506) (Tr. Vol. 15, Platt, p. 2403).
- 123. Mr. McKillip read and considered the comments submitted by Petitioners when determining the reasonableness of Mission's proposal and determined that those comments did not change the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 3. (Tr. Vol. 1, McKillip, p. 55, 78; Tr. Vol. 2, McKillip, p. 258).
- 124. The Agency's finding that the Mission Application was conforming to Statutory Review Criterion 3 was based on its finding that the utilization projections were adequately supported by the information in the Mission Application, exhibits, comments, and responses to comments. (Tr. Vol. 1, McKillip, p. 102).
- 125. The Agency determined Mission's projections were reasonable after reviewing the information in the application, reviewing the exhibits to the application, reviewing the comments

in opposition to the application, and reviewing Mission's response to the comments to the application. (Tr. Vol. 1, McKillip, p. 102).

- 126. The Mission Application provided historical market share data and made assumptions about how Mission felt its project would affect the proposed service area. The Agency determined that Mission's utilization projections were reasonable and adequately supported. (Tr. Vol. 1, McKillip, 124).
- 127. In support of Criterion 3, Mission completed Section C of the CON application. (Jt. Ex. 1, Mission Application MH 33-81) (Tr. Vol. 14, Platt, p. 2334).

Scope

128. In Section C of its Application, Mission first described the scope of its proposed project. Mission provided information on its background and its experience operating FSEDs. Further, Mission addressed the benefits of a FSED. Specifically, a FSED is smaller in scale than a hospital-based emergency department so a FSED can be located in a community to bring closer access to emergency services. In addition, FSEDs provide for greater operational efficiency because they are smaller in scale and patients can move through a FSED quicker, as opposed to a hospital-based emergency department like that at Mission Hospital, which is a trauma center and receives high acuity and complex patients. (Tr. Vol. 14, Platt, pp. 2334-36) (Jt. Ex. 1, Mission Application MH 33-36).

Population to be Served

Service Area

- 129. In identifying the population to be served, Mission began by identifying the service area for the proposed project. The 2022 SMFP does not define service areas for FSEDs. In the absence of any requirements for the definition of a FSED service area, Mission defined the service area in its application by ZIP codes in southern Buncombe County and northern Henderson County. The service area was divided into a Primary Service Area ("PSA") and a Secondary Service Area ("SSA"). The Primary Service Area consisted of the following ZIP codes: 28704; 28730; 28732; 28759; 28791; and 28803. The Secondary Service Area was comprised of ZIP codes: 28806; 28792; and 28742. Mission developed the PSA and SSA utilizing several factors, including travel times and demographic trends consisting of population growth and age breakdowns of the population in each ZIP code and the number of patients from each ZIP code that were already utilizing Mission for their emergency services. (Tr. Vol. 14, Platt, pp. 2338-41) (Jt. Ex. 1, Mission Application MH 46-50).
- 130. Regarding the use of travel times in the development of the service area, Mission examined the travel times from each of the ZIP codes in the PSA and SSA to both the proposed FSED and the existing EDs at Mission, AdventHealth and Pardee. Mission also looked to roadways in the service area as well to determine travel times in addition to distance because ZIP codes are not evenly shaped. Further, analyzing proximity based solely on a ZIP code might not provide an adequate picture because parts of one ZIP code might be closer to one existing ED

while another part of the same ZIP code might be closer to the proposed FSED. While utilizing ZIP codes is the easiest method to analyze historical demand for ED services, it is a balance, from a health planning perspective, to determine which ZIP codes contain areas that will have improved access to care and be the most proximate to the FSED. (Tr. Vol. 14, Platt, pp. 2339-40). By establishing a FSED in Arden, Mission will enhance timely geographical access for patients seeking emergency services. (Jt. Ex. 1, Mission Application MH 51). Mission analyzed traffic routes from southern Buncombe County as well as Henderson County and determined that a FSED in Arden would increase access to emergency services. (Jt. Ex. 1, Mission Application MH 51) (Tr. Vol. 14, Platt, p 2349-50).

Service Area Population Trends

- 131. In its application, Mission provided data for population estimates starting in 2022 through 2027 for the proposed FSED County and ZIP code service area. The data shows that Mission's proposed service area is growing and continuing to age. The data was obtained from Claritas Spotlight, which is a demographic data company. The data Claritas provides is routinely accepted for health planning purposes and is typically used in CON applications. (Jt. Ex. 1, Mission Application MH 47-48) (Tr. Vol. 14, Platt, pp. 2343-44).
- 132. Regarding the population growth and age breakdowns, Mission demonstrated heavy growth in the elderly population in the proposed service area. Mission's Application shows that the age 65 and older population was projected to grow by 15% in the PSA and by 12.1% in the SSA between 2022 and 2027. This is significant because individuals 65 and older generally use more healthcare services, including emergency department services, than younger age groups. (Tr. Vol. 14, Platt, pp. 2341-42) (Jt. Ex. 1, Mission Application MH 47-49). In addition, there will be a substantial amount of growth in the service area, from approximately 189,000 residents in 2022 to approximately 195,000 residents in 2027. (Tr. Vol. 14, Platt, pp. 2342-43) (Jt. Ex. 1, Mission Application MH 48).
- 133. The Agency determined that Mission adequately identified the patient origin for the population it proposed to serve and that its assumptions were reasonably and adequately supported based on the historical utilization of emergency services by patients who reside in the proposed service area. (Jt. Ex. 2, Agency File AF 502).
- 134. Ms. Platt's testimony describing and explaining the identification of the proposed Service Area and the designation of the PSA and SSA supports this determination. (Tr. Vol. 14, Platt, pp. 2339-40). The Tribunal finds this testimony to be credible, reliable and persuasive.

Demonstration of Need

135. In Mission's Application, Mission proposed to develop a 12 room FSED in Arden to offer emergency services. (Jt. Ex. 1, Mission Application MH 37-38, 45). Mission stated in its Application that the need for the new FSED was based on significant estimated population growth, including growth in the age 65 and older population, in the service area; the increase in residential and commercial development in the service area; suboptimal access to Mission Hospital's ED to due traffic congestion; increasing ED volume in the service area; Mission's rising ED volume and

the increase in high acuity patients; and capacity constraints at Mission Hospital's ED due to volume, acuity, operational constraints, and bed capacity constraints. (Jt. Ex. 1, Mission Application MH 36-40, MH 45-46) (Tr. Vol. 14, Platt, pp. 2337-38).

Service Area and Service Area Population Trends

136. First, Mission addressed the population that it would serve. This Tribunal has summarized this evidence previously in Findings of Fact 131 – 132 and incorporates it here.

Traffic Congestion

137. The Mission Application provided information to document issues with traffic congestion impacting the proposed service area. There are several interstate highways that run through Buncombe County, which carry high traffic loads. Further, there are several other smaller surface roads that travel through the service area, and which travel into downtown Asheville to the Mission Hospital main campus. The heavy traffic loads on these roads impact access to care for emergency services at Mission Hospital. Therefore, the proposed location for the FSED in Arden will bring emergency department services closer to the community where patients live and prevent Emergency Medical Services ("EMS") and patients from having to drive through congested areas to obtain care at the Mission Hospital ED. (Jt. Ex. 1, Mission Application MH 51-52) (Tr. Vol. 14, Platt, pp. 2347-48).

Development in the Service Area

138. The Mission Application also addressed growth and development in the proposed service area. The Application documented that there is an increase in residential and business development activity in the Southern Buncombe County area. This increase in development will increase traffic counts and congestion, which will lead to delays traveling to downtown Asheville to access emergency care services at Mission Hospital. (Jt. Ex. 1, Mission Application MH 51-52) (Tr. Vol. 14, Platt, pp. 2349-50).

Access to Emergency Services in the Service Area

139. The Mission Application also provided information regarding access to emergency services in the proposed service area. Specifically, Mission is the major tertiary and quaternary medical center and trauma center for Western North Carolina, which leads to Mission treating a level of high acuity services that no other hospital does in the area. The Application showed that the number of patients being transferred or referred to Mission Hospital from other community hospitals, including AdventHealth and Pardee, in 2021, was 6,910 patients. This high volume demonstrates a demand for services for high acuity patients at Mission; that Mission is relied upon by other community hospitals in Western North Carolina for these higher acuity services; and that the proposed FSED is projected to serve somewhat lower acuity patients, would help decant volume from Mission Hospital's ED and provide capacity to Mission Hospital's ED for these high acuity transfers. (Jt. Ex. 1, Mission Application MH 50) (Tr. Vol. 14, Platt, pp. 2351-52).

Mission Hospital ED Operations

- 140. The Mission Application also addressed capacity constraints that Mission Hospital currently faces. (Jt. Ex. 1, Mission Application MH 53-54) (Tr. Vol. 14, Platt, pp. 2352-53). The Mission Application explained how the last redesign of the Hospital ED actually began with project planning in 2012 and took several years to complete. Also, the redesign planning occurred prior to HCA acquiring Mission Hospital so the plans did not incorporate the experience of HCA Healthcare, which is known nationally for its efficiency and operation of emergency departments. Mission further described the functional and operational constraints that slow patient throughput and efficiency of the Mission Main emergency department, including for example problems with inadequate or diminished line of sight from parts of the emergency department to other parts of the emergency department. The Application also addressed the average emergency department visit wait times at Mission's main emergency department, which are higher than the average for similar sized emergency departments by volume in North Carolina. (Jt. Ex. 1, Mission Application MH 53-54).
- FSED from government officials. These letters of support included one from the Buncombe County Manager who is responsible for the Buncombe County EMS service. The County Manager had informed Mission that paramedics encountered problems with transferring patients into the emergency department and the delays due to capacity, which in turn delayed the paramedics from being able to return to the field. The Buncombe County Manager supported the proposed FSED to help alleviate the capacity issues so that the county EMS paramedics could quickly return to calls in the field. There was a similar letter of support from Dr. William Hathaway, the CEO of Mountain Area Health Education Center ("MAHEC"), who expressed support for the project in order to help with capacity issues at Mission's main ED. (Tr. Vol. 13, Smith, pp. 2037-38) (Jt. Ex. 1, Mission Application MH 55, 491, 499-500).
- 142. Mission witness Sondra Smith testified regarding the Mission Hospital ED's operational issues. The design of the ED created inefficiencies which have resulted in patient transfers being denied. The layout of the ED is very inefficient for staff providing care to patients and there is no direct line of sight across the ED which impacts operations. (Tr. Vol. 13, Smith, pp. 2033-34).
- 143. In addition, Mission witness Wyatt Chocklett testified that the Mission Hospital ED was the most challenging ED he has worked at in his career, including his 12 years with HCA. The Mission Hospital ED is divided into seven pods that are geographically dispersed from one another with hallways separating them. The pods function as separate islands within the ED, which limits the ability to scale efficiencies in the form of supply rooms, medications, cross-communication or coverage, and the ability to respond to an emergent event in the ED. (Tr. Vol. 14, Chocklett, p. 2259).
- 144. Mission's expert witness Kathy Platt testified regarding several of the factors impacting capacity constraints at Mission Hospital's ED. Mission described the increasing acuity level of patients needing care and the reliance on Mission Hospital by residents of Buncombe County and the surrounding area for tertiary services. The capacity issues at Mission Hospital

with respect to acute care beds have also impacted the ED at Mission Hospital. There is competition for space in the Mission Hospital ED because patients that are on observation status and patients that are being admitted but need to be held in the ED until an acute care bed is available limit the number of ED beds that are available for new incoming patients at the ED. (Tr. Vol. 14, Platt, pp. 2352-53).

- 145. Mission did not have to demonstrate that it had capacity constraints to be found conforming with Statutory Review Criterion 3. (Tr. Vol. 1, McKillip, p. 116).
- 146. Ms. Platt explained that an applicant for a FSED is not required to demonstrate capacity constraints to support its application. There are no CON standards or criteria that dictate how a CON applicant must demonstrate need for a FSED so the need for the FSED could be justified by the need for increased access or by bringing the service closer to the community. In this case though, Mission did show that there were capacity constraints in the emergency department at Mission Hospital. (Tr. Vol. 14, pp. 2353-54).
- 147. This Tribunal finds the testimony of Ms. Platt to be credible, reliable and persuasive. Mission was not required to demonstrate capacity constraints at its Mission Main Emergency Department in order to demonstrate conformity with Statutory Review Criterion 3.

Projected Utilization

- 148. Mission's Application projected the utilization of the proposed FSED through the first three full fiscal years of operation. The methodology Mission used to make these projections involved four steps. (Jt. Ex. 1, Mission Application MH 63-71)
- 149. In Step 1, Mission established a historical trend in ED volume for the proposed service area as a whole for all providers from 2017-2019. Mission intentionally used the 2017-2019 timeframe in order to eliminate the COVID-19 impact on 2020 data which has skewed volumes for healthcare providers. For each ZIP code in the PSA and SSA, Mission identified the volume of ED visits for 2017, 2018 and 2019. Mission then calculated the compound annual growth rate ("CAGR") for 2017-2019 for each ZIP code. The CAGR for the total service area was 2.6%. Next, Mission calculated a projected utilization for 2021 because at the time of the application preparation, the full year of 2021 market data was not yet available. To calculate the 2021 projected ED volume figure, Mission utilized a 10.6% growth rate and applied it to 2020 market volume. The 10.6% growth rate reflects the average one-year growth in Mission's ED volume from 2020 to 2021. This was done to capture the catch-up from the impacts of COVID on ED utilization. (Jt. Ex. 1, Mission Application MH 64) (Tr. Platt, Vol. 14, pp. 2376-78)
- 150. In Step 2, Mission projected the market ED volume based on the historical trends from Step 1. In this step, Mission first projected that 2022 market ED volume would rebound to pre-COVID levels and projected a service area ED market volume by ZIP codes and a total service area market volume of 64,898. Then, Mission applied the CAGR by ZIP code to project market ED volume for 2023 to 2027. Mission presented the overall market projection in a graph in its application at page MH-66. This chart demonstrated that Mission's methodology accounts for the actual decline in ED visits at the outset of the COVID pandemic while utilizing its market historical

CAGR for ED services. The chart shows the comparison and relative trend lines of historical ED visits, trended visits (non-COVID), and projected visits demonstrating the reasonability and conservative nature of the projections. (Jt. Ex. 1, Mission Application MH 65-66) (Tr. Platt, Vol. 14, pp. 2378-80).

- 151. In step 3, after projecting market volumes, Mission established its baseline 2021 market share by acuity and ZIP code in Step 3. In this step, Mission used 2021 data as the starting point. Mission categorized its ED acuity levels as low or high through the use of six ED Current Procedural Terminology ("CPT") codes. Mission then calculated the number of Mission ED visits in 2021 by high vs. low acuity by ZIP code in the service area. Finally, Mission calculated its 2021 volume as a percentage of the total market by acuity. (Jt. Ex. 1, Mission Application MH 66-67) (Tr. Vol. 14, Platt, pp. 2380-83).
- 152. In the last step, Step 4, Mission projected both the shift and the incremental market share it expected to capture because of its proposed FSED and the increased access it would provide. The incremental market share and the historical market share were then used to project utilization for Mission's ED and the proposed FSED for 2025 2027, which represent the first full three years of operation of the proposed FSED. In order to calculate the projections, Mission first determined its first partial year (2024) and its first full year (2025) market share by acuity and ZIP code. Mission initially needed to calculate a partial year for 2024 because the proposed project was expected to become operational mid-2024. In establishing these figures, Mission made several assumptions. (Jt. Ex. 1, Mission Application MH 67-68) (Tr. Vol. 14, Platt, pp. 2383-84).
- 153. Mission assumed that there would be a greater incremental market share in ZIP codes which were closer to the location of the proposed FSED in Arden and a lower incremental market share in ZIP codes that were closer to either Mission Hospital's ED or other existing hospital EDs. Next, Mission assumed that the incremental market share for the partial 2024 year would be half of the incremental market share experienced in the first full year of operation. Mission then grew the incremental market share for the subsequent years by 0.5% for low acuity patients and 0.1% for high acuity patients. The figures were reflected in the Mission Application on page 68, Figure 23. (Jt. Ex. 1, Mission Application MH 67-68) (Tr. Vol 14, Platt, pp. 2382-2384).
- 154. After Mission determined the incremental market share gains for the ZIP codes in the service area, Mission then projected its ED market share by acuity, Mission Hospital's ED market share volume by acuity, established the projected percent shift of volume to the proposed FSED by acuity, and then projected the FSED volume. In making these projections, Mission utilized the information from the previous steps. The shift in market share represents the number of patients that will use the proposed FSED instead of using the Mission Hospital ED. This figure represents patients that would otherwise have gone to Mission Hospital ED but are projected to now use the proposed FSED instead. The Mission Hospital ED market share and volume and the proposed FSED market share and volume data were all presented in charts in the Mission Application (Jt. Ex. 1, Mission Application MH 69-71) (Tr. Vol 14, Platt, pp. 2385-2391).
- 155. The Agency determined that Mission adequately supported its projected utilization for the following reasons:

- a. The projected utilization was supported by the historical utilization of ED services at the Mission Main Hospital campus by the residents of Mission's proposed service area:
- b. The projected utilization was supported by Mission's historical (2021) ED market share by ZIP code area in the proposed service area; and
- c. The utilization projections were supported by the projected population growth and aging in the proposed service area.

(Jt. Ex. 2, Agency File AF 505).

Access to Medically Underserved

- 156. To be conforming with Criterion 3, the applicant must demonstrate how underserved populations including low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed. (Jt. Ex. 2, Agency File AF 505-06), see also N.C. Gen. Stat. §131E-183(a)(3).
- 157. In its Application, Mission described how it would provide access to the FSED and its services for the following groups: low-income persons; racial and ethnic minorities; women; persons with disabilities; persons 65 and older; Medicare beneficiaries; and Medicaid recipients. Mission also described how its financial policies would apply in order to continue to meet the need of low-income individuals. (Jt. Ex. 1, Mission Application MH 77).
- 158. The Mission Application also provided a table identifying the estimated percentage of total patients from the above groups who would be served at the proposed FSED during the third full fiscal year of operation. A table in the Application included the projected percentage of low-income persons, which includes self-pay and charity care patients; racial and ethnic minorities; women; persons with disabilities; persons 65 and older; Medicare beneficiaries; and Medicaid recipients. (Jt. Ex. 1, Mission Application MH 78).
- 159. The Agency determined that Mission adequately described in its Application the extent to which residents of the service area, including underserved groups, were likely to have access to the proposed services. (Jt. Ex. 2, Agency File AF 506).

Petitioners' Contentions Regarding Review Criterion 3

Service Area

160. Petitioners contended that the population in the service area was declining from 2021 to 2022 and not growing. (Jt. Ex. 116). Ms. Platt rebutted that testimony. She testified that there was not a decline from 2021 to 2022 in the service area. Specifically, Ms. Platt explained that Mission used 2021 data from the U.S. Census Bureau in its previous 2021 application for an FSED in Arden, which was denied by the Agency. However, in 2022, the U.S. Census Bureau updated its data based on the 2020 census, which resulted in a new base with a slightly lower

growth rate. There was no decline in population but just a slower growth rate which resulted in new projections for growth in the market. (Tr. Vol. 14, Platt, pp. 2344-45).

161. Also, the Petitioners presented testimony contending that the rate of growth in the service area was lower than the state. (Tr. Vol. 7, Carter, p. 1138-39) (Jt. Ex. 116). Ms. Platt rebutted this testimony. She testified that overall growth rates between the service area and the state are similar. The Mission Application shows that the PSA is projected to grow at 3.5% and the SSA at 3.0% while the state is projected to grow at 2.7%. (Tr. Vol. 14, Platt, pp. 2345-46) (Jt. Ex. 1, Mission Application, MH 49).

Access

- 162. Petitioners argued that the FSED would not increase access to care in the service area and also argued that Buncombe County and Henderson County were rural counties and thus provided healthcare services to rural populations. Petitioners claimed that the development of the FSED would impact their operations and impede access for their rural populations.
- 163. Ms. Platt rebutted this testimony. Ms. Platt testified that she did not agree with the testimony. Specifically, the proposed FSED is very critical to improving access to care for both residents of Buncombe County and the broader service area, as well as those patients who are being referred to Mission from the surrounding community hospitals. The proposed FSED would bring emergency services closer to a densely populated portion of the proposed service area, which would allow patients to access those services closer to their homes. In addition, increased access would decant volume from Mission Hospital's ED which would allow it to operate more efficiently so that patients, including the high acuity patients, continuing to use the Mission Hospital ED will have reduced wait times and more efficient throughput. (Tr. Vol. 14, Platt, pp. 2350-51)
- 164. Ms. Platt testified that Buncombe County is part of a metropolitan statistical area defined by the U.S. Census Bureau, which also includes Henderson and Haywood Counties. Ms. Platt further testified that for purposes of health planning purposes, Buncombe and Henderson Counties are not considered rural counties. (Tr. Vol. 14, Platt, p. 2346) (Agency Ex. 800).

ACEP Guidelines

- 165. Pardee expert witness Dawn Carter contended that the American College of Emergency Room Physicians ("ACEP") guidelines demonstrated that Mission Hospital has capacity in its ED to meet its current and expected needs and that Mission's ED is underutilized. (Tr. Vol. 6, Carter, p. 1083-88) (Jt. Ex. 116).
- 166. Ms. Platt rebutted this testimony. There is no requirement in North Carolina to use the ACEP guidelines in a FSED CON application and there is no rule or requirement that the Agency consider ACEP guidelines in its review of any FSED application. The ACEP guidelines are merely a starting point and a tool for architects and facility designers for renovation, expansion and development of a new or future ED. The ACEP guidelines were not intended to be a population-based analysis tool to evaluate the need for a certain number of ED bays from a historical or look-back perspective. The guidelines are not designed for health planning in a CON context. (Tr. Vol. 14, Platt, pp. 2355-2359) (Jt. Ex. 160, p. 5) (Jt. Ex. 170).

- 167. In fact, Ms. Carter conceded that there are no regulations or rules that require the use of the ACEP guidelines for a CON application and that the ACEP guidelines are not binding on the Agency. (Tr. Vol. 8, Carter, p. 1372).
- 168. AdventHealth expert witness Karin Sandlin did not offer any opinions regarding the ACEP guidelines. (Tr. Vol. 10, Sandlin, p. 1775).

Capacity Constraints

- Pardee contended that Mission's visits per ED bay do not demonstrate capacity constraints and that Mission has existing capacity. (Tr. Vol. 6, Carter, p. 1055). Ms. Platt rebutted this testimony. Ms. Platt presented a chart, Mission Ex. 644, which shows the visits per ED bay by designated type and use. Ms. Platt created this chart utilizing internal Mission data that was used for the Mission Application. The chart breaks out the 94 ED bays at Mission Hospital by designated type and use: 12 pediatric bays; 22 behavioral health bays; 4 trauma bays; and 56 general use bays. Then the chart listed the ED visits for each designated type and use, which was then used to calculate the visits per bay by designated type and use. This chart reveals several important issues. First, while the visits per bay appear low for the pediatric, behavioral health, and trauma uses, that does not mean that the bays are empty. For instance, those bays could have patients in them while they are being held until an inpatient bed is available. Second, it demonstrates that there are 80,358 patients using the 56 general use ED bays, which results in a visit per bay figure of 1,435. Ms. Platt testified that the visit per bay figure of 1,435 is a very high number especially considering the complexity and acuity level of the patients seeking treatment at the Mission Hospital ED. This demonstrates significant capacity constraints in the Mission ED from a health planning perspective. (Tr. Vol. 15, Platt, pp. 2484-85) (Mission Ex. 644).
- because the Left Without Treatment ("LWOT") figure for Mission was reported as 0%, meaning that patients are not waiting to receive care. Mission rebutted this testimony. First, Ms. Smith explained LWOT as it relates to Mission as the time period from when the patient enters the ED until some sort of triage or treatment occurs. At Mission, there is a best practice to function in a way that intentionally reduces the LWOT figure. That happens because Mission sends providers into the ED waiting room to immediately triage a patient upon arrival to understand what the medical issue is. This initial interaction, triage, begins the treatment. Therefore, it is a very short time from when a patient enters the ED until the patient is triaged so it is rare at Mission that a patient will leave prior to that initial triage because there is little time in between presenting at the ED and an initial triage. (Tr. Vol. 13, Smith, pp. 2034-35).
- 171. This Tribunal finds that Ms. Platt's and Ms. Smith's testimony regarding capacity constraints at Mission Hospital ED was credible, reliable and persuasive.

Ms. Platt's Opinions

172. Ms. Platt opined that the Agency was correct in finding that the Mission Application was conforming to Criterion 3 because the Agency conducted the review in the

manner in which it typically conducts a FSED CON application review, considered the same factors, and concluded that Mission reasonably projected information in its Application. Further, Mission provided information and data in its application to demonstrate that it met all aspects of Criterion 3. (Tr. Vol. 15, Platt, p. 2403) (Jt. Ex. 160, pp. 4-6).

173. This Tribunal finds Ms. Platt's testimony and opinions regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 3 to be credible, reliable and persuasive.

- 174. Criterion 4 applied to the Mission Application. Following its review, the Agency found Mission's Application conforming to Statutory Review Criterion 4. (Jt. Ex. 2, Agency File AF 507).
- 175. Statutory Review Criterion 4 requires that the applicant demonstrate that where alternative methods of meeting the needs for the proposed service project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed. (Jt. Ex. 2, Agency File AF 506; *see also* N.C. Gen. Stat. §131E-183(a)(4)) (Tr. Vol. 15, Platt, p. 2407).
- 176. In its application, Mission demonstrated that it considered alternative methods for meeting the needs for the proposed project. Those alternatives included maintaining the status quo, expanding emergency department capacity at Mission Hospital, developing an FSED at an existing Mission-owned facility, and developing an FSED elsewhere. (Jt. Ex. 1, Mission Application MH 86-87) (Tr. Vol. 15, Platt, p. 2407).
- 177. Mission determined that maintaining the status quo was not an effective alternative due to both residential and commercial population growth as well as the increase in tourism in Western North Carolina, which could result in delays for access to emergency services for residents of south Buncombe and north Henderson County residents. (Jt. Ex. 1, Mission Application MH 86) (Tr. Vol. 15, Platt, p. 2407-08).
- 178. Mission determined that expanding emergency department capacity at Mission Hospital was not an effective alternative because capacity issues are not the only factor. The expansion would not address traffic, timely access, and the provision of emergency services in an area closer to where patients reside, specifically, southern Buncombe and northern Henderson County. (Jt. Ex. 1, Mission Application MH 86-87) (Tr. Vol. 15, Platt, p. 2408-09).
- 179. Mission determined that developing a FSED at an existing Mission-owned facility in the area, the Mission Pardee Health Campus, would not be an effective alternative because of a legal agreement between Mission and Pardee that prohibits Mission from developing a FSED at that location and the Mission section of the property in Buncombe County does not provide a suitable site for the project. (Jt. Ex. 1, Mission Application MH 87) (Tr. Vol. 15, Platt, p. 2409).
- 180. Mission determined that developing a FSED at an area other than Arden would not be an effective alternative because of the lack of access to emergency services, traffic issues, travel times to ED services, and rapid population growth in southern Buncombe County make developing

services in Arden a high priority. (Jt. Ex. 1, Mission Application MH 87) (Tr. Vol. 15, Platt, p. 2409).

- 181. The Agency determined that Mission adequately demonstrated that the proposed project to develop a FSED in Arden was the most effective alternative to meet the need identified in Mission's Application. (Jt. Ex. 2, Agency File AF 507).
- 182. The Agency reviewed the application, the exhibits to the application, the written comments, the remarks made in lieu of the public hearing, and the responses to comments before determining that Mission's Application was conforming to Statutory Review Criterion 4. (Jt. Ex. 2, Agency File AF 507).
- 183. AdventHealth contended that the Agency erred in determining that the Mission Application was conforming to Statutory Review Criterion 4 on the basis that Mission's proposed project was not the most effective alternative. Ms. Sandlin testified that her opinion alleging nonconformance with Criterion 4 was based on the same facts as her opinion on Criterion 3 in that the project is not needed and is thus not the most effective alternative (Tr. Vol. 10, Sandlin, pp. 1773-74).
- 184. Pardee contended that the Agency erred in determining that the Mission Application was conforming to Statutory Review Criterion 4 on the basis that it should have been found nonconforming to Statutory Review Criterion 3 and because of that could not be conforming to Statutory Review Criterion 4 as well. (Tr. Vol. 7, Carter, pp. 1252-53).
- 185. Ms. Carter also testified that the proposed location of the FSED in Arden was not the most effective alternative because relative to drive time, there would be only two ZIP codes in the service area that would be closer to the proposed FSED than other existing emergency departments so the remainder of the ZIP codes in the service area would have to drive a farther distance to the proposed FSED. (Tr. Vol. 7, Carter, p. 1253).
- 186. Pardee also contended that developing an urgent care center ("UCC") was a more appropriate alternative for Mission than developing a FSED.
- 187. Mission addressed the issue of an UCC being an alternative to the proposed FSED. Specifically, a UCC is not equivalent to a FSED and the Agency does not consider a UCC to be an alternative to a FSED. Notably, the Agency has approved 16 FSEDs in other areas of the State. UCCs are generally a walk-in physician office with extended hours but are not open 24 hours a day. A FSED is open 24 hours a day. In addition, a FSED is capable of treating, and does treat, a higher acuity level patient than a UCC. (Tr. Vol. 15, Platt, pp. 2410-11; Tr. Vol. 13, Smith, pp. 2024-25; Tr. Vol. 14, Smith, 2219-20) (Jt. Ex. 160, p. 5) (Jt. Ex. 161 (Ex. 9)).
- 188. Ms. Platt testified that Mission provided the documentation of the alternatives that were considered and discussed each one and documented that the FSED project proposed in the Mission Application was the best alternative in terms of meeting the patient's needs and most cost-effective. (Tr. Vol. 15, Platt, p. 2411).

- 189. Ms. Platt opined that the Mission Application was conforming to Statutory Review Criterion 4. (Tr. Vol. 15, Platt, p. 2411) (Jt. Ex. 160, p. 6).
- 190. This Tribunal finds that Ms. Platt's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 4 to be credible, reliable and persuasive.

AGENCY REVIEW OF STATUTORY REVIEW CRITERION 5

- 191. Criterion 5 applied to the Mission Application. The Agency found Mission's Application conforming to Statutory Review Criterion 5. (Jt. Ex. 2, Agency File AF 511) (Tr. Vol. 15, Platt, p. 2412).
- 192. Statutory Review Criterion 5 requires that the Agency determine that financial and operational projections for the project demonstrate the availability of funds for capital and operational needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the applicant. (Jt. Ex. 2, Agency File AF 508; *see also* N.C. Gen. Stat. §131E-183(a)(5)) (Tr. Vol. 15, Platt, pp. 2411-12).
- 193. The Agency made its determination that Mission's Application was conforming to Statutory Review Criterion 5 because Mission adequately demonstrated:
 - a. The capital costs proposed by Mission are based on reasonable and adequately supported assumptions for all the reasons listed in Mission's Application;
 - b. Mission adequately demonstrated the availability of sufficient funds for the capital needs of the proposal; and
 - c. Mission adequately demonstrated sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses based on the information contained in Mission's Application.

(Jt. Ex. 2, Agency File AF 511).

- 194. The Agency incorporated by reference its discussion found in Criterion 3 regarding projected utilization. (Jt. Ex. 2, Agency File AF 503-505, 510).
- 195. The Agency reviewed the application, the exhibits to the application, the written comments, the remarks made in lieu of the public hearing, and the responses to comments before determining that Mission's Application was conforming to Statutory Review Criterion 5. (Jt. Ex. 2, Agency File AF 510-11).
- 196. AdventHealth alleged that the Mission Application was not conforming to Statutory Review Criterion 5 because the application failed to demonstrate that Mission's volume projections were reasonable. Ms. Sandlin opined that the Mission Application was non-conforming to Statutory Review Criterion 5 because the application did not demonstrate that its volume projections were based on reasonable and adequately supported assumptions. She testified that

volume projections inform the costs and revenues for a project so the projections of costs and revenues would be unsupported and therefore should result in a finding of nonconformity. (Tr. Vol. 10, Sandlin, p. 1774).

- 197. Pardee alleged that the Agency should have found the Mission Application non-conforming to Statutory Review Criterion 5 because the projected utilization of the FSED as described in Criterion 3 was not based on reasonable and adequately supported assumptions. Pardee and Ms. Carter contend that the Mission Application should therefore be nonconforming to Criterion 5 because financial feasibility is predicated on the projected utilization. (Tr. Vol. 7, Carter, pp. 1255-56).
- 198. Mission provided the Agency with the proposed cost of the project, a funding letter showing that funds would be made available for the project, and documents showing the project's financial feasibility, including financial statements. (Tr. Vol. 15, Platt, p. 2412).
- 199. This Tribunal has previously summarized in detail findings of fact regarding the projected utilization of the project in the section addressing Criterion 3. The reasonableness of the projected utilization as previously set out under Criterion 3 supports the financial feasibility of the proposed project. (Tr. Vol. 15, Platt, p. 2413).
- 200. Mission provided all the required documentation and demonstrated with the financial projections that the project would be financially feasible. (Tr. Vol. 15, Platt, p. 2414).
- 201. Ms. Platt testified that she agreed with the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 5. (Tr. Vol. 15, Platt, p. 2414) (Jt. Ex. 160, p. 6).
- 202. This Tribunal finds Ms. Platt's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 5 to be credible, reliable and persuasive.

- 203. Criterion 6 applied to the Mission Application. Statutory Review Criterion 6 requires that an applicant demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. (Jt. Ex. 2, Agency File AF 511; *see also* N.C. Gen. Stat. § 131E-183(a)(6)) (Tr. Vol. 15, Platt, p. 2414) (Tr. Vol. 10, Sandlin, p. 1616).
- 204. Statutory Review Criterion 6 requires the applicant to identify the other providers who provide the same services in the proposed service area. (Tr. Vol. 2, McKillip, p. 225).
- 205. After identifying the other providers in the service area, the applicant must then explain why the proposed project will not be an unnecessary duplication of services. (Tr. Vol. 2, McKillip, p. 225) (Tr. Vol. 15, Platt, p. 2415).

- 206. The Agency, when reviewing an application, decides if the information provided by the applicant demonstrates that the proposed project will result in an unnecessary duplication of existing or approved services. (Tr. Vol. 2, McKillip, pp. 225-26).
- 207. Regarding Statutory Review Criterion 6, Ms. Pittman testified, "You just have to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities." (Tr. Vol. 5, Pittman, p. 895).
- 208. Statutory Review Criterion 6 does not require that the Agency look at how other providers currently providing the same services will be impacted by the proposed service. (Tr. Vol. 5, Pittman, p. 867).
- 209. In evaluating Mission's CON application under Statutory Review Criterion 6, it was not necessary for the Agency to conduct a capacity evaluation of either Pardee or AdventHealth because it is not relevant to the Agency's evaluation of Criterion 6. (Tr. Vol. 1, McKillip, p. 138).
- 210. When reviewing the Mission Application under Statutory Review Criterion 6, the Agency reviewed both the written comments of Petitioners in opposition to the Mission Application and Mission's response to those comments regarding drive times and access to emergency departments. (Tr. Vol. 1., McKillip, p. 140).
- 211. Section G of the Mission Application relates to its conformity with Statutory Review Criterion 6. (Tr. Vol. 15, Platt, p. 2414) (Jt. Ex. 1, Mission Application MH-97-98).
- 212. Section G of the Mission Application states, "The proposed FSER will provide more timely access to critical care services in the South Buncombe County market and to patients in North Henderson County." (Jt. Ex. 1, Mission Application MH-97).
- 213. Section G of the Mission Application identifies the existing providers in the proposed service area that provide the same service components proposed in the Mission Application as: Pardee, AdventHealth, and Mission Main Hospital. (Jt. Ex. 1, Mission Application MH-97) (Tr. Vol. 15, Platt, pp. 2414-15).
- 214. The Agency reviewed and applied Statutory Review Criterion 6 to the Mission Application. Following its review, the Agency found Mission's Application to be conforming to Statutory Review Criterion 6. (Jt. Ex. 2, Agency File AF 512) (Tr. Vol. 15, Platt, pp. 2427-28) (Tr. Vol. 1, McKillip, pp. 130-31).
- 215. The Agency determined that Mission's Application was conforming to Statutory Review Criterion 6 because it adequately demonstrated that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on:
 - a. The fact there are no other FSEDs in the proposed service area; and
 - b. Mission adequately demonstrated that the proposed FSED is needed in addition to the existing or approved providers of emergency services in the service area.

(Jt. Ex. 2, Agency File AF 512).

- 216. AdventHealth argued that the Agency erred in determining that the Mission Application was conforming to Statutory Review Criterion 6 because the proposed service would unnecessarily duplicate existing services. Ms. Sandlin opined that Mission's Application was non-conforming to Statutory Review Criterion 6 because the proposed project is an unnecessary duplication of already existing services. (Tr. Vol. 10, Sandlin, p. 1636) (Jt. Ex. 144).
- 217. Ms. Sandlin was questioned several times regarding her assertion that either Mission or the Agency were required to perform an analysis of the impact of Mission's proposed FSED on other providers in terms of lost patients, market share or revenues. (Tr. Vol. 10, Sandlin, pp. 1761-62). Ms. Sandlin did not affirmatively state that the statute required that analysis. *Id.* Ms. Sandlin only stated, "The Agency was responsible for applying Criterion 6 and 18a in this review." *Id.*
- 218. Pardee argued that the Agency erred in determining that the Mission Application was conforming to Statutory Review Criterion 6 because the project will result in unnecessary duplication of services. (Jt. Ex. 116). Ms. Carter opined regarding Statutory Review Criterion 6: "And in my opinion, the statute is very clear that that is the purpose of Criterion 6 to evaluate unnecessary duplication of the existing facilities and providers." (Tr. Vol. 7, Carter, p. 1258). Ms. Carter further stated the Agency did not conduct an analysis regarding unnecessary duplication under Statutory Review Criterion 6. (*Id.* at p. 1259).
- 219. The key determination in the analysis of unnecessary duplication under Criterion 6 is whether the proposed service is unnecessary. (Tr. Vol. 15, Platt, p. 2415).
- 220. Ms. Platt opined that the Agency's application form is specific and that it asks the applicant to identify the existing and approved providers that are either in the service area or near the proposed service area. (Tr. Vol. 15, Platt, p. 2414-15).
- 221. Mission provided in its application a narrative describing why the proposed Arden FSED was not unnecessarily duplicative of existing and approved providers related to capacity constraints at the Mission Hospital main emergency department in downtown Asheville, population growth in the area that will increase demand for emergency department services, and existing demand for the services. (Tr. Vol. 15, Platt, pp. 2415-16, 2427).
- 222. Mission, through its expert Ms. Platt, demonstrated that the Agency reviewed the Mission Application in the same manner it has reviewed prior applications when evaluating Criterion 6. (Tr. Vol. 15, Platt, pp. 2418-21) (Jt. Ex. 140, 141). The Atrium Health Ballantyne ED Agency Findings ("Ballantyne Findings") were issued on October 22, 2021, in which the Agency approved the Ballantyne FSED project. In the Ballantyne Findings, the Agency's analysis of Criterion 6 consisted of the identification of the service area, identification of the existing and approved providers of the same service in the service area, and a summary of the narrative the applicant provided addressing why there is no unnecessary duplication of services. The analysis by the Agency of the Mission Application was consistent with the Agency's analysis in the

Ballantyne Findings. In both the Ballantyne and Concord Agency Findings, the Agency reviewed the providers in or around the service area, summarized the narratives provided by the applicants, and reached a similar conclusion regarding conformity. (Tr. Vol. 15, pp. 2418-19) (Jt. Ex. 140, pp. 22-24) (Jt. Ex. 2, Agency File AF 511-12).

- 223. Similarly, the Atrium Health Concord ED Agency Findings ("Concord Findings") were issued on April 21, 2022 and approved a FSED. In analyzing Criterion 6, the Concord Findings show that the Agency identified the service area defined by the applicant, identified the existing and approved providers of the same service in the service area, and quoted the narrative explanation provided by the applicant of why the project was not unnecessarily duplicative. Again, the analysis and approach used for Criterion 6 in the Mission Application was consistent with the approach and analysis by the Agency in the Concord Findings. (Tr. Vol. 15, pp. 2419-21) (Jt. Ex. 141, pp. 15-16) (Jt. Ex. 2, AF 511-12).
- 224. Further, Statutory Review Criterion 6 does not require that an applicant perform any adverse impact assessment or analysis of a proposed project's impact on other providers. (Tr. Vol. 15, Platt, p. 2415). Ms. Platt, Ms. Pittman, and Mr. McKillip all affirmatively testified that Statutory Review Criterion 6 does not require that an applicant demonstrate the impact the proposed services in its application will have on existing providers. (Tr. Vol. 15, Platt, p. 2415) (Tr. Vol. 1, McKillip, p. 138) (Tr. Vol. 5, Pittman, p. 867).
- 225. Ms. Platt agreed with the Agency and opined that the Mission Application was conforming to Statutory Review Criterion 6. (Tr. Vol. 15, Platt, p. 2428) (Jt. Ex. 160, p. 6).
- 226. The Tribunal finds that the testimony of Ms. Pittman, Mr. McKillip and Ms. Platt regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 6 was credible, reliable and persuasive.
- 227. This Tribunal finds that the Agency's application of Statutory Review Criterion 6 was reasonable and adequately supported. Statutory Review Criterion 6 does not require that an applicant perform any adverse impact assessment or analysis of a proposed project's impact on other providers.

- 228. Criterion 7 applied to the Mission Application. Following a review of the Mission Application, the Agency found Mission's Application conforming to Statutory Review Criterion 7. (Jt. Ex. 2, Agency File AF 513) (Tr. Vol. 15, Platt, p. 2428).
- 229. Statutory Review Criterion 7 requires that the applicant show evidence of the availability of resources, including health manpower and management personnel, for the services proposed to be provided. (Jt. Ex. 2, Agency File AF 513; *see also* N.C. Gen. Stat. §131E-183(a)(7)) (Tr. Vol. 15, Platt, p. 2428).
- 230. Mission provided information in its application demonstrating the proposed staffing arrangements for the Arden FSED, a discussion of how Mission intended to recruit staff,

and the resources for the recruitment of staff. Mission also discussed a training proposal for the new staff. (Tr. Vol. 15, Platt, pp. 2428-29).

- 231. The Agency reviewed the application, the exhibits to the application, the written comments, the remarks made in lieu of the public hearing, and the responses to comments before determining that Mission's Application was conforming to Statutory Review Criterion 7. (Jt. Ex. 2, Agency File AF 513-14; Jt. Ex. 1, Mission Application MH 401-47).
- 232. The Agency determined that Mission's Application was conforming to Statutory Review Criterion 7 because the application adequately demonstrated the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provide in the application as well as the exhibits to the application. (Jt. Ex. 2, Agency File AF 513-14).
- 233. Neither AdventHealth nor Pardee presented any testimony contending that the Agency erred in determining Mission's Application was conforming to Statutory Review Criterion 7. However, there was evidence presented regarding criticisms of Mission with respect to allegations of nursing shortage and union complaints.
- 234. Mission addressed the criticisms regarding its nursing shortage and complaints from former staff members. Ms. Platt testified that there are staffing shortages that affect the healthcare industry nationwide which have been exacerbated by the COVID pandemic. Mission and HCA have implemented multiple strategies to address staffing shortages, including participating in and developing clinician training programs. (Tr. Vol. 15, Platt, pp. 2429).
- 235. Ms. Platt opined that the Agency properly determined that the Mission Application was conforming to Statutory Review Criterion 7. (Tr. Vol. 15, pp. 2429-30) (Jt. Ex. 160, p. 6).
- 236. This Tribunal finds Ms. Platt's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 7 to be credible, reliable, and persuasive.

- 237. Criterion 8 applied to the Mission Application. Following a review of the Mission Application, the Agency found Mission's Application conforming to Statutory Review Criterion 8. (Jt. Ex. 2, Agency File AF 514) (Tr. Vol. 15, Platt, p. 2430).
- 238. Statutory Review Criterion 8 requires that the applicant demonstrate that the provider of the proposed services will make available or otherwise make arrangements for the provision of necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system. (Jt. Ex. 2, Agency File AF 514; *see also* N.C. Gen. Stat. §131E-183(a)(8)) (Tr. Vol. 15, Platt, p. 2430).
- 239. The Agency reviewed the application, the exhibits to the application, the written comments, the remarks made in lieu of the public hearing, and the responses to comments before

determining that Mission's Application was conforming to Statutory Review Criterion 8. (Jt. Ex. 2, Agency File AF 514).

- 240. The Agency determined that Mission's Application was conforming to Statutory Review Criterion 8 because the application adequately demonstrated that the necessary ancillary and support services will be made available. (Jt. Ex. 2, Agency File AF 514).
- 241. Neither AdventHealth nor Pardee presented any evidence contending that the Agency erred in determining that Mission's Application was conforming to Statutory Review Criterion 8.
- 242. Ms. Platt testified that Mission provided all required information in its Application and documented that it would have all required ancillary and support services and would coordinate those services with its existing healthcare delivery system. (Tr. Vol. 15, Platt, pp. 2430-31).
- 243. Ms. Platt opined that the Agency properly found that the Mission Application was conforming to Criterion 8. (Tr. Vol. 15, Platt, pp. 2430-31) (Jt. Ex. 160, p. 7).
- 244. This Tribunal finds Ms. Platt's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 8 to be credible, reliable, and persuasive.

- 245. Criterion 12 applied to the Mission Application. The Agency found Mission's Application conforming to Statutory Review Criterion 12. (Jt. Ex. 2, Agency File AF 515) (Tr. Vol. 15, Platt, p. 2431).
- 246. Statutory Review Criterion 12 requires that the applicant demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increases the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health service by other persons, and that applicable energy saving features have been incorporated into the construction plans. (Jt. Ex. 2, Agency File AF 515; *see also* N.C. Gen. Stat. § 131E-183(a)(12)) (Tr. Vol. 15, Platt, p. 2431).
- 247. The Agency reviewed the application, the exhibits to the application, the written comments, the remarks made in lieu of the public hearing, and the responses to comments before determining that Mission's Application was conforming to Statutory Review Criterion 12. (Jt. Ex. 2, Agency File AF 516; Jt. Ex. 1, Mission Application MH 449-64).
- 248. The Agency determined that the Mission Application adequately identified any applicable energy saving features that will be incorporated into the construction plans in its application. (Jt. Ex. 2, Agency File AF 516).

- 249. Neither Pardee nor AdventHealth presented any testimony contending that the Agency erred in determining that Mission's Application was conforming to Statutory Review Criterion 12.
- 250. Ms. Platt opined "that Mission again provided all of the required documentation in terms of information about the specific design and construction of the proposed freestanding ED and documented that the cost and design were reasonable and cost-effective." (Tr. Vol. 15, Platt, p. 2431) (Jt. Ex. 161, p. 7).
- 251. This Tribunal finds Ms. Platt's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 12 to be credible, reliable, and persuasive.

- 252. Criterion 13 applied to the Mission Application. The Agency found Mission's Application conforming with Statutory Review Criterion 13 and its subparts (a-d). (Jt. Ex. 2, Agency File AF 518-20).
- 253. Statutory Review Criterion 13 requires that the applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and medically underserved groups. (Jt. Ex. 2, Agency File AF 516; *see also* N.C. Gen. Stat. §131E-183(a)(13)).
- 254. The Agency reviewed the application, the exhibits to the application, the written comments, the remarks made in lieu of the public hearing, and the responses to comments before determining that Mission's Application was conforming to Statutory Review Criterion 13(a-d). (Jt. Ex. 2, Agency File AF 518-20; Jt. Ex. 1, Mission Application MH 465-73).
- 255. AdventHealth argued that the Agency erred in finding Mission's Application conforming to Criterion 13. Ms. Sandlin stated that her opinion was based on the same facts as her opinion regarding Criterion 3 and that "the internal basis for approval for the project and the representations made in the executive management review regarding payor mix, which project a much higher payor mix of managed care and a lower payor mix of what the CON Section considers as medically underserved. Based on those inconsistencies, there should be a finding of nonconformity." (Tr. Vol. 10, Sandlin, p. 1775).
- 256. Pardee did not present any evidence contending that the Agency erred in determining Mission's Application was conforming to Statutory Review Criterion 13.
- 257. Statutory Review Criterion 13 requires that an applicant demonstrate that if it is an existing provider, it is accessible to all populations including those traditionally underserved. (Tr. Vol. 15, Platt, p. 2432).
- 258. In its Application, Mission provided all the required information in terms of its historical services to all populations including underserved populations which included, for example, Medicaid, low income, and all races and ethnicities. Further, that information was then

projected in the Mission Application for the FSED to document how Mission would ensure that the FSED would be accessible to all populations. (Tr. Vol. 15, Platt, p. 2432).

- 259. This Tribunal has previously summarized in detail its findings of fact regarding access to the medically underserved in the section addressing Criterion 3 and incorporates them here.
- 260. Ms. Platt opined that the Mission Application was conforming to Statutory Review Criterion 13. (Tr. Vol. 15, Platt, p. 2432) (Jt. Ex. 160, p. 7).
- 261. This Tribunal finds Ms. Platt's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 13 to be credible, reliable, and persuasive.

- 262. Criterion 14 was applicable to the Mission Application. The Agency found Mission's Application conforming with Statutory Review Criterion 14. (Jt. Ex. 2, Agency File AF 520-21) (Tr. Vol. 15, Platt, p. 2433).
- 263. Statutory Review Criterion 14 requires that the applicant demonstrate that the proposed health services will accommodate the clinical needs of health professional training programs in the area. (Jt. Ex. 2, Agency File AF 520; *see also* N.C. Gen. Stat. §131E-183(a)(14)) (Tr. Vol. 15, Platt, p. 2433).
- 264. The Agency found the Mission Application conforming based on the information provided in Mission's Application in section M. The Agency determined that Mission adequately demonstrated that health professional training programs in the area will have access to the facility for training purposes. (Jt. Ex. 2, Agency File AF 520).
- 265. The Agency reviewed the application, the exhibits to the application, the written comments, the remarks made in lieu of the public hearing, and the responses to comments before determining that Mission's Application was conforming to Statutory Review Criterion 14. (Jt. Ex. 2, Agency File AF 520-21; Jt. Ex. 1, Mission Application MH 474-82).
- 266. Neither AdventHealth nor Pardee presented any testimony contending that the Agency erred in determining that Mission's Application was conforming to Statutory Review Criterion 14. (Tr. Vol. 15, Platt, pp. 2433-34)
- 267. Mission in its application provided narrative documentation and a table that showed its extensive relationships with medical school training programs and described its other involvement with other clinical health training programs such as therapy services, social work, mental health counseling, psychology, and nursing. (Tr. Vol. 15, Platt, p. 2433).

- 268. Ms. Platt opined that Mission provided all the necessary information for the Agency to find the Mission Application conforming with Statutory Review Criterion 14. (Tr. Vol. 15, Platt, p. 2434) (Jt. Ex. 160, p. 7).
- 269. This Tribunal finds Ms. Platt's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 14 to be credible, reliable, and persuasive.

- 270. Criterion 18a was applicable to the Mission Application. Statutory Review Criterion 18a requires that the applicant 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. (Jt. Ex. 2, Agency File AF 521; see also N.C. Gen. Stat. §131E-183(a)(18a)).
- 271. The impact the proposed services will have on other providers is not something that is relevant to the evaluation of Criterion 18a and the Agency is not required to perform any analysis of the alleged harm to the applicant's existing competitors when evaluating a CON application under Review Criterion 18a. (Jt. Ex. 178 McKillip Deposition Testimony, p. 123) (Tr. Vol. 1, McKillip, pp 143-44).
- 272. The applicant needs to demonstrate what the applicant expects the effect of its proposed project will be on competition. (Tr. Vol. 1, McKillip, p. 144).
- 273. There is nothing in Criterion 18a that mentions market share. (Tr. Vol. 2, McKillip, p. 203).
- 274. The Agency did not analyze the impact of Mission's proposed FSED on nearby competitors when evaluating the Mission Application under Review Criterion 18a, "(b)ecause competitors are not part of the analysis under Criterion 18a. It's competition, and in particular, how any enhanced competition will have a positive impact on cost-effectiveness, quality and access." (Tr. Vol. 2, McKillip, p. 224).
- 275. The information requested by the Agency for Criterion 18a in a CON application is related to the applicant and does not include information about other competitors. (Tr. Vol. 2, McKillip, p. 225).
- 276. Ms. Pittman testified that Statutory Review Criterion 18a does not mention "competitors" but instead mentions "competition." (Tr. Vol. 5, Pittman, p. 895). "[T]he applicant has to address 18a, which is about competition. That's whether it's going to be a positive or negative effect on competition. That doesn't say you have to have an in-depth analysis of all the competitors. That's not what we generally do. We look at what the applicant provides and whether they are primarily going to continue to serve -- post continue to serve patients that have been

coming to them or whether it's a new service in the area -- in the service area for which they've never had patients. You have to take all of that into account." (Tr. Vol. 5, Pittman, p. 932).

- 277. In evaluating Criteria 18a, the Agency examines the big picture without going into detail on the specific competitors. (Tr. Vol. 5, Pittman, p. 932).
- 278. The Agency found Mission's Application conforming to Statutory Review Criterion 18a. (Jt. Ex. 2, Agency File AF 523) (Tr. Vol. 1, McKillip, p. 141).
- 279. In determining whether Mission's Application was conforming to Statutory Review Criterion 18a, the Agency reviewed the application, exhibits to the application, the written comments submitted by Petitioners in opposition to the application, written comments submitted by members of the public in lieu of an in-person public hearing, and Mission's responses to comments. (Jt. Ex. 2, Agency File AF 523; Jt. Ex 1, Mission Application MH 483-505).
- 280. Based on its review the Agency determined that Mission adequately demonstrated in its application the expected effects of the proposed services on competition in the service area and adequately demonstrated that the proposal will have a positive impact on cost-effectiveness, quality, and access to services because:
 - a. The proposal is cost effective because Mission has demonstrated that there is a need for the services proposed, the proposal will not result in the unnecessary duplication of services, and the projected revenues and operating costs are reasonable;
 - b. Mission demonstrated that quality care would be provided; and
 - c. Medically underserved groups will have access to the proposed services based on Mission's representations about access by medically underserved groups and the projected payor mix.

(Jt. Ex. 2, Agency File AF 522-23).

- 281. The Mission Application stated that the proposed FSED in Arden, "will enhance competition in the area because it will promote increased access to emergency services, enhance quality of emergency services, and promote efficiency, which is an important contributor to cost effectiveness. The proposed project will expand Mission's capacity to provide emergency services to area residents who choose Mission Hospital as their provider of care, ensuring access to personal medical records, supporting ease of follow up treatments and ultimately enhancing continuity of care." (Jt. Ex. 1, Mission Application MH 120).
- 282. The Mission Application provided that it will have a positive impact on cost effectiveness, quality of care, and access by medically underserved groups to the proposed services. *Id.*
- 283. Regarding the impact Mission's proposed FSED will have on cost effectiveness, the Mission Application stated that "By expanding its emergency services to Arden, Mission will extend access to leading edge, 24/7 emergency care in a setting that is closer to homes and businesses in the service area. The proposed location of the FSER will reduce travel time

significantly for residents in the service area and will reduce travel on congested highways fraught with continual construction. The project will also improve efficiency of EMS by providing a closer location for ambulances to offload patients and quickly return to their home-base station." *Id.*

- 284. The Mission Application further stated, "In addition, area residents and employers will realize the added efficiencies of a satellite emergency department, such as reduced wait times for emergency care, faster treatment, and faster turnaround time-all factors that contribute to cost effectiveness by reducing time away from work and home." *Id.*
- 285. Regarding the impact Mission's proposed FSED will have on quality of care, the Mission Application provided that the proposed FSED will adopt the same high-quality standards and quality of care that Mission Hospital currently provides and will provide services according to the licensure and certification standards of the state. (Jt. Ex. 1, Mission Application MH 121).
- 286. The Mission Application also provided an overview of Mission's quality performance, its accreditation by various healthcare accrediting organizations, and various recognitions Mission has received for outstanding performance by organizations according to clinical metrics. The application included a list of all the other affiliated healthcare facilities operated by or affiliated with Mission Hospital that the Agency then reviews in terms of licensure history to ensure that they are all in compliance with licensure and quality standards. (Tr. Vol. 15, Platt, p. 2436).
- 287. Regarding the impact Mission's proposed FSED will have on access to services by the medically underserved, the Mission Application stated that Mission does not turn patients away when they require emergency care regardless of the patient's ability to pay and will not do so at the proposed FSED. Further, the FSED in Arden will be designed to ensure timely access to high quality care and ensure accessibility for elderly patients, handicapped persons, and those with disabilities. (Jt. Ex. 1, Mission Application MH 121).
- 288. Both Pardee and AdventHealth allege that the Agency failed to properly apply Statutory Review Criterion 18a to the Mission Application.
- 289. AdventHealth argued that the Agency erred in finding the Mission Application conforming to Statutory Review Criterion 18a because the Agency failed to conduct any analysis of the impact the proposed project would have on competition. (Tr. Vol. 10, Sandlin, pp. 1624-25) (Jt. Ex. 144).
- 290. AdventHealth's expert Ms. Sandlin testified that, "The agency, in the 2022 review, merely copy and pasted the narrative from the application into the findings, despite information submitted by AdventHealth in the written comments specifically addressing concerns of quality, of cost, of excessive -- excessive cost with respect to the cost of healthcare, concerns about access. And as we know from the letter submitted by the Attorney General, there are real concerns from members of the community that Mission is serving, including in the ZIP codes identified in the freestanding ED applications, that there are real concerns regarding the quality of care administered by Mission, regarding the cost of healthcare, regarding the negative impacts of the market dominance that Mission has, regarding its ability to influence cost and increase the cost of

healthcare in Buncombe County and surrounding communities, and with respect to access. And the agency performed no analysis." (Tr. Vol. 10, Sandlin, p. 1625).

- 291. Pardee also argued that the Agency erred in finding the Mission Application conforming to Statutory Review Criterion 18a because the Agency failed to analyze competition under Criterion 18a. (Jt. Ex. 116).
- 292. Pardee's expert Ms. Carter testified that the Agency erred when it failed to consider competitors under Statutory Review Criterion 18a. (Carter Vol. 7, pp. 1223-24). "In my opinion, they did not analyze competition under Criterion 18a." (*Id.* at p. 1260). Ms. Carter contended that the Agency failed to evaluate competition in the service area. (*Id.*).
- 293. Ms. Carter further argued that the Agency erred by not considering Mission's market dominance when it evaluated Statutory Review Criterion 18a. (*Id.* at 1224).
- 294. Ms. Carter stated, "If you have a dominant provider, as I believe you do in this market that is proposing to develop a service or a new location as an outpost that will essentially give them an opportunity to expand their reach, expand their dominance, then that is particularly with a service that's kind of a front door to the system, which an emergency department often is, point of access for the patients." (*Id.* at p. 1225).
- 295. However, Ms. Carter conceded that a provider can see its volumes increase while seeing its market share decrease. (*Id.* at p. 1344).
- 296. In rebuttal Mission presented evidence that the Agency did not err when analyzing whether Mission's Application conformed to Statutory Review Criterion 18a. Mission contended that the Agency did not err because:
 - a. The Agency applied Statutory Review Criterion 18a in this case the same way it has in reviews of other CON applications;
 - b. The Agency is not required to perform any analysis of harm to or impact on existing providers or competitors of the applicant; and
 - c. The information in the Mission Application regarding the impact the proposed FSED in Arden would have on competition was reasonable.
- 297. Further, in reviewing the Mission Application for conformity with Statutory Review Criterion 18a, the Agency referenced that Mission identified the proposed service area and identified three existing providers of emergency services. The Agency reviewed and quoted Mission's language related to enhancing competition and referenced Mission's discussion about providing cost-effective and quality services to medically underserved groups. (Tr. Vol. 15, Platt, pp. 2438-39).
- 298. Mission's Application provided the Agency with an overview of the cost-effectiveness of the project, a discussion of the quality of care related to the services, and a discussion of the access to the services by medically underserved groups in the proposed service area. (Tr. Vol. 15, Platt, p. 2435).

- 299. Mission's Application demonstrated that in regard to cost-effectiveness, the proposed project would:
 - a. Reduce travel times and increase access to care for emergency services.
 - b. Improve the efficiency of EMS services and access to Mission's emergency department.
 - c. Reduce capacity constraints at Mission's main emergency department.

(Tr. Vol. 15, Platt, pp. 2235-36).

- 300. The Mission Application provided all the required information and documented that the project met the required standards of the criterion. (Tr. Vol. 15, Platt, pp. 2444-45).
- 301. Ms. Platt testified that Statutory Review Criterion 18a requires the applicant to document the expected effects of the proposed service on competition in the proposed service area, including how enhanced competition will have a positive impact on cost-effectiveness, quality, and access to care. (Tr. Vol. 15, Platt, p. 2434).
- 302. Ms. Platt's interpretation of Statutory Review Criterion 18a is consistent with the Agency's interpretation that neither a CON applicant nor the Agency is required to perform any harm or impact analysis on existing competitors of the applicant under Statutory Review Criterion 18a. (Jt. Ex. 178 McKillip Deposition Testimony, p. 123).
- 303. Specifically, "what's typically provided and reviewed by the agency is again a narrative discussion provided by the applicant with regard to cost-effectiveness, quality and accessibility. It is not typical to provide any type of quantitative analysis related to impact on any other provider." (Tr. Vol. 15, Platt, p. 2437).
- 304. In terms of service to medically underserved groups, Mission provided a discussion in its application of how its existing emergency department is accessible to all populations without regard to ability to pay, including all underserved groups and how those same policies and procedures would be in place at the freestanding ED. (Jt. Ex. 2, Agency File AF 522; Jt. Ex. 1, Mission Application MH 121). Mission also provided attachments to its CON application that included Mission's policies and procedures governing the provision of care to underserved groups. (Tr. Vol. 15, Platt, pp. 2436-37; Jt. Ex. 1, Mission Application MH 467-73).
- 305. Ms. Platt demonstrated in her report that, contrary to AdventHealth's position that the proposed Mission FSED will cause it to lose patients, in 2027 AdventHealth will see an increase in visits to its emergency department over what it currently sees in 2022. (Jt. Ex. 160 pp. 7-8) (Jt. Ex. 161 (Exhibit 12)).
- 306. Additionally, the "freestanding ED will allow Mission to continue to serve all those patient populations in the proposed service area and improve the access to care for those patients at the freestanding ED." (Tr. Vol. 15, Platt, pp. 2436-37).

- 307. The Agency in this case took the same approach to its analysis of Criterion 18a as it had in previous reviews. (Tr. Vol. 15, Platt, p. 2441) (Jt. Ex. 140, 141).
- 308. In the Agency's review of Criterion 18a in <u>both</u> the Atrium Health Ballantyne Emergency Department and Atrium Health Concord Emergency Department Agency Findings, the Agency identified the ZIP code service area and the existing and approved providers that were in and around that service area, and then quoted various excerpts of the applicant's narrative in relation to cost-effectiveness, quality, and access by medically underserved groups. Neither of these sets of Agency Findings included any analysis of potential harm or negative impact on existing competitors of the applicant. (Tr. Vol. 15, Platt, p. 2440-41; Jt. Ex. 140, pp. 32-34; Jt. Ex. 141, pp. 24-26).
- 309. Again, the Agency's analysis of Criterion 18a in those cases was consistent with its approach and analysis of the Mission Application in this review. (Tr. Vol. 15, Platt, p. 2441) (Jt. Ex. 2 Agency Findings AF 521-23) (Jt. Ex. 140, 141).
- 310. Mission's expert Ms. Platt opined that the Agency did not err in finding the Mission Application conforming with Statutory Review Criterion 18a. (Tr. Vol. 15, Platt, pp. 2444-45) (Jt. Ex. 160, pp. 7-8).
- 311. This Tribunal finds Ms. Platt's, Mr. McKillip's and Ms. Pittman's testimony regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 18a to be credible, reliable, and persuasive.
- 312. This Tribunal finds that the Agency's application of Statutory Review Criterion 18a was reasonable and adequately supported. Statutory Review Criterion 18a does not require the Agency or an applicant to perform any harm or impact analysis on existing competitors of the applicant.

- 313. Criterion 20 was applicable to the Mission Application. Statutory Review Criterion 20 requires applicants that are already involved in the provision of health care services to provide evidence that quality care has been provided in the past. (McKillip Vol. 2, p. 227) (Tr. Vol. 15, Platt, p. 2445) (Jt. Ex. 2, Agency File AF 523; *see also* N.C. Gen. Stat. §131E-183(a)(20)).
- 314. When evaluating Statutory Review Criterion 20 the Agency relies on the information provided to it by the Acute Home Care Certification and Licensure Section of the N.C. Department of Health and Human Services, Division of Health Service Regulation that reflects an applicant's prior licensure history. (Tr. Vol. 2, McKillip, p. 227).
- 315. The licensure inspections conducted by the Acute and Home Care Licensure section are important because the Licensure Section is part of DHHS. As such, the reviews conducted by the Acute and Home Care Licensure section are conducted as required by the U.S. Centers for Medicaid and Medicare Services and are not based on hearsay or accusations. (Tr. Vol. 5, Pittman, p. 860).

- 316. In evaluating Criterion 20, the Agency reviews what the applicant provides in the application in addition to what the Agency receives from the Acute and Home Care Certification and Licensure Section. (Tr. Vol. 5, Pittman, pp. 933-34).
- 317. Ms. Pittman testified that "[t]he agency has determined that in cases where we could look to sections within Health and Human Services, sections that are tasked with dealing with quality, that we look there, that's what we have determined is the best way to approach Criteria 20." (Tr. Vol. 5, Pittman, pp. 934-35).
- 318. The Agency relies on the Acute and Home Care Licensure Section in a hospital review because that is the entity that conducts surveys of hospitals in North Carolina and follows up on complaints or issues. (Tr. Vol. 2, McKillip, p. 227).
- 319. The Agency does not rely on allegations made in the media when considering compliance with Statutory Review Criterion 20. (Tr. Vol. 1, McKillip, p. 155).
- 320. The Agency, after it reviewed and considered the information provided by Mission and the information provided by the Acute and Home Care Licensure and Certification Section, and after it considered the historical quality of care at the six facilities owned or managed by Mission, found that the Mission Application was conforming to Statutory Review Criterion 20. (Jt. Ex. 2, AF 523).
- 321. AdventHealth contended that the Agency erred in finding the Mission Application conforming with Statutory Review Criterion 20.
- 322. Ms. Sandlin, AdventHealth's expert, argued that the Agency did not consider reports of issues at Mission including unsafe working conditions, comments by Attorney General Josh Stein, and a \$30,000 fine imposed by the N.C. Department of Labor, Occupational Safety and Health Division in 2021. (Jt. Ex. 144, Sandlin Expert Report pp. 23-25).
- 323. Ms. Carter did not offer any opinions about Criterion 20 in this review. (Tr. Vol. 8, Carter, p. 1473).
- 324. Ms. Platt stated that in her experience the Agency checks the licensure track record of the applicant and its affiliates to make sure there are no uncorrected licensure deficiencies which were cited and that the applicant is meeting all the requirements of licensure. (Tr. Vol. 15, Platt, p. 2446). In fact, Ms. Sandlin, AdventHealth's expert, agreed that the Agency's standard practice in analyzing Criterion 20 is to use the Acute and Home Care Licensure and Certification Section review to evaluate an applicant's conformity with the criterion. (Tr. Vol. 10, Sandlin, p. 1662).
- 325. Further, the CON Application form asks CON applicants to "identify each facility that was determined by the Division of Health Service Regulation to have had any situations resulting in a finding of immediate jeopardy during the 18-month look back period" and to then summarize the situation leading to such a finding, to indicate whether the facility is back in compliance as of the application filing date and, if not, to estimate the date of the facility's return to compliance. (Jt. Ex. 1, Mission Application MH 125-127).

- 326. In its Application, Mission provided information to address Criterion 20. Specifically, Mission listed hospitals it is affiliated with on Form O. Mission also provided a narrative of the methods it uses to achieve quality of care and its record of quality care. Mission provided a number of attachments and exhibits regarding policies for quality and safety, infection control, and utilization review. (Jt. Ex. 1, Mission Application MH 123-28, 508-56). It also provided documentation of its licensure by the Acute and Home Care Licensure Section, certification by the federal Medicare and Medicaid programs, and several accreditations it has achieved, including specialty accreditations and certificates. (Jt. Ex. 1, Mission Application MH 557-75). Further, Mission provided information regarding the recognition of its quality from a variety of sources including its LeapFrog Safety Score of A and its recognition as a top cardiovascular hospital by Fortune and IBM Watson. (Tr. Vol. 15, Platt, pp. 2445-46) (Jt. Ex. 1, Mission Application MH 123-28) (Tr. Vol. 13, Smith, pp. 2008-9).
- 327. The Leapfrog Safety score is issued by The Leapfrog Group, an independent group measuring patient safety in hospitals. In determining a score, the Leapfrog Group measures metrics that address patient safety and injuries in a hospital. (Tr. Vol. 13, Smith, pp. 2008-9).
- 328. In further rebuttal to the contentions of poor quality raised by AdventHealth, Mission provided additional evidence in support of its high quality of care. Specifically, Mission has the highest survival rate for heart attacks in North Carolina. (*Id.* at pp. 2007-8). Also, Mission is graded as a gold center for stroke treatment as determined by the American Heart Association and the American Stroke Association. (*Id.* at p. 2008). In addition, Mission has taken steps to combat the opioid crisis by offering anesthesia that is opioid free. (*Id.* at p. 2010).
- 329. Ms. Platt also addressed the testimony regarding alleged complaints about quality of care and staffing issues at Mission. Ms. Platt testified that the complaints lacked objective evidence for support and that a review of the objective licensure information reviewed regarding Mission's quality of care, licensure, accreditations, and certifications demonstrates quality care. (Tr. Vol. 15, Platt, p. 2447).
- 330. Specifically, Ms. Platt stated that the testimony of Ms. Sandlin and the evidence presented by AdventHealth regarding alleged non-compliance with Statutory Review Criterion 20 was "a lot of assertions without evidence to support them." *Id.* Mission clearly provides quality care to its patients based on an examination of Mission's actual licensure, accreditation, certifications and quality awards. *Id.*
- 331. Ms. Platt agreed with the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 20. (Tr. Vol. 15, Platt, p. 2447) (Jt. Ex. 160, p. 8).
- 332. This Tribunal finds the testimony of Ms. Platt, Mr. McKillip and Ms. Pittman regarding the Agency's determination that the Mission Application was conforming to Statutory Review Criterion 20 to be credible, reliable, and persuasive.

EMR

- 333. During the contested case hearing, Petitioners argued that Mission's March 22, 2021, internal business plan or "EMR," which related solely to the 2021 Mission FSED Application, not the 2022 Application at issue in this case—showed intentional dishonesty by Mission in the 2022 CON application it submitted to the Agency and that the approval of the Mission Application should be reversed as a result. (Jt. Exs. 69, 75, 97; Tr. Vol. 9, Sandlin, pp. 1563-65).
- 334. In particular, AdventHealth contended that the EMR showed Mission's "true intent" regarding the expected performance of Mission's proposed FSED in Arden. AdventHealth suggested that the EMR demonstrated how the proposed Mission FSED in Arden would "harm" AdventHealth in terms of lost patients, reduced market share and lost revenues, and that the EMR demonstrated harm to AdventHealth even greater than that which AdventHealth claims would derive from the proposed FSED as described in Mission's 2022 Application. (Jt. Exs. 36a; Tr. Vol. 10, Sandlin, pp. 1697-98).
- 335. The EMR was neither contained in the Mission Application nor available to the Agency during its review of the Mission Application. (Tr. Vol. 8, Carter, pp. 1452; Tr. Vol. 13, Smith, pp. 2048-49; Tr. Vol. 15, Platt, pp. 2450-55; see generally Jt. Ex. 1, Mission Application).
- 336. Petitioners argue that Mission so materially misrepresented the truth in its application that Mission should be disqualified as an applicant and the approval of its Application should be reversed, despite the lack of any evidence or claim of Agency error in this regard.
- 337. More importantly, however, when questioned, no Mission witness provided any testimony that would support AdventHealth's theory that Mission intentionally misrepresented information in its Application. In fact, all the testimony from both the Mission and the Agency witnesses contradicted AdventHealth's contentions.
- 338. Sondra Smith testified that, "An EMR is a document. ... And [the EMR is] basically a mechanism to disperse funds from HCA to the hospital that's asking for it." The EMR is created by the Capital Asset Management Services or "CAMS" department within HCA's national office. CAMS is responsible for managing large capital projects. (Jt. Ex. 188-A, pp. 20, 22, 26; Tr. Vol. 13, Smith, p. 2042; Tr. Vol. 14, Smith, p. 2227).
- 339. In March 2021, prior to the preparation of Mission's 2021 Arden FSED Application, the CAMS department created an EMR related to the funding of the 2021 project before the development and submission of Mission's actual 2021 Application. (Jt. Exs. 69, 75, 97; Ex. 188-A, pp. 26; Tr. Vol. 13, Smith, pp. 2042-43, 2124).
- 340. After the 2021 CON Application and review cycle, Mission leadership concluded that the development of an EMR by the CAMS department was more appropriate after the approval of an application by the CON Section. Ms. Smith made it clear that an EMR is not needed in order to submit a CON application. (Jt. Ex. 188-A, pp. 26-30; Tr. Vol. 13, Smith, p. 2042, 2124; Tr. Vol. 14, Smith, pp. 2227-30). Ms. Smith testified that after a CON is issued by the Agency to Mission

for development of the FSED proposed in Mission's 2022 Application, and prior to the development of the FSED project, a new EMR would be created to authorize the actual disbursement of funds for the project. (Tr. Vol. 13, Smith, pp. 2042-44).

- 341. As a result of this change in internal procedures within Mission and HCA, an EMR was not created in advance of the submission of the Mission 2022 Arden FSED Application. Mission did, however, obtain a funding letter from the group financial officer which pledged the funds needed to fund the proposed project in the 2022 Application. This letter was included in the application in the section responding to Statutory Review Criterion 5. (Jt. Ex. 1, Mission Application MH-234; Jt. Ex. 188-A, pp. 29-30; Tr. Vol. 13, Smith, pp. 2042-44; Tr. Vol. 14, Smith, pp. 2227-30).
- 342. The 2021 EMR was, likewise, not used by Ms. Platt for any purpose as she developed the 2022 Application. In fact, Ms. Platt testified that she never relies upon her clients' internal business plans when developing a CON application. Rather Ms. Platt independently develops applications based upon the information requested by the Agency in its application form, the applicable law, individual facts related to the proposed project, and data available to her to demonstrate the conformity with the applicable review criteria. (Tr. Vol. 14, Smith, pp. 2228; Tr. Vol. 15, Platt, pp. 2450-55).
- 343. Notwithstanding this fact, Ms. Platt testified that a vast majority of her clients create business models and / or plans, similar to the EMR, as part of their internal assessment as to whether a particular CON-regulated project is worthy of development. The Agency does not require, or even request, that internal business plans be included in an applicant's CON application. To this end, Ms. Platt as well as the experts for AdventHealth and Pardee, all testified that their clients typically do not include internal business plans and / or models in their CON applications. (Tr. Vol. 8, Carter, pp. 1450-54; Tr. Vol. 10, Sandlin, pp. 1707-11, 1717-18; Tr. Vol. 15, Platt, pp. 2450-55).
- 344. The Agency focuses on the application and whether the information contained in the application is adequately supported and based upon reasonable assumptions. (Jt. Ex. 178a pp. 33-34; Jt. Ex. 177a, p. 66; Tr. Vol. 15, Platt, pp. 2450-55).
- 345. This Tribunal finds Ms. Smith's and Ms. Platt's testimony regarding the EMR to be credible, reliable, and persuasive.

MISSION'S 2021 FSED ARDEN APPLICATION

- 346. As discussed above, the Agency approved Mission's 2022 Arden Application on May 24, 2022, and that approval is the subject of this contested case.
- 347. In this contested case, both Petitioners have argued that the Agency erred by approving Mission's 2022 Arden Application, after denying Mission's 2021 Arden Application, when the two applications were not materially different. (Tr. Vol. 7, Carter, p. 1258) (Tr. Vol. 9, Sandlin, pp. 1546-48).

- 348. On or about June 15, 2021, Mission submitted a CON Application (the "2021 Arden Application") to the Agency proposing to develop a FSED in Arden, Buncombe County, North Carolina identified by Project I.D. # B-12093-21. (Jt. Ex. 8, 2021 Mission Arden Application).
- 349. The Project Analyst assigned to the Agency's review of the 2021 Application was Celia Inman and the Co-Signer was Lisa Pittman. (Jt. Ex. 9, 2021 Agency File CON 297) (Tr. Vol. 4, Pittman, p. 630).
- 350. The Agency issued a Decision and Agency Findings on November 16, 2021 denying Mission's 2021 Application. (Tr. Vol. 1, McKillip, p. 73) (Jt. Ex. 9, 2021 Agency File CON 297-328) (Jt. Ex. 2, Agency File AF 464-95) (Tr. Vol. 14, Platt, p. 2327).
- 351. Mission appealed the denial of the 2021 Arden Application. (Jt. Ex. 1, Mission Application MH. 36).
- 352. On February 15, 2022, while the appeal of the 2021 Arden Application was pending, Mission filed a second application seeking to develop a FSED at the same Arden site proposed in the 2021 Arden Application and made clear in that application that it only planned to develop one FSED at the Arden site (the "2022 Arden Application"). (Jt. Ex. 1, Mission Application MH 36).
- 353. AdventHealth's expert Ms. Sandlin testified that the same bases for nonconformity that were present in the 2021 application also existed in the 2022 application. (Tr. Vol. 9, Sandlin 1546).
- 354. Ms. Sandlin stated that in her opinion, there was nothing new in Mission's 2022 Arden Application that justified the Agency reversing its findings of nonconformity regarding Mission's 2021 Arden Application. (Tr. Vol. 9, Sandlin, p. 1546).
- 355. Ultimately Ms. Sandlin testified, "So there was just there was nothing new in the 2022 application to reverse the bases for which the application was just very briefly a few months before found nonconforming." (Tr. Vol. 9, Sandlin, p. 1547).
- 356. Pardee's expert witness Dawn Carter opined that the Mission 2022 Arden Application should have been found nonconforming to Statutory Review Criterion 3 because:
 - a. "[S]pecifically, there were two assumptions in the 2021 application that were found nonconforming in 2021. There were no changes to those assumptions, no changes to the explanation of those assumptions in the 2022 application. That was brought out in the Pardee comments and I believe the agency erred in not addressing that."
 - b. "[T]here's no evidence that Mission did not have sufficient capacity at its main campus to accommodate ED volume."
 - c. "[T]he proposed freestanding Arden ED does not improve any drive time or any accessibility for the patients who are already accessing emergency departments in the service area."

(Tr. Vol. 6, Carter, p. 1042).

- 357. Ms. Carter opined that she did not believe Mr. McKillip analyzed the written comments submitted as part of this application process. (Tr. Vol. 6, Carter, p. 1038).
- 358. Ms. Carter's opinion was based on the allegation that statements and assumptions from the Arden 2021 Application that the Agency found nonconforming were not changed or modified in the 2022 Mission Application. Also, Ms. Carter contended that the Agency should have looked back at the 2021 Arden Application and the 2021 Agency Findings during the review of the 2022 Mission Application and the Agency did not. (Tr. Vol. 6, Carter, p. 1038).
- 359. Project Analyst Mike McKillip did not review Mission's 2021 Arden Application or the 2021 Agency Decision denying that application as part of his review of the 2022 Arden Application. (Tr. Vol. 2, McKillip, p. 181).
- 360. McKillip testified that he only reviewed the 2022 Arden Application. He was aware that the 2021 Arden Application had been denied by the Agency, and that the Agency found that application nonconforming to Review Criteria 3 (need), 6 (unnecessary duplication of existing services) and 18a (impact of project on competition). He testified, however, that the Agency's findings of nonconformity to Review Criteria 6 and 18a were based entirely on the Agency's finding of nonconformity to Review Criterion 3. (Tr. Vol. 2, McKillip, p. 184).
- 361. The Agency testified that it does not look back at prior applications. (Tr. Vol. 5, Pittman, pp. 892, 940).
- 362. McKillip also testified that he read and reviewed all of the written comments filed by AdventHealth and Pardee in this review and that those comments referenced the Agency's reasons for denying Mission's 2021 Arden Application. (Tr. Vol. 2, McKillip, p. 182).
- 363. Both Petitioners detailed their allegations that Mission's 2021 and 2022 Applications were not materially different and thus the 2022 Application should not be approved in the extensive comments they filed with the Agency in opposition to the 2022 Arden Application during this review, which McKillip testified that he reviewed and considered. (Jt. Ex. 2, Agency File AF 65-184, 186-199) (Tr. Vol. 2, McKillip, p. 182); (Tr. Vol. 6, Carter, p. 1038) (Tr. Vol. 9, Sandlin, pp. 1546-48).
- 364. McKillip discussed the Mission 2021 Arden Application and the Agency's denial of that Application and the reasons for that denial with the Agency's Assistant Chief, Lisa Pittman, who was also the co-signer on the Agency Decision approving Mission's 2022 Arden Application. (Tr. Vol. 2, McKillip, p. 182).
- 365. When the Agency reviews an application by an applicant who previously filed a CON application, even one proposing the same CON-covered health care asset that was previously denied, the Agency does not compare the applicant's prior application to the one under review. Rather, the Agency only reviews the application that is before it in a given review, that includes

the most recent information from the application, along with comments filed in opposition to that application and the applicant's responses to those comments. (Tr. Vol. 2, McKillip, p. 184).

- 366. When reviewing a CON application, the Agency only reviews the application at issue and the written comments filed in opposition to the application and the applicant's responsive comments. (Tr. Vol. 5, Pittman, p. 892).
- 367. Agency witness Lisa Pittman testified that the Agency does not review prior applications, including those filed by the same applicant, because:
 - a. The Agency only reviews what is submitted by the current applicant in the current review;
 - b. Reviewing a prior application is "just not helpful;"
 - c. "If the other second application was if the first application reviewed was denied and they submit another one, there could just be very few things that need to be fixed to make the second one comparable, and it really is irrelevant what happened in a prior application." (Tr. Vol. 5, Pittman, p. 892).
 - d. "[A]ny applicant is entitled to submit whatever they want to in a second application or a third or whatever. They could change the methodology. They can rewrite every word of it. They can just fix a paragraph." (Tr. Vol. 5, Pittman, p. 939).
 - e. "What we review is the current application. We do not go back and review prior applications to see if it comports" with an earlier one. "We review what is in it [the pending application], and if it makes sense and is reasonably supported. That is what we focus on. (Tr. Vol. 5, Pittman, p. 939-40).
- 368. Mr. McKillip testified that Mission's 2022 Arden application was "not the same application" as Mission's 2021 Arden Application. (Tr. Vol. 2, McKillip, p. 185).
- 369. Rather, it was "a separate, a new application with new information that had new comments and new responsive comments, so a completely different set of documents, in fact, was reviewed in the course of the 2022 review." (Tr. Vol. 2, McKillip, pp. 185).
- 370. AdventHealth's counsel on cross-examination of Agency witness Lisa Pittman elicited testimony further demonstrating that differences existed in some of the data and projections Mission included in its 2021 Arden Application and its 2022 Arden Application. (Tr. Vol. 4, Pittman, pp. 739-41, 745-46, 748).
- 371. It was not necessary for the Agency to compare Mission's 2021 Arden Application to its 2022 Arden Application to determine if the 2022 Application was conforming to applicable Review Criteria and the Agency has never undertaken such a comparison in past reviews. (Tr. Vol. 4, Pittman, p. 668-69).
- 372. The Agency also testified that the 2021 application was denied based on a few limited issues. (Tr. Vol. 5, Pittman, p. 893).

- 373. Specifically, Ms. Pittman testified that the Agency denied the 2021 Mission Application for two primary reasons. The first reason was that the 2021 Application proposed to relocate an existing CT scanner in Buncombe County to the new proposed FSED. The Agency was concerned that the relocation of the CT scanner would impact accessibility for the population the existing location served. (Tr. Vol. 5, Pittman, p. 893).
- 374. The second reason involved questions regarding the projections made by Mission in the 2021 Application to calculate the demand for and projected future utilization of emergency department services coming out of the COVID-19 pandemic and the existence of limited post-COVID utilization data to show the recovery of services post-pandemic. Pittman testified that the Agency's denial of Mission's 2021 Arden Application was based primarily on Mission's projection of a post-COVID utilization rebound, which was based on only two months of emergency department utilization data for the year 2021. The Agency did not feel it had sufficient information to find that projection reasonable, based on such a limited amount of data from 2021. (Tr. Vol. 5, Pittman, p. 784-805, 893).
- 375. Ms. Pittman conceded, however, that Mission's 2022 Arden Application, which contained a full year of Mission's historical emergency department utilization data for 2021, ended up demonstrating that Mission's emergency department utilization data projections in its 2021 Arden Application were, in fact, reasonable and accurate. (Tr. Vol. 5, Pittman, pp. 785, 893).
- 376. Ms. Pittman testified that as co-signer of the Agency Decision, she believed that Project Analyst McKillip's analysis of the 2022 Arden Application justified his approval of the project. (Tr. Vol. 5, Pittman, p. 804, 898).
- 377. On cross-examination by counsel for AdventHealth, Agency witness Ms. Pittman again detailed the differences in Mission's 2021 and 2022 Arden Applications, including the following:
 - a. In its 2022 Application, Mission used a full year of 2021 historical utilization data to project utilization for its proposed new FSED, not just two months of data as it had done in the 2021 Arden Application;
 - b. That full year of data demonstrated to the Agency that Mission's 2021 Application utilization projections were reasonable and accurate;
 - c. Mission further explained the basis of its projection that approximately 7.3% of patients projected to be treated at the proposed FSED would be high acuity with the rest projected to be lower acuity patients. In the 2021 Arden Agency Decision, the reviewing Project Analyst didn't feel that Mission provided her with enough explanation of the basis for Mission's projected ratio of high acuity to low acuity patients. However, based on that Project Analyst's deposition testimony, which Ms. Pittman had reviewed, this issue was simply noted by the 2021 Project Analyst as something she didn't "love," but was not a basis for denial of the 2021 Arden Application; and
 - d. Mission's 2022 Arden Application did not propose to relocate a CT Scanner from its existing location so any issues with the proposal in the 2021 Arden Application were not present in the 2022 Arden Application. In the 2022 Arden Application,

- Mission proposed to acquire a new CT Scanner for the proposed FSED. (Tr. Vol. 5, Pittman, pp. 739-759, 784-805).
- 378. Mission adequately addressed the issues that led to the denial of its 2021 Arden Application in its 2022 Arden Application, to the satisfaction of the Agency. (Tr. Vol. 5, Pittman, p. 892-3).
- 379. The testimony of Mission's expert, Kathy Platt, supports the Agency's position that the 2021 and 2022 Arden Applications were different in numerous respects and were, in fact, materially different in a manner that addressed the issues identified by the Agency as reasons for denial of the 2021 Arden Application and justified the Agency's approval of the 2022 Arden Application.
 - a. Specifically, Ms. Platt testified that the Agency's primary reasons for denying the 2021 Arden Application were:
 - i. Based on Mission's plan to relocate an existing CT Scanner from its current location to the proposed new FSED, and a concern that would leave patients currently having access to the CT Scanner without that service;
 - ii. The Agency did not believe it had sufficient information to find Mission's future FSED utilization projections reasonable because, in the Agency's view, those future multi-year projections relied on only two months of 2021 internal Mission utilization data for ED services reflecting a rebound from the declining utilization all health care providers experienced during the height of the Covid pandemic; and
 - iii. The Agency didn't feel Mission provided a sufficient explanation for the ratio of low acuity to high acuity patients Mission expected to treat at the new FSED.
- (Tr. Vol. 14, Platt, pp. 2327-28; Tr. Vol. 15, Platt, pp. 2400-02) (Jt. Ex. 160, p. 4).
- 380. Ms. Platt testified that she had a key role in both the 2021 and 2022 Arden Applications and fully reviewed both Applications. She testified that the two Applications were materially different in many respects and that she disagreed with the testimony of Petitioners' witnesses that the two Application were not "materially different." (Tr. Vol. 14, Platt, pp. 2327-2331, 2375-2376; Tr. Vol. 15, Platt, pp. 2400-02, 2448, 2490-91 and 2535-36).
- 381. Mission addressed each of the issues identified by the Agency in its denial of the 2021 Arden Application by providing additional explanations, updated information, and additional and/or updated data in the 2022 Arden Application. (Tr. Vol. 14, Platt, pp. 2327-2331, 2375-2376; Tr. Vol. 15, Platt, pp. 2400-02, 2448, 2490-91 and 2535-36) (Jt. Ex. 160, p. 4).
- 382. Ms. Platt testified extensively and in great detail about the differences in Mission's 2021 and 2022 Arden Applications and how the 2022 Arden Application set forth for the Agency additional explanatory narrative, updated projections and other data, and other differences. (Tr.

- Vol. 14, Platt, pp. 2327-2331, 2375-2376; Tr. Vol. 15, Platt, pp. 2400-02, 2448, 2490-91 and 2535-36).
- 383. Ms. Platt testified that with respect to the reasons cited by the Agency for denial of the 2021 Arden Application, Mission:
 - a. Provided a full year of 2021 utilization data in the 2022 Arden Application that demonstrated that Mission's utilization projections in the 2021 Application were actually accurate, coming within 400 visits of Mission's actual 2021 historical experience;
 - b. Mission did not propose to relocate an existing CT Scanner in its 2022 Arden Application, thus addressing the issue the Agency had with that equipment relocation in the 2021 Application; and
 - c. Mission provided further explanation in support of its high acuity to low acuity ratio of patients expected to be treated at the proposed Arden FSED, including the experience of Mission at its existing main emergency department; the experience of a Tennessee FSED operated by Mission's parent company, HCA, and further detail explaining that Mission would be required to, and would, treat all patients arriving at the proposed FSED but based on historical experience, FSEDs in general treat a higher percentage of low acuity patients than a typical hospital-based emergency department.
- (Tr. Vol. 14, Platt, pp. 2327-2331, 2375-2376; Tr. Vol. 15, Platt, 2400-02, 2448, 2490-91 and 2535-36).
- 384. This Tribunal finds Ms. Platt's, Ms. Pittman's, and Mr. McKillip's testimony regarding Mission's 2021 FSED Arden Application to be credible, reliable, and persuasive.

PETITIONERS' ALLEGATIONS OF SUBSTANTIAL PREJUDICE

385. Throughout this contested case AdventHealth and Pardee have alleged that they are substantially prejudiced by the Agency's decision to approve Mission's 2022 Arden FSED Application. Petitioners have argued several theories of substantial prejudice which this Tribunal has divided into three categories: public hearing; agency error; and competition-based claims.

Public Hearing

- 386. The Tribunal has already summarized in great detail the Petitioners' evidence regarding the Agency's public hearing process and the Agency's failure to conduct a public hearing as required by statute. *See supra*, Findings of Fact 72-110.
- 387. AdventHealth and Pardee's representatives and experts each testified to their belief that Pardee had a legal right to a public hearing. (Tr. Vol. 3, Nudd, pp. 399, 435; Tr. Vol. 3, Murrill, p. 563; Tr. Vol. 6, Kirby, pp. 979-80; Tr. Vol. 7, Carter, p. 1257; Tr. Vol. 10, Sandlin, pp. 1629-30).

- 388. Pardee's representatives would have attended a public hearing and encouraged others to attend. (Tr. Vol. 6, Kirby, p. 980). AdventHealth's representative would have spoken at a public hearing. (Tr. Vol. 3, Nudd, p. 400).
- 389. There are important differences in the opportunity for input afforded to Advent Health and Pardee by a public hearing and the opportunity to submit written comments, including but not limited to the ability to speak directly to the analyst, express opinions that they may not be able to put as easily in writing, for the Agency to ask questions and the public to demonstrate in person support or opposition to a project. (Tr. Vol. 6, Kirby, p. 984; Tr. Vol. 6, Carter, pp. 1031-32, Tr. Vol. 10, Sandlin, pp. 1630-31).
- 390. The Agency has issued Findings that include incorporation and discussion of comments made at a public hearing, in other reviews. (Tr. Vol. 6, Carter, pp. 1034-35).
- 391. Deprivation of AdventHealth's and Pardee's right to speak at a public hearing in and of itself is substantial prejudice.
- 392. The Tribunal finds that the Agency's failure to hold a public hearing regarding Mission's Application substantially prejudiced Petitioners as a matter of law.

Agency Error

Agency Review of Mission Application with respect to Statutory Review Criteria

- 393. AdventHealth contends that it was substantially prejudiced by the Agency's application and review of the statutory review criteria to Mission's Application, or simply, agency error. Specifically, AdventHealth contends that the Agency erred in its application of the following Statutory Review Criteria 3, 4, 5, 6, 13, 18a, and 20. (Tr. Vol. 9, Sandlin, p. 1545) (AdventHealth Re-Filed Petition for Contested Case Hearing, p. 8).
- 394. Pardee similarly contends that it was substantially prejudiced in this case by the Agency's application and review of certain statutory review criteria to Mission's Application. Pardee contends that the Agency erred in its application of the following Statutory Review Criteria: 3, 4, 5, 6, and 18a. (Tr, Vol. 6, Carter, p. 1030) (Pardee Re-Filed Petition for Contested Case Hearing, p. 11).
- 395. This Tribunal has set forth previously its review and summary of the evidence regarding the Agency's review of the Mission Application with respect to the Statutory Review Criteria. *See supra*, Findings of Fact 111 332.

2021 Application v. 2022 Application

396. In addition, both Petitioners contend that they were substantially prejudiced by the Agency's action in approving Mission's 2022 Application following the denial of Mission's 2021 Application. Petitioners argue that there were no material differences between the 2021 Mission Application and the 2022 Mission Application which justify the Agency's decision to approve the

- 2022 Mission Application. (Tr. Vol. 7, Carter, p. 1258) (Pardee Re-Filed Petition for Contested Case Hearing, p. 14) (AdventHealth Re-Filed Petition for Contested Case Hearing, p. 12).
- 397. This Tribunal has already summarized in detail the evidence regarding the 2021 Mission Application, the 2022 Mission Application, and the differences therein. *See supra*, Findings of Fact 346 384.
- 398. The Petitioners' allegations of being substantially prejudiced by the Agency's review and approval of Mission's Application and the Agency's application of the Statutory Review Criteria to the Mission Application to determine that the Mission Application was conforming all amount to allegations of agency error.

Competition-Based Claims

AdventHealth

- 399. Next, AdventHealth claims that it was substantially prejudiced because the Agency's failure to review the Mission Application in accordance with the CON law will result in "the further entrenchment of Mission's monopoly over acute care services." (AdventHealth Re-Filed Petition pp. 8, 20).
- 400. At the hearing, AdventHealth's witnesses advanced various theories of substantial prejudice in this category including:
 - a. The purpose of Mission's proposed FSED in Arden is to move market share away from competitors and further Mission's monopoly; (Tr. Vol. 3, Murrill, p. 558).
 - b. Mission's proposed FSED in Arden will not increase competition in the proposed service area; (Tr. Vol 3, Murrill, p. 561).
 - c. Mission's market dominance in the community causes harm to patients, reduces access, increases cost, and adding a new Mission FSED in Arden would further those impacts; (Tr. Vol. 4, Murrill, p. 621).
 - d. AdventHealth would be harmed by Mission's proposed project because AdventHealth would lose patients, would lose money, and would impact the services AdventHealth could provide; (Tr. Vol. 3, Nudd, pp. 389-91).
 - e. The proposed Mission FSED in Arden is a duplication of services that threatens the existence of not only AdventHealth but generally the "people's choice in healthcare providers and threatens competition in the area." (Tr. Vol. 3, Fields, p. 464).
- 401. AdventHealth also created a document which outlined the alleged harm that AdventHealth claim it will suffer if Mission is allowed to build a FSED in Arden. (Tr. Vol. 3, Murrill, pp. 566-69) (Jt. Ex. 36).
- 402. AdventHealth through Exhibit 36 attempted to demonstrate how it will suffer financial harm if Mission's proposed FSED in Arden is constructed. (Tr. Vol. 3, Murrill, pp. 583-85).

- 403. AdventHealth's analysis assumed that people would go to the nearest emergency department and conducted the analysis strictly on the basis of proximity to the closest ED. (Tr. Vol. 3, Murrill pp. 569, 574-75).
- 404. Ms. Sandlin also repeated AdventHealth's theory that "proximity is a legitimate factor in terms of how patients utilize emergency department services" to support the contention that patients decide what provider to use based of their proximity to a certain provider. (Tr. Vol. 10, Sandlin, p. 1763).
- 405. AdventHealth's analysis did not factor in existing patient/provider relationships when considering which provider a patient decides to use. (Tr. Vol. 3, Murrill, p. 606).
- 406. AdventHealth's analysis predicted that AdventHealth would lose 100 percent of the patients it currently serves from the 28704 ZIP code. (Jt. Ex. 36; Tr. Vol. 3, Murrill, p. 574). However, when Mr. Murrill was questioned at trial, he conceded that not all patients from that ZIP code would actually be lost and it could be less. (Tr. Vol. 3, Murrill, p. 604).
- 407. Mr. Murrill conceded that his proximity analysis failed to consider that all points in a given ZIP code are not equidistant from a certain provider (Tr. Vol. 6, Murrill, pp. 605).
- 408. Mr. Murrill also admitted that Exhibit 36 contains ZIP codes in the analysis that were not included in the Primary Service Area or Secondary Service Area that Mission proposed in its Application. (Tr. Vol 3, Murrill, p. 602) (Tr. Vol. 15, Platt, pp. 2473-74).
- 409. Ms. Platt rebutted the evidence presented by AdventHealth regarding the allegations of harm from Exhibit 36. Specifically, Ms. Platt testified that there were several areas in which she disagreed with the approach and analysis AdventHealth used to attempt to identify the potential impact that the approval of the proposed Mission FSED would have on AdventHealth.
 - a. First, Ms. Platt noted that AdventHealth included extra ZIP codes in its analysis which were not part of the proposed service area in the Mission Application. These extra ZIP codes were much farther away from the location of the proposed FSED so the inclusion in the analysis does not make sense. (Tr. Vol. 15, Platt, p. 2474)
 - b. Second, Ms. Platt testified that the AdventHealth analysis includes projections for certain ZIP codes which result in a 100% loss of patients. Ms. Platt explained that in her experience as an expert in health in health planning, there is never this "sort of an all or none phenomenon." *Id*.
 - c. In fact, Pardee's expert Ms. Carter opined that it would be very unlikely that Pardee or AdventHealth would lose 100 percent of their existing patient base market share from any of the zip codes that Mission proposed to serve. (Tr. Vol. 8, Carter, p. 1472).
 - d. Also, Ms. Platt testified that the AdventHealth analysis did not take into account any consideration of population growth in the service area. (Tr. Vol. 15, Platt, 2474) (Jt. Ex. 161, (Ex 12-13)).

- 410. Ms. Platt explained that Exhibit 36 was a static analysis set in 2021 which did not consider that ED visits would grow based on population growth. Ms. Platt opined that there would be more ED visits for all providers of ED services in the service area in the third year of operation of the proposed Mission FSED. Ms. Platt opined that the AdventHealth analysis was simplistic and not consistent with her experience in health planning. (Tr. Vol. 15, Platt, 2473-80) (Jt. Ex. 161, (Ex 12-13)).
 - 411. Exhibit 36 lacks credibility and fails to demonstrate credible harm to AdventHealth.
- 412. Further, Exhibit 36 was not submitted to the Agency and was not part of AdventHealth's written comments in opposition to Mission's Application. At trial, Mr. Murrill conceded that AdventHealth could have prepared an analysis earlier to submit to the Agency or provide in its written comments but chose not to do so. (Tr. Vol. 3, Murrill, pp. 601-02).
- 413. Taken together these bases of AdventHealth's substantial prejudice claims are that the Agency failed to consider Mission's alleged monopoly; that AdventHealth will lose market share if Mission is allowed to construct a FSED in Arden; that AdventHealth will lose revenue; and AdventHealth will lose patients.

Pardee

- 414. Pardee also made claims that the Agency's decision to approve the Mission Application substantially prejudiced Pardee due to various forms of increased competition.
- 415. Pardee's witnesses advanced various theories of this category of substantial prejudice including that:
 - a. If Mission is allowed to construct an FSED in Arden it would reduce the utilization of Pardee's urgent care center ("UCC") that is in close proximity to the proposed site; (Tr. Vol. 6, Kirby, p. 991).
 - b. The market share projections in the Mission Application do not match the market share projections in an internal HCA business development document and Pardee has been substantially prejudiced. (Tr. Vol. 7, Carter, p. 1264).
 - c. If Mission is allowed to build an FSED in Arden, it will further strengthen Mission's dominance in the market. (Tr. Vol. 6, Kirby, p. 995).
- 416. Taken together, the bases of Pardee's substantial prejudice evidence are that the Agency failed to consider Mission's alleged monopoly; Pardee will lose market share as a result if the Mission is allowed to construct a FSED in Arden; Pardee will lose revenue; and Pardee will lose patients.
- 417. Contrary to attempts made by AdventHealth, Pardee made no effort to quantify any of the alleged harm it contended it would suffer due to the approval of Mission's Application. (Tr. Vol. 15, Platt, p. 2480).

Monopoly Arguments

- 418. Witnesses from both Pardee and AdventHealth alleged that the Agency failed to consider Mission's "monopoly" on acute care services in the region and as a result approved the Mission Application instead of disproving the application. (Tr. Vol. 6, Kirby, p. 995); (Tr. Vol. 3, Murrill, p. 558); (Tr. Vol. 4, Murrill, p. 621).
- 419. The CON section does not analyze, decide or interpret claims regarding monopoly. (Tr. Vol. 5, Pittman, p. 870). Further, the Agency is not tasked with addressing monopolies in its review of CON applications. (Tr. Vol. 5, Pittman, p. 889). The CON law does not address or define monopoly and the term monopoly is not contained in the CON Statutory Review Criteria the Agency utilizes in reviewing and analyzing CON applications. (Tr. Vol. 5, Pittman, p. 932) (Tr. Vol. 15, Platt, p. 2462) (See N.C.G.S. § 131E–183).
- 420. When asked about the monopoly issue and if the Agency needed to decide if Mission has a monopoly, Ms. Pittman stated, "I'm not aware of anybody asking us to make a decision, but [Pardee and AdventHealth are] asking us to consider that possibility when it hasn't been rendered in a court case and it's not our job to do so." (Tr. Vol. 5, Pittman, p. 933).
- 421. Petitioners' monopoly arguments amount to new ways of arguing that Petitioners will suffer economic harm; lose market share; lose patients; or be harmed by competition. All these our courts have held do not constitute substantial prejudice.
- 422. As discussed *supra*, while the Statutory Review Criteria do not address monopoly, Statutory Review Criterion 18a refers to "competition." *See supra*, Findings of Fact 270 312.
- 423. However, in response, and as discussed *supra*., Mission presented evidence showing that both Pardee and AdventHealth provide services in the proposed service area for Mission's Arden FSED and are competitors in the service area.
- 424. Mission currently competes with both Pardee and AdventHealth for emergency department services. Both Mission and AdventHealth demonstrated that the current division of emergency department services show Advent and Pardee, together, control about 47 percent of the market share for emergency services in the proposed service area for Mission's FSED in Arden. Specifically, Ms. Platt, utilizing the information from Jt. Ex. 36, calculated market share data for the proposed FSED service area. (Jt. Ex. 161 (Ex. 16)). According to 2021 actual market data, while the market share for the ZIP codes varies, the overall market share for the service area for ED services was the following: Mission-50%; AdventHealth-27.2%; and Pardee-19.8%. In addition, in certain ZIP codes Pardee had the highest market share (28791 and 28792) while in others AdventHealth had the highest market share (28732 and 28759). (Jt. Ex. 161 (Ex. 16); Jt. Ex. 36) (Tr. Vol. 15, Platt, pp. 2461-62).
- 425. Petitioners contended that the existence of the Certificate of Public Advantage ("COPA") allowed Mission to enhance its "monopoly" in Western North Carolina. (Tr. Vol. 9, Sandlin, pp. 1583-85).

- 426. The COPA was enacted in the mid-1990's and permitted Mission Hospital and St. Joseph's Hospital to merge. The COPA was repealed by the General Assembly in 2016. (Tr. Vol. 5, Kirby, p. 1006) (Tr. Vol. 10, Sandlin, pp. 1652, 1736-38).
- 427. Petitioners argued that due to Mission's alleged monopoly, Mission's position in Buncombe County is unique. Ms. Platt rebutted this testimony. Mission's position in Buncombe County is not unique or unusual. Mission presented clear evidence showing that other providers throughout the state are similarly positioned. (Tr. Vol. 15, Platt, pp. 2463-73) (Jt. Ex. 160, p. 8)(Jt. Ex. 161 (Ex. 19)) (Jt. Ex. 162).
- 428. Ms. Platt examined all the counties in North Carolina and identified where there was one sole health provider, either a single hospital or a single health system operating within the county. Ms. Platt then identified the county population and the inpatient acute care market share that the sole provider has in its home county. The results showed that there were two other counties where the sole hospital or health system had a larger market share of inpatient services in their home county than Mission. Ms. Platt noted that there were several other single hospital counties with high market shares. In addition, both Durham and Cumberland counties have a sole healthcare provider and are more populated than Buncombe County. Ms. Platt opined that based on her analysis and review, there was nothing unusual or unique about Mission's position as the sole provider within Buncombe County. (Tr. Vol. 15, Platt, pp. 2463-65) (Jt. Ex. 161 (Ex. 19)).
- 429. Ms. Platt also examined Mission's market position in western North Carolina and compared it to other hospital systems across multiple counties. Ms. Platt explained that her analysis showed that while Mission had over a 90% market share in two counties, there were several other hospitals across the state in a similar position. For example, New Hanover Regional Medical has over a 90% market share in two counties (New Hanover and Pender Counties), ECU Health has 90% market share in one county and Sentara Albemarle Medical Center has over 90% market share in two counties. Ms. Platt opined that this analysis further shows that there is nothing unique about Mission and its market share in the Western North Carolina market. (Tr. Vol. 15, Platt, pp. 2466-73) (Jt. Ex. 162, pp. 9-12) (Jt. Ex. 160, p. 8).
- 430. This Tribunal finds Ms. Platt's testimony regarding Mission's position as a sole health provider within in a county and Mission's market position to be credible, reliable, and persuasive.
- 431. The Agency in its review of the Mission Application was not required to consider or determine if Mission has a monopoly on acute care services, or emergency department services, in western North Carolina.
- 432. Neither the Agency nor this Tribunal have the power to make a determination as to whether Mission has a monopoly on acute care services, or emergency department services, in western North Carolina.

Summary of Agency Error and Competition Based Claims

433. Petitioners' identified bases for claiming substantial prejudice, discussed above, as detailed by its witnesses, taken together, which amount to either allegations of agency error, or speculative, non-specific claims of competition-based "harm", do not amount to substantial prejudice as our appellate courts have defined that term.

On the basis of these Findings of Fact, the Tribunal makes the following:

CONCLUSIONS OF LAW

- 1. The Office of Administrative Hearings has jurisdiction over the parties and the subject matter of this contested case pursuant to Chapters 131E and 150B of the North Carolina General Statutes. All parties have been correctly designated and there is no question as to misjoinder or nonjoinder and the notice of hearing was proper.
- 2. To the extent that the Findings of Fact contain Conclusions of Law, or that the Conclusions of Law are Findings of Fact, they should be so considered without regard to the given labels. *Charlotte v. Heath*, 226 N.C. 750, 755, 40 S.E.2d 600, 604 (1946); *Peters v. Pennington*, 210 N.C. App. 1, 15, 707 S.E.2d 724, 735 (2011).
- 3. A court "need not make findings as to every fact which arises from the evidence and need only find those facts which are material to the settlement of the dispute." *Brewington v. N.C. Dep't of Public Safety, Sate Bureau of Investigation*, 254 N.C. App. 1, 23, 802 S.E.2d 115, 130 (2017) (citation omitted).
- 4. AdventHealth and Pardee both timely filed their petitions for contested case hearing pursuant to N.C. Gen. Stat. § 131E-188(a).
- 5. Upon the Agency's decision to issue, deny, or withdraw a certificate of need, any affected person is entitled to a contested case hearing. N.C. Gen. Stat. § 131-188(a). Likewise, any affected person may intervene in a contested case hearing. Id.
- 6. As Petitioners, AdventHealth and Pardee bear the burden of proof on each element of its respective case. *Overcash v. N.C. Dep't of Env't & Natural Res.*, 179 N.C. App. 697, 704, 635 S.E.2d 442, 447 (2006).
- 7. Pursuant to N.C. Gen. Stat. § 150B-23(a), in a contested case hearing, "the ALJ is to determine whether the petitioner has met its burden in showing that the agency substantially prejudiced petitioner's rights, and that the agency also acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule." *Presbyterian Hosp. v. N.C. Dep't of Health & Hum. Servs.*, 177 N.C. App. 780, 784, 630 S.E.2d 213, 215 (2006) (citation omitted).
- 8. "The administrative law judge shall decide the case based upon the preponderance of the evidence, giving due regard to the demonstrated knowledge and expertise of the agency with respect to the facts and inferences within the specialized knowledge of the agency." N.C. Gen.

- Stat. § 150B-34(a). The burden of persuasion placed upon a petitioner is the "greater weight of the evidence." *Dillingham v. N.C. Dep't of Human Res.*, 132 N.C. App. 704, 712, 513 S.E.2d 823, 828 (1999).
- 9. The Agency must evaluate CON applications pursuant to North Carolina's CON statute. See N.C. Gen. Stat.§§ 131E-182, 131E-183; see also Living Centers-Southeast v. N.C. Dep't of Health and Hum. Servs., Div. of Facility Servs., Certificate of Need Section, 138 N.C. App. 572, 574-75, 532 S.E.2d 192, 194 (2000).
- 10. "The fundamental purpose of the [CON Act] is to limit the construction of health care facilities in North Carolina to those that are needed by the public and that can be operated efficiently and economically for its benefit." *Id.*; *In re Humana Hosp. Corp. v. N.C. Dep't of Hum. Res.*, 81 N.C. App. 628, 345 S.E.2d 235 (1986).
- 11. The General Assembly adopted the statutory review criteria so that all proposals are evaluated for need, cost of service, accessibility to services, quality of care, and feasibility and to thereby ensure that only appropriate and needed health services are made available. N.C. Gen. Stat. §§ 131E-175(7), 131E-183(a).
- 12. To obtain a CON for a proposed project, a CON application must satisfy all of the review criteria in N.C. Gen. Stat. § 131E-183(a). If an application fails to conform with any one of these criteria, then the applicant is not entitled to a CON for the proposed project. *Presbyterian-Orthopedic Hospital v. N.C. Dep't of Hum. Res.*, 122 N.C. App. 529, 534-35, 470 S.E.2d 831, 834 (1996).
- 13. N.C. Gen. Stat. § 131E-186(b) requires the Agency "provide written notice of all the findings and conclusions upon which it based its decision, including the criteria used by the [Agency] in making its decision."
- 14. While there is a presumption that "an administrative agency has properly performed its official duties," that presumption can be rebutted by showing the CON Section's decision is subject to reversal under one or more of the standards enumerated in N.C. Gen. Stat. § 150B-23(a). *E. Carolina Internal Med. v. N.C. Dep't of Health and Hum. Servs.*, 211 N.C. App. 397, 411, 710 S.E.2d 245, 255 (2011).
- 15. According to N.C. Gen. Stat. § 150B-23(a), an agency decision is subject to reversal if the agency substantially prejudiced Petitioner's rights and:
 - 1. Exceeded its authority or jurisdiction.
 - 2. Acted erroneously.
 - 3. Failed to use proper procedure.
 - 4. Acted arbitrarily or capriciously; or
 - 5. Failed to act as required by law.
- 16. As the Petitioners in this contested case, Pardee and AdventHealth must establish that their rights were substantially prejudiced as a result of the Agency's decision, in addition to

establishing that the Agency acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule. *Parkway Urology, P.A. v. N.C. Dep't of Human Servs.*, 205 N.C. App. 529, 696 S.E. 2d 187 (2010); *see also* N.C. Gen. Stat. §§ 131E-188(a) and 150B-23(a).

- The Court of Appeals has affirmed more than once that a CON petitioner must show both agency error and substantial prejudice; lack of one or the other is fatal to a petitioner's case. Britthaven, Inc. v. N.C. Dep't of Human Res., 118 N.C. App. 379, 382, 455 S.E.2d 455, 459 (1995); Presbyterian Hosp. v. N.C. Dep't of Health & Human Servs., 177 N.C. App. 780, 784-85, 630 S.E.2d 213, 216 (2006); Parkway Urology, P.A. v. N. Carolina Dep't of Health & Hum. Servs., Div. of Health Serv. Regul., Certificate of Need Section, 205 N.C. App. 529, 536–37, 696 S.E.2d 187, 193 (2010); Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Hum. Servs., Div. of Health Serv. Regul., Certificate of Need Section, 235 N.C. App. 620, 624, 762 S.E.2d 468, 471 (2014).
- 18. Agency Findings in prior cases are not persuasive or controlling in determining whether the Agency erred in a subsequent case. *Charlotte-Mecklenburg Hosp. Auth. v. N.C. Dep't of Health and Human Servs.*, No. COA11-339, 2011 N.C. App. LEXIS 2629, at *27-8 (N.C. Ct. App. Dec. 20, 2011) (unpublished opinion).
- 19. While "an agency's interpretation of a statute that it is tasked with administering should be accorded some deference by the reviewing tribunal," "[t]he agency's interpretation is only entitled to such deference, however, if it is both reasonable and based on a permissible construction of the statute." *AH North Carolina Owner LLC v. N.C. Dep't of Health & Human Servs.*, 240 N.C. App. 92, 110, 771 S.E.2d 537, 547-48 (2015) (citing Good Hope Health Sys., *LLC v. N.C. Dep't of Health & Human Servs.*, 189 N.C. App. 534, 544, 659 S.E.2d 456, 463, aff'd, 362 N.C. 504, 666 S.E.2d 749 (2008) (per curiam)); Craven Reg'l Med. Auth. v. N.C. Dep't of Health and Human Servs., 176 N.C. App. 46, 58, 625 S.E.2d 837, 844 (2006).
- 20. The weight given to the agency's interpretation by this tribunal depends upon "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade[.]" *AH North Carolina Owner LLC v. N.C. Dep't of Health & Human Servs.*, 240 N.C. App. 92, 110, 771 S.E.2d 537, 548 (2015) (quoting *Good Hope Health Sys., LLC v. N.C. Dep't of Health & Human Servs.*, 189 N.C. App. 534, 544, 659 S.E.2d 456, 463, *aff'd per curiam*, 362 N.C. 504, 666 S.E.2d 749 (2008)).
- 21. "The cardinal principle of statutory construction is that the intent of the legislature is controlling. In ascertaining the legislative intent, courts should consider the language of the statute, the spirit of the statute, and what it seeks to accomplish." *AH North Carolina Owner LLC v. N.C. Dep't of Health & Human Servs.*, 240 N.C. App. 92, 110, 771 S.E.2d 537, 548 (2015), (quoting *State ex rel. Utils. Comm'n v. Pub. Staff*, 309 N.C. 195, 210, 306 S.E.2d 435, 443–44 (1983)).
- 22. "A longstanding and consistent interpretation of a statute by an administrative agency warrants greater deference than an inconsistent or novel interpretation," but "courts will

not defer to an agency's interpretation of a statute that is an impermissible construction of the statute." AH North Carolina Owner LLC v. N.C. Dep't of Health & Human Servs., 240 N.C. App. 92, 111, 771 S.E.2d 537, 548 (2015), (citing Martin v. N.C. Dep't of Health & Human Servs., 194 N.C. App. 716, 724, 670 S.E.2d 629, 635, disc. review denied, 363 N.C. 374, 678 S.E.2d 665 (2009); Craven Reg'l Med. Auth. v. N.C. Dep't of Health and Human Servs., 176 N.C. App. 46, 58, 625 S.E.2d 837, 844 (2006)).

- 23. A court will, "under no circumstances," "follow an administrative interpretation in direct conflict with the clear intent and purpose of the act under consideration." *AH North Carolina Owner LLC v. N.C. Dep't of Health & Human Servs.*, 240 N.C. App. 92, 110, 771 S.E.2d 537, 548 (2015), (quoting *High Rock Lake Partners, LLC v. N.C. Dep't of Transp.*, 366 N.C. 315, 319, 735 S.E.2d 300, 303 (2012)).
- 24. An Agency's interpretation of the law is not entitled to deference if it is simply "because I said so," and if the Agency's interpretation of the law is only the decision in the case, that interpretation may be viewed skeptically by the reviewing court, and if the agency's own employees are unable to provide a coherent reason for their interpretation of the law, their interpretation is entitled to no deference. *See AH North Carolina Owner LLC v. N.C. Dep't of Health & Human Servs.*, 240 N.C. App. 92, 113, 771 S.E.2d 537, 549-50 (2015); *Cashwell v. Dep't of State Treasurer*, 196 N.C. App. 81, 89, 675 S.E.2d 73, 78 (2009).
- 25. Throughout this contested case Petitioners have alleged they were substantially prejudiced by the Agency's decision to approve the Mission Application. Each of Petitioners claims of substantial prejudice fall into one of three categories: 1) the Agency's failure to hold a Public Hearing regarding the Mission Application; 2) allegations of Agency error; and 3) speculative, non-specific claims competition-based of "harm".

Public Hearing

26. Pursuant to N.C. Gen. Stat. § 131E-185(a1)(2), the Agency was required to ensure that a public hearing was conducted at a place within the appropriate service area so long as one or more of the following circumstances applied: the review to be conducted is competitive; the proponent proposes to spend five million dollars (\$5,000,000) or more; a written request for a public hearing is received before the end of the written comment period from an affected party as defined in G.S. 131E-188(c); or the agency determines that a hearing is in the public interest. The use of the word "or" signifies that each circumstance stated in the statute is a separate, independent ground for a public hearing and the requirements for one part to apply cannot be interposed into a different, independent ground that the legislature determined alone triggered the right to a public hearing. Davison v. Duke Univ., 282 N.C. 676, 707, 194 S.E.2d 761, 780 (1973) ("Further, the disjunctive participle 'or' is used to indicate a clear alternative. The second alternative is not part of the first, and its provisions cannot be read into the first." (quotation omitted)); Grassy Creek Neighborhood All., Inc. v. City of Winston-Salem, 142 N.C. App. 290, 297, 542 S.E.2d 296, 301 (2001) ("In its elementary sense the word 'or', as used in a statute, is a disjunctive particle indicating that the various members of the sentence are to be taken separately " (quotation omitted)).

- 27. The Agency was required to hold a public hearing under N.C. Gen. Stat. § 131E-185(a1)(2) because the total projected capital expenditure for Mission's Project is \$13,320,500. (Jt. Ex. 1, Mission Application, MH-002, 173).
- 28. The statute's mandate is unequivocal and affords the Agency no discretion to consider or adopt an alternative to a public hearing where one is otherwise required.
- 29. While this Tribunal recognizes the severity of the COVID-19 pandemic, at the time the Agency was required to conduct a public hearing on Mission's 2022 Arden Application, there were no restrictions on public gatherings, such restrictions having been lifted pursuant to Executive Order No. 215, which was issued by Governor Cooper on May 14, 2021, about one year prior to the date upon which a public hearing should have been held in this review.
- 30. Additionally, the Agency has not identified any executive order or other authority relieving the CON Section of its statutory obligation to hold public hearings under N.C. Gen. Stat. § 131E-185(a1)(2) because of the COVID-19 pandemic when the hearing for this review would have otherwise been held in April 2022. (Tr. Vol. 4, Pittman, p. 675).
- 31. Despite the Agency's contention that it was justified in not conducting a public hearing because the original State of Emergency issued in Executive Order 116 was still in effect, the undisputed evidence shows that there is nothing in Executive Order 116 that would have prevented a public hearing from occurring, and the Agency did, in fact, conduct public hearings while the State of Emergency was in effect, both prior to, and after, the date upon which a public hearing should have been held in this review. Thus, the Agency cannot rely on the existence of the State of Emergency to justify its failure to conduct the public hearing on Mission's Application as required by N.C. Gen. Stat. § 131E-185(a1)(2).
- 32. Although the Agency further contends that it was aware at the time it conducted the public hearing on the 2022 Acute Care Bed CON that the State of Emergency was going to be lifted at a future date, if the State of Emergency had precluded public hearings, which the Tribunal concludes as a matter of law that it did not, only its actual repeal, rather than its anticipated repeal, could support the Agency's argument on this point. Pursuant to the decision in *AH N.C. Owner LLC*, 240 N.C. App. at 110, 771 S.E.2d at 547–48, this interpretation by the Agency is not entitled to deference as it is neither reasonable nor based on a permissible construction of N.C. Gen. Stat. § 131E-185(a1)(2).
- 33. Likewise, the attempts by the Agency to shift the burden to Petitioners to request a public hearing are of no avail. N.C. Gen. Stat. § 131E-185(a1)(2) unequivocally by its terms requires the Agency to "ensure that a public hearing is conducted at a place within the appropriate service area," and no reasonable interpretation of the statute required Petitioners to request a public hearing where Mission proposed to spend five million dollars (\$5,000,000) or more. While the plain reading of N.C. Gen. Stat. § 131E-185(a1)(2) reveals that a request for a public hearing by an affected party can also trigger the Agency's duty to conduct a public hearing, a determination by this Tribunal that Petitioners were required to request a public hearing would amount to an impermissible construction of the statute, and this Tribunal is not required to defer to the Agency on such a construction. *AH N.C. Owner LLC*, 240 N.C. App. at 110, 771 S.E.2d at 548.

- 34. Similarly, the Tribunal is unwilling, and is not required, to accept the Agency and Mission's position that because the Agency issued various notices to the public that were received by persons acting on behalf of Petitioners, Petitioners cannot challenge the Agency's failure to conduct a public hearing because it failed to raise the issue in its written comments. First, neither Mission nor the Agency cite to any statute, rule, regulation, or case law supporting this position, nor is the Tribunal aware of any. Secondly, accepting this position would create an exception to the Agency's statutory duty to ensure that a public hearing takes place when the Agency announced in advance that it would not comply with the statute. Finally, Petitioners would not have been aware of the harm they incurred until the point in time that the Agency issued its decision approving the Mission Application. A decision to deny the application would have meant that the failure to conduct a public hearing, while error, did not result in substantial prejudice to Petitioners' rights. Further, nothing under the CON law causes an affected person to lose its right to challenge an Agency action or inaction unless it raised the issue in its response to written comments.
- 35. Likewise, the procedures for written public remarks in lieu of a public hearing that were afforded Petitioners and others by the Agency, are merely a duplication of an existing right—the right to comment in writing—afforded to Affected Persons, and do not excuse the Agency's failure to conduct the statutorily required public hearing, nor are they a substitute for the ability of a member of the public, such as Petitioners, to comment orally at a public hearing. Had the General Assembly concluded that written comments were sufficient, it would not have included the requirement of a public hearing *in addition to* the requirement of permitting written comments. See In re K.W., 191 N.C. App. 812, 815, 664 S.E.2d 64, 66 (2008) ("[I]n interpreting a statute, we must presume the legislature meant for every word and provision to have meaning, and that our interpretation, if possible, does not render any provision meaningless.") An interpretation in this matter that the use of written comments in lieu of a public hearing would render the requirement of a public hearing meaningless.
- 36. The Legislature made clear that the process related to public hearings is materially different from filing written comments. With respect to public hearings, N.C. Gen. Stat. § 131E-185(a1)(2), provides:

At such public hearing oral arguments may be made regarding the application or applications under review; and this public hearing shall include the following:

- a. An opportunity for the proponent of each application under review to respond to the written comments submitted to the Department about its application;
- b. An opportunity for any person, except one of the proponents, to comment on the applications under review;
- c. An opportunity for a representative of the Department, or such other person or persons who are designated by the Department

to conduct the hearing, to question each proponent of applications under review with regard to the contents of the application;

- 37. The opportunity to ask questions in person and hear oral argument, as provided by the above statute, is unquestionably not present in the written comment process proposed by the Agency.
- 38. Mission and the Agency's contention that 86 separate CON reviews where a public hearing was required would be nullified if this Tribunal determines that the Agency erred in not having a public hearing and that AdventHealth was substantially prejudiced as a result is incorrect, and irrelevant even if it was correct.
- 39. Pursuant to N.C. Gen. Stat. § 131E-188(a), an affected person seeking to challenge a decision of the Agency to award a CON must file a petition for a contested case hearing within 30 days of the entry of the Agency decision, otherwise, pursuant to N.C. Gen. Stat. § 131E-187(c)(1), the Agency is required to issue the certificate of need to the applicant within 35 days of its decision if no request for a contested case hearing is made. Therefore, even assuming that the Agency took the maximum time allowable of 150 days for review of the applications provided for in N.C. Gen. Stat. §§ 131E-186 and 131E-185(a1) and (c), the time for filing a contested case hearing with respect to Agency decisions on each of the applications identified by the Agency would have run as of the date of this Final Decision.
- 40. Neither Mission nor the Agency has identified which of the 86 reviews, if any, are the subject of contested case hearings, and thus the information before the Tribunal is insufficient for it to determine whether any other Agency decision not involving the parties to this contested case will be affected as a result of this Final Decision. Regardless, and more importantly, the extent to which any other decision of the Agency is affected by the terms of this Final Decision is wholly irrelevant as to whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to act as required by law, failed to use proper procedure, acted arbitrarily and capriciously, or failed to act as required by rule or law when it failed to conduct the public hearing required under N.C. Gen. Stat. § 131E-185 with respect to Mission's Application. Violations of law do not become acceptable because they occur multiple times or because parties choose not to pursue legal avenues to have their rights enforced. Repeated errors by the Agency are not validated, excused, or made lawful simply because they were made numerous times.
- 41. While AdventHealth and Pardee have made the required showing of Agency error, they must also establish substantial prejudice as a matter of law to be entitled to summary judgment in this contested case. *Hospice at Greensboro, Inc. v. N.C. Dep't of Health & Human Servs.*, 185 N.C. App. 1, 17, 647 S.E.2d 651, 662 (2007); *Wake Radiology Servs., LLC v. N.C. Dep't of Health & Human Servs.*, 16 DHR 2092 (2016).
- 42. Specifically, courts of this State have held that where the Agency ignores the express language of the Certificate of Need law, substantial prejudice is proven as a matter of law. *See id.*

43. In Wake Radiology Services, LLC, v. North Carolina Department of Health and Human Services, ALJ Donald Overby issued a Final Decision reversing the Agency's decision to approve a certificate of need application filed by Pinnacle Health Services, LLC ("Pinnacle") for a diagnostic center to be located in Wake County. (16 DHR 2092, 16 DHR 2122, 16 DHR 2126 (N.C.O.A.H. Aug. 18, 2016)). The Agency permitted Pinnacle to change the type of equipment applied for during the Agency's review of the CON application after the statutorily mandated ability to file written comments and attend a public hearing had been offered to Affected Persons. (Id. at ¶ 46.) ALJ Overby concluded that permitting the project to be changed midstream effectively denied Affected Persons the right to file comments and attend a public hearing on the project to be implemented. (Id. at ¶¶ 45–49.) ALJ Overby reasoned:

The Agency's position that it may allow the applicant to change the scope of the application is in direct conflict both with the purpose of the CON law in N.C. Gen. Stat. § 131E-175(7) and with the clear intent of N.C. Gen. Stat. § 131E-182(a1) to permit the public (and especially competitors of the applicant) to comment, both in writing and in a public hearing, on the proposal submitted by the applicant. Otherwise, there is no opportunity for the public to present information which may contradict the applicant's assertions about the need for the service. (*Id.* at ¶ 45.)

Citing *Hospice at Greensboro, Inc. v. N. Carolina Dep't Health & Human Servs.*, 185 N.C. App 1, 17, 647 S.E. 2d 651, 661–62 (2007), ALJ Overby further concluded that the petitioners were substantially prejudiced as a matter of law "because they never had the opportunity to submit written comments or request a public hearing on Pinnacle's proposal[.]" *Wake Radiology Servs., LLC*, 16 DHR 2092, 16 DHR 2122, 16 DHR 2126, at ¶ 50.

- 44. In *Hospice at Greensboro*, the Court of Appeals held that "the issuance of a 'No Review' letter, which results in the establishment of a 'new institutional health service' without a prior determination of need, substantially prejudices a licensed, pre-existing competing health service provider as a matter of law." 185 N.C. App. at 18, 647 S.E.2d at 662. By issuing a "No Review" letter, the Agency allowed Liberty Home Care, L.L.C. ("Liberty") to open a hospice office in Greensboro, North Carolina without first obtaining a CON. (*Id.* at 3, 647 S.E.2d at 653). Having concluded that Liberty's proposed hospice office was a new institutional health service for which a CON was required, the Court of Appeals held that, as a hospice care provider in the service area, Hospice at Greensboro, Inc. ("HGI") was among the categories of persons entitled to "participate in the CON application process by filing 'written comments and exhibits concerning a proposal [for a new institutional health service] under review with the Department." (*Id.* at 16–17, 647 S.E.2d at 661 (quoting N.C. Gen. Stat. § 131E–185(a1) (2005)).
- 45. The *Hospice at Greensboro* Court concluded that, as a pre-existing, non-applicant, HGI, had a significant interest in the establishment of a new institutional health service in its service area, and this interest is vetted during the CON application process. Id. at 16, 647 S.E.2d at 661. Therefore, the Department's grant of an exemption from CON law, which deprived HGI of the opportunity to comment, "'substantially prejudice[d] a licensed, pre-existing [non-

applicant] competing health service provider as a matter of law' because it ke[pt] the competitor from being able to protect its interests[.]" *Ridge Care, Inc. v. N. Carolina Dep't of Health & Human Servs.*, 214 N.C. App. 498, 506, 716 S.E.2d 390, 395–96 (2011)(citing *Hospice at Greensboro*, 185 N.C. App. at 16–18, 647 S.E.2d at 661–62).

46. The Tribunal finds *Wake Radiology Services* persuasive and concludes that *Hospice at Greensboro* is controlling. In this case, the undisputed evidence reveals that no public hearing took place, and that AdventHealth and Pardee, pre-existing, non-applicants, were deprived of the opportunity to give oral comments at and to participate in a public hearing, and thus in accordance with the decision in *Hospice at Greensboro* can show, and have shown, that the Agency's failure to conduct the public hearing substantially prejudiced them as a matter of law.

Agency Error and Application of Statutory Review Criteria

- 47. This Tribunal has thoroughly reviewed the evidence of the record and finds no error in the Agency's determination that the Mission Application conformed with all applicable statutory (and, additionally, regulatory) criteria. The Agency's determination that the Mission Application conformed with all statutory criteria is supported by substantial evidence in the record in all respects.
- 48. Neither AdventHealth nor Pardee alleged that the Agency erred in finding the Mission Application conforming to Statutory Review Criteria 1, 7, 8, 12, or 14. As such the substantial evidence before this Tribunal is that the Agency's decision to find the Mission Application conforming to Statutory Review Criteria 1, 7, 8, 12, and 14 is reasonable and adequately supported.
- 49. This Tribunal finds no error and the Agency's decision finding the Mission Application conforming to Statutory Review Criteria 1, 7, 8, 12, and 14 is upheld.

Statutory Review Criterion 3

- 50. The Agency properly reviewed Mission's Application with respect to Statutory Review Criterion 3. The Agency's review of Mission's Application correctly identified that the information provided by Mission adequately and reasonably demonstrated the need for its proposed Arden FSED. The information submitted in the Mission Application adequately demonstrated the need for the project by identifying the proposed service area, providing historical market data, and the needs of the population proposed to be served.
- 51. The volume projections in the Mission Application are reasonable and adequately supported.
- 52. This Tribunal has already extensively discussed the Agency's application of Statutory Review Criterion 3.
- 53. The Agency was correct in finding the Mission Application conforming to Statutory Review Criterion 3. Mission provided information and data in its application to demonstrate that

it met all aspects of Criterion 3, and the Agency concluded that Mission reasonably projected the information in its Application.

54. The Agency's determination that the Mission Application conformed with Statutory Review Criterion 3 is supported by substantial evidence in the record in all respects. The Agency's decision finding the Mission Application conforming to Statutory Review Criterion 3 is upheld.

Statutory Review Criterion 4

- 55. The Agency properly reviewed Mission's Application with respect to Statutory Review Criterion 4. Both Pardee and AdventHealth allege because the Agency should not have found the Mission Application conforming to Statutory Review Criterion 3 that the Mission Application could not then be conforming to Statutory Review Criterion 4.
- 56. This tribunal has already determined that the Agency did not err in applying Statutory Review Criterion 3 to the Mission Application.
- 57. The substantial evidence before this Tribunal is that Mission adequately demonstrated that the proposed project to develop a FSED in Arden was the most effective alternative to meet the need identified in Mission's Application.
- 58. The Agency's determination that the Mission Application conformed with Statutory Review Criterion 4 is supported by substantial evidence in the record in all respects. The Agency's decision finding the Mission Application conforming to Statutory Review Criterion 4 is upheld.

Statutory Review Criterion 5

- 59. The Agency properly reviewed Statutory Review Criterion 5.
- 60. The Agency made its determination that Mission's Application was conforming to Statutory Review Criterion 5 because Mission adequately demonstrated the capital costs proposed by Mission are based on reasonable and adequately supported assumptions for all the reasons listed in Mission's Application; Mission adequately demonstrated the availability of sufficient funds for the capital needs of the proposal; and Mission adequately demonstrated sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses based on the information contained in Mission's Application.
- 61. Both Pardee and AdventHealth allege that Mission's projections and assumptions in its Application are not reasonable.
- 62. This Tribunal has already found and concluded that the assumptions and projections in the Mission Application are reasonable and adequately supported. The substantial evidence

before this Tribunal is that the Agency did not err in applying Statutory Review Criterion 5 to the Mission Application.

63. The Agency's determination that the Mission Application conformed with Statutory Review Criterion 5 is supported by substantial evidence in the record in all respects. The Agency's decision finding the Mission Application conforming to Statutory Review Criterion 5 is upheld.

Statutory Review Criterion 6

- 64. The Agency properly reviewed Mission's Application with respect to Statutory Review Criterion 6. The Agency's review of Statutory Review Criterion 6 correctly concluded that the proposed project by Mission to establish a FSED in Arden will not unnecessarily duplicate existing services.
- 65. Statutory Review Criterion 6 does not require that an applicant demonstrate the impact the proposed new service may have on other providers. Rather, Statutory Review Criterion 6 requires that an applicant identify existing providers and demonstrate that the proposed new health service will not be an unnecessary duplication of already existing services.
- 66. The Agency reviewed and applied Statutory Review Criterion 6 to the Mission Application in a manner consistent with how the Agency has evaluated other CON applicants under review Criterion 6, including AdventHealth.
- 67. Statutory Review Criterion 6 does not require the applicant to include in its CON application any harm or impact analysis on nearby competitors offering the same or similar services as those proposed in the application pending before the Agency.
- 68. Statutory Review Criterion 6 does not require the Agency to perform any harm or impact analysis to existing providers identified by an applicant.
- 69. The Agency did not determine that Pardee and AdventHealth were "irrelevant" as Pardee's expert Ms. Carter contends. Rather the Agency gave proper weight to the written comments of both Petitioners in opposition to the Mission Application, and to the issues raised by Pardee and AdventHealth regarding Review Criterion 6, and simply disagreed with those comments by Petitioners.
- 70. The Agency's decision finding the Mission Application conforming to Statutory Review Criterion 6 is reasonable and adequately supported. The proposed Mission FSED in Arden will increase access to emergency department services to the residents of Mission's proposed service area.
- 71. The Agency's determination that the Mission Application conformed with Statutory Review Criterion 6 is supported by substantial evidence in the record in all respects. The Agency's decision finding the Mission Application conforming to Statutory Review Criterion 6 is upheld.

Statutory Review Criterion 13

- 72. AdventHealth has alleged that the Agency erred in finding Mission's Application conforming to Criterion 13. AdventHealth's expert Ms. Sandlin stated that her opinion was based on the same facts as her opinion regarding Criterion 3. Pardee did not allege that the Agency erred in finding Mission's Application conforming to Statutory Review Criterion 13.
- 73. This Tribunal has previously summarized in detail its findings of fact regarding access to the medically underserved in the section addressing Criterion 3 and incorporates them here.
- 74. This tribunal has already determined that the Agency did not err in applying Statutory Review Criterion 3 to the Mission Application.
- 75. In its Application, Mission provided all the required information in terms of its historical services to all populations including underserved populations which included for example, Medicaid, low income, and all races and ethnicities. Further, that information was then projected in the Mission Application for the FSED to document how Mission would ensure that the FSED would be accessible to all populations.
- 76. The substantial evidence before this Tribunal is that the Agency's review and application of Statutory Review Criterion 13 is reasonable and adequately supported.
- 77. The Agency's determination that the Mission Application conformed with Statutory Review Criterion 13 is supported by substantial evidence in the record in all respects. The Agency's decision finding the Mission Application conforming to Statutory Review Criterion 13 is upheld.

Statutory Review Criterion 18a

- 78. The Agency properly reviewed Mission's Application with respect to Statutory Review Criterion 18a. The Agency's review of Statutory Review Criterion 18a correctly identified that Mission adequately demonstrated the expected effects of the proposed services in its Application on competition in the service area and adequately demonstrated that the proposal will have a positive impact on cost-effectiveness, quality, and access.
- 79. Mission provided the Agency with all the necessary information required under Statutory Review Criterion 18a. Mission provided the Agency with a detailed discussion of its proposed project's positive impact on competition, cost-effectiveness, quality of care, and access by medically underserved groups to services.
- 80. Statutory Review Criterion 18a does not require the Agency or Mission to perform any analysis of harm to or impact on analysis existing providers or competitors of the applicant.

- 81. The Agency's application of Statutory Review Criterion 18a was both reasonable and its decision was adequately supported. The Agency did not err in applying Statutory Review Criterion 18a to the Mission Application in this case.
- 82. The Agency's determination that the Mission Application conformed with Statutory Review Criterion 18a is supported by substantial evidence in the record in all respects. The Agency's decision finding the Mission Application conforming to Statutory Review Criterion 18a is upheld.

Statutory Review Criterion 20

- 83. The Agency properly reviewed Mission's Application with respect to Statutory Review Criterion 20 in this case.
- 84. The substantial evidence before this Tribunal is that the Agency conducted a review of Mission's licensure records as it does in all other CON reviews.
- 85. The Mission Application contains a detailed history of the compliance status and various certifications and quality-based recognitions of Mission and its affiliated providers. The Mission Application adequately and reasonably demonstrates that it is conforming to Statutory Review Criterion 20.
- 86. The Agency's determination that the Mission Application conformed with Statutory Review Criterion 20 is supported by substantial evidence in the record in all respects. The Agency's decision finding the Mission Application conforming to Statutory Review Criterion 20 is upheld.

Agency Review of 2022 Application and 2021 Application

- 87. Our courts have previously held that the Agency is not bound by prior decisions or findings, each application being unique and standing on its own.
- 88. The undersigned finds the testimony of the Agency's and Mission's witnesses regarding the differences in the 2021 Arden Application and the 2022 Arden Application to be reasonable and supported by competent evidence in the record. The undersigned finds that the Agency did not err in approving the 2022 Arden Application based upon Petitioners' claims that the 2022 Arden Application was not materially different from the 2021 Arden Application.
- 89. The Agency properly reviewed the information that was before it from the Mission Application in assessing Mission's conformity to applicable review criteria.
- 90. Mission adequately demonstrated conformity to each review criteria in its 2022 Arden FSED Application.

Petitioners' Arguments Regarding Mission's 2021 EMR

- 91. Petitioners' theory that the 2021 EMR demonstrates that Mission intentionally lied in its 2022 Application in an attempt to mislead the Agency and misrepresented the expected performance of the proposed FSED in Arden is not supported by the evidence. Rather, Petitioners' entire theory is grounded in assumptions unsupported by substantial evidence.
- 92. Given the lack of evidence either tying the information contained in the 2021 EMR to the 2022 Application or that there was any obligation on the part of Mission to include projections or models developed as part of its internal business plan related to a different application, the allegations in the instant case by the Petitioners regarding the EMR prepared by Mission in connection with its 2021 denied CON application are both unpersuasive and unsupported.

Petitioners' Speculative Competition Claims

- 93. Harm that is "simply the result of normal competition" does not equate to substantial prejudice. *CaroMont Health, Inc. v. N.C. HHS Div. of Health Serv. Regulation,* 231 N.C. App. 1, 8, 751 S.E.2d 244, 249 (2013).
- 94. "The law does not protect one against competition." *Bruton v. Smith*, 225 N.C. 584, 586, 36 S.E.2d 9, 10 (1945).
- 95. Parkway Urology made clear that substantial prejudice requires more than increased competition: "[Petitioner's] argument, in essence, would have us treat any increase in competition resulting from the award of a CON as inherently and substantially prejudicial to any preexisting competing health service provider in the same geographic area. This argument would eviscerate the substantial prejudice requirement contained in N.C. Gen. Stat. § 150B-23(a)." Parkway Urology, 205 N.C. App. at 539, 696 S.E.2d at 195.
- 96. Economic loss from the approval or denial of a CON application does not amount to substantial prejudice, as it amounts to harm from normal competition. *Cumberland County Hosp. Sys. v. N.C. HHS*, 237 N.C. App. 113,123, 764 S.E.2d 491, 498 (2014); *CaroMont Health, Inc.* 231 N.C. App. at 10, 751 S.E.2d at 251.
- 97. "[Everyone has the] right to enjoy the fruits and advantages of his own enterprise, industry, skill[,] and credit. He has no right to be protected against competition." *Coleman v. Whisnant*, 225 N.C. 494, 506, 35 S.E.2d 647, 655 (1945).
- 98. The loss of patients and profits does not amount to substantial prejudice. *See Blue Ridge Healthcare Hosp. Inc. v. N.C. HHS*, 255 N.C. App. 451, 464, 808 S.E.2d 271, 279; *see also Ridge Care, 214 N.C. App.* at 506, 716 S.E.2d at 396.
- 99. Pardee's and AdventHealth's identified bases for claiming substantial prejudice, other than that substantial prejudice resulting from the failure of the Agency to conduct a public hearing, amount to either allegations of agency error, or speculative, non-specific claims of competition-based "harm" and do not constitute "substantial prejudice" as that term has been

consistently defined by our courts. *See generally, e.g., Parkway Urology*, 205 N.C. App. 529, 696 S.E.2d 187.

- 100. However, as set forth above, because the Agency erred in failing to comply with the terms of N.C. Gen. Stat. § 131E-185(a1)(2) when it failed to conduct a public hearing, Petitioners have established substantial prejudice as a matter of law. See Hospice at Greensboro, Inc. v. N. Carolina Dep't Health & Human Servs., 185 N.C. App 1, 17, 647 S.E. 2d 651, 661–62 (2007); Wake Radiology Servs., LLC v. N.C. Dep't of Health & Human Servs., 16 DHR 2092 (2016).
- 101. Accordingly, the Tribunal concludes as a matter of law that Pardee and AdventHealth have met their respective burdens of proof to demonstrate substantial prejudice as a matter of law, resulting from the Agency's failure to conduct a public hearing. This, standing alone, requires a Final Decision reversing the Agency Action of approving the Mission Application.

FINAL DECISION

The Undersigned finds and holds that there is sufficient evidence in the record to properly and lawfully support the Conclusions of Law cited above. Based upon the foregoing Findings of Fact and Conclusions of Law, the Undersigned enters this Final Decision pursuant to N.C. Gen. Stat. § 150B-34 and N.C. Gen. Stat. § 131E-188, based upon the preponderance of the evidence, having given due regard to the demonstrated knowledge and expertise of the Agency with respect to facts and inferences within the specialized knowledge of the Agency.

The Agency decision is REVERSED. AdventHealth and Pardee met their respective burdens to show that the Agency acted erroneously, failed to use proper procedure, and failed to act as required by law or rule when the Agency approved Mission's Application without having held a statutorily mandated public hearing. AdventHealth and Pardee also established that they were substantially prejudiced as a result of the Agency's failure to hold a public hearing prior to approving the Mission Application.

NOTICE

This is a Final Decision issued under the authority of N.C. Gen. Stat. § 131E-188.

Under the provisions of North Carolina General Statute 131E-188(b), any party wishing to appeal the final decision of the Administrative Law Judge must file a Notice of Appeal with the Office of Administrative Hearings and serve the Notice on the N.C. Department of Health and Human Services and all other affected persons who were parties to the contested case. The appealing party must file the Notice within 30 days after being served with a written copy of the Administrative Law Judge's Final Decision. Pursuant to N.C. Gen. Stat. 131E-188(b1) before filing an appeal of a final decision granting a certificate of need, the affected person shall deposit a bond with the Clerk of the Court of Appeals. In conformity with the Office of Administrative Hearings' Rule 26 N.C.A.C. 03.012 and the Rules of Civil Procedure, N.C. Gen. Stat. 1A-1, Article 2, this Final Decision was served on the parties the date it was placed in the mail as indicated by the date on the Certificate of Service attached to this Final Decision.

IT IS SO ORDERED.

This the 22nd day of June, 2023.

David F Sutton

Administrative Law Judge

CERTIFICATE OF SERVICE

The undersigned certifies that, on the date shown below, the Office of Administrative Hearings sent the foregoing document to the persons named below at the addresses shown below, by electronic service as defined in 26 NCAC 03 .0501(4), or by placing a copy thereof, enclosed in a wrapper addressed to the person to be served, into the custody of the North Carolina Mail Service Center who subsequently will place the foregoing document into an official depository of the United States Postal Service.

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This the 22nd day of June, 2023.

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