STATE AGENCY ACTION REPORT
ON APPLICATION FOR CERTIFICATE OF NEED

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number:

Braden Clinic, LLC/CON #10522
5068 Annunciation Circle, Suite 111
Ave Maria, Florida 34142

Authorized Representative: Beau Braden
Chief Executive Officer
(239) 867-4395

2. Service District/Subdistrict

District 8/Subdistrict 8-2 (Collier County)

B. PUBLIC HEARING

A public hearing was not held or requested for the proposed project submitted.

Letters of Support

The Braden Clinic provides a volume of letters of support from entities and individuals identified as collaborative partners in health care, community leaders, patients from within the service area, residents of the community and existing health providers. A form letter excerpt is present among the letters of support. A petition from Ave Maria University students and staff along with Immokalee form letters are also included in the letters of support volume.

Letters of support endorse the proposal in light of the applicant's historical provision of outpatient services to the community, the need for additional medical services within the rural communities of Collier County, rapid expansion and demand for services in the area, the potential capacity for the proposal to enhance the health, safety and wellness of residents in the rural area, the need to provide a broader range of health services to the community, the time/cost of traveling to Naples or elsewhere for medical services, the deterrence from accessing

care facilitated by the constraints of travel within the service area, the need to access emergency services within a timely manner, reducing the time to access emergency care, the need to access obstetrical care within a reasonable time frame and the preventable disability/death from chronic illnesses attributed to delays and barriers to accessing care within the proposed service area.

Letters of support are noted from:

- Michael J. Choate, Fire Chief/District Manager, Immokalee Fire Control District
- Jaysen Roa, President & Chief Executive Officer, Avow Hospice
- Reverend Cory A. Mayer, S.T.L, S.T. Dc, Pastor and President of Ave Maria Parish, INC
- Jim Towey, President, Ave Maria University
- William L. McDaniel, Jr., Vice Chairman, Collier County Commissioner, District 5
- Oscar Hentschel, Executive Director, Collier County Housing Authority
- Norma Garcia, Chair, Immokalee MTSU Advisory Committee
- Gayane Stepaniam, Executive Director, Redlands Christian Migrant Association
- Dr. Frank Nappo, Chairman, Immokalee CRA Advisory Board
- AthenaHealth
- Mike Ellis, CEO, Healthcare Network of Southwest Florida

C. PROJECT SUMMARY

Braden Clinic, LLC (CON application #10522) BC or the applicant, is seeking to establish a new general acute care hospital consisting of 25 beds in Ave Maria, Florida in Collier County (Subdistrict 8-2). The proposal, Braden Clinic Hospital, is a private not-for-profit hospital operated by Braden Clinic, LLC. The applicant currently runs a multispecialty clinic within the service area with eight practitioners. The applicant indicates that services offered at the Braden Clinic include:

- Pediatric and adult medicine
- Psychiatric
- Addiction
- Urgent care
- Audiology
- Psychotherapy services

The applicant indicates that most patients served by Braden Clinic are from Ave Maria, Immokalee and surrounding rural communities. BC indicates that clinic operations have been a tremendous success and that quality of care has been excellent within a community that lacks access to health care particularly for addiction medicine services, which are not readily available throughout the region. A narrative description of the applicant's three-phase process of developing services in the Ave Maria area are outlined on pages 9-16 CON application #10522. The three phases of Braden Clinic's health care service development are noted to include: Phase I with the establishment of urgent care services; Phase II the addition of a new clinic space, exam rooms, a procedure room, administrative space and the recruitment of providers to Ave Maria in order to support the growth and needs of the population; and Phase III which involves the establishment of the hospital in this proposal.

The applicant states that the proposal will offer an efficient pared-down "micro-hospital" service complement, which will meet the needs of the service area while maintaining cost-efficient and high quality care. BC maintains that the hospital will not be a direct competitor of existing medical centers but serve as a mutually beneficial collaborator that partners with area medical centers in order to successfully sustain hospital operations and provide a seamless continuum of care as a result of this model. The applicant determines that the proposed hospital will further competition.

With this proposal, BC states that it will provide emergency services and essential outpatient/inpatient hospital services to the severely underserved residents of the rural service area. The applicant expects the proposed hospital to serve as a bridge between residents with little access to care and the medical center that can best address their complex care needs.

BC maintains that there is an immediate and urgent need to provide a hospital for the residents of the primary service area (PSA) and notes that the population within Zip Code 34142 is a medically underserved community which lacks primary care physicians, an acute care hospital and outpatient services. The applicant notes that the lack of medical access adversely impacts health outcomes in the area as evidenced by high rates of infant mortality within the targeted service area and the poor standard of care for stroke victims. The applicant maintains that residents must drive 40 to 70 minutes to the closest hospital and that rapid population growth in the PSA will contribute to greater need for adequate medical access.

The applicant does not indicate any Schedule C conditions in this proposal.

D. REVIEW PROCEDURE

The evaluation process is structured by the certificate of need review criteria found in Sections 408.035 and 408.037, Florida Statutes; and applicable rules of the State of Florida, Chapters 59C-1 and 59C-2, Florida Administrative Code. These criteria form the basis for the goals of the review process. The goals represent desirable outcomes to be attained by successful applicants who demonstrate an overall compliance with the criteria. Analysis of an applicant's capability to undertake the proposed project successfully is conducted by evaluating the responses and data provided in the application, and independent information gathered by the reviewer.

Applications are analyzed to identify strengths and weaknesses in each proposal. If more than one application is submitted for the same type of project in the same subdistrict, applications are comparatively reviewed to determine which applicant best meets the review criteria.

Rule 59C-1.010(3) (b), Florida Administrative Code, prohibits any amendments once an application has been deemed complete; however, two exceptions exist regarding receipt of information concerning general hospital applications. Pursuant to Section 408.039(3)(c), Florida Statutes, an existing hospital may submit a written statement of opposition within 21 days after the general hospital application is deemed complete and is available to the public. Pursuant to Section 408.039(3)(d), Florida Statutes, in those cases where a written statement of opposition has been timely filed regarding a certificate of need application for a general hospital, the applicant for the general hospital may submit a written response to the Agency within 10 days of the written statement due date. The burden of proof to entitlement of a certificate rests with the applicant. As such, the applicant is responsible for the representations in the application. This is attested to as part of the application in the certification of the applicant.

As part of the fact-finding, the consultant, Bianca Eugene, analyzed the application in its entirety.

E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

The following indicate the level of conformity of the proposed project with the review criteria and application content requirements found in Sections 408.035, and 408.037, and applicable rules of the State of Florida, Chapters 59C-1 and 59C-2, Florida Administrative Code.

The reviewer presents the following analysis and review of CON application #10522 with reference to the identified statutory criteria of Section 408.035, Florida Statutes.

1. Statutory Review Criteria

For a general hospital, the Agency shall consider only the criteria specified in ss. 408.035 (1)(a), (1)(b), except for quality of care, and (1)(e), (g), and (i), Florida Statutes. ss.408.035(2), Florida Statutes.

a. Is need for the project evidenced by the availability, accessibility and extent of utilization of existing health care facilities and health services in the applicant's service area? ss. 408.035(1)(a) and (b), Florida Statutes.

Acute Care Hospital Utilization District 8/Subdistrict 8-2/Statewide 12-Month Period Ending June 30, 2017				
Hospital/Area	**Beds**	**Bed Days**	**Patient Days**	**Utilization**
Naples Community Hospital	368	134,320	67,100	49.96%
NCH Healthcare System North Naples Hospital Campus	249	90,885	48,121	52.95%
Physicians Regional Medical Center – Collier Blvd.	100	36,500	13,154	36.04%
Physicians Regional Medical Center – Pine Ridge	101	36,865	24,259	65.80%
Subdistrict 8-2 Total	**818**	**298,570**	**152,634**	**51.12%**
District 8 Total	**4,184**	**1,512,120**	**816,523**	**54.00%**
Statewide	**51,096**	**18,795,983**	**10,868,728**	**57.82%**

Source: Florida Hospital Bed and Service Utilization by District, published January 2018

For the 12-month period ending on June 30, 2017 District 8, Subdistrict 8-2 had 818 licensed acute care beds and a utilization rate of 51.12 percent. The subdistrict utilization rate was lower than the total utilization rate for District 8, 54.00 percent and the statewide utilization rate, 57.82 percent. Acute care utilization in Subdistrict 8-2 is depicted for the three-year period ending June 30, 2017 in the chart below.

District 8, Subdistrict 8-2 Acute Care Hospital Utilization: Three Years Ending June 30, 2017			
	JUL 2014 - JUN 2015	**JUL 2015 - JUN 2016**	**JUL 2016 - JUN 2017**
Number of Acute Care Beds	823	823	818
Percentage Occupancy	51.49%	51.99%	51.12%

Source: Florida Bed Need Projections and Services Utilization, published January 2016 - January 2018
Note: Bed counts are as of June 30 for the appropriate years

From the three-year period between July 1, 2014 – June 30, 2015 and July 1, 2016 – June 30, 2017, the acute care inventory within Subdistrict 8-2 experienced a five-bed reduction and a 1.06 percent loss of patient days.

In District 8, Subdistrict 2, Collier County, Physicians Regional Medical Center – Pine Ridge is currently approved to add five acute care beds via notification #NF120011.

The following is a chart depicting District 8 population estimates for July 2017 and January 2024.

District 8 Total Population Estimates and Percent Changes by County: July 2017 to January 2024

County	Total Pop. JUL'17	Total Pop. JAN '24	Percent Change	Age 65+ JUL '17	Age 65+ JAN '24	65+ Percent Change
Charlotte	170,175	179,315	5.37%	61,812	68,787	11.28%
Collier	360,545	403,492	11.91%	101,551	120,177	18.34%
Desoto	34,750	35,322	1.65%	6,720	7,393	10.01%
Glades	13,185	13,878	5.26%	3,188	3,552	11.42%
Hendry	38,610	39,575	2.50%	5,141	5,996	16.63%
Lee	714,094	818,400	14.61%	178,338	218,587	22.57%
Sarasota	404,859	434,295	7.27%	136,141	156,269	14.78%
District 8 Total	1,736,218	1,924,277	10.83%	492,891	580,761	17.83%
State Total	20,382,303	22,132,607	8.59%	3,946,081	4,754,114	20.48%

Source: Agency Population Estimates published February 2015

Collier has the third largest total population and 65+ population across all subdistricts within District 8. The total population and 65+ population are expected to increase at rates that exceed the forecasted changes in population anticipated within District 8 and the State of Florida.

The Service Area

Braden Clinic identifies the PSA/proposed home Zip Code for the facility as 34142 in Collier County (600 square miles), the secondary service area (SSA) consists of Zip Codes 34143, 34141 and 34120. The applicant determines that need for a hospital is evident in the lack of an inpatient hospital within the proposed service area which has a current population estimated to be 34,213. BC notes that the service area has experienced major population growth with new planned communities that are expected to contribute to significant growth over the next five years.

The applicant indicates that the proposed service area was determined through review of certificates of need applications, data of patients from BC and consultation with acute care hospitals within Subdistrict 8-2. In particular, BC corresponded with the Director of the Medical Staff Services office at Naples Community Hospital (NCH) who stated that NCH

uses a 15-mile radius around their acute care hospitals in order to determine their service area. The applicant states that the staff of the Medical Staff Services office explained that policies are maintained mandating that physicians live and practice within these boundaries and are able to travel to the hospital within 30 minutes in order to join the medical staff. From these parameters and a geographic analysis of the Immokalee and Ave Maria communities within Collier County, BC determined that the Immokalee and Ave Maria communities are not within the NCH geographical boundaries and consequently physicians that reside in practice in Ave Maria and Immokalee cannot join the medical staff at NCH.

In analyzing the proposed service area, BC determines that:

- 91.0 percent of the patients currently seen at the BC are from Zip Code 34142
- 1.0 percent of the patients currently seen at the BC are from Zip Code 34143
- 6.0 percent of the patients currently seen at the BC come from Zip Code 34120
- 1.0 percent come from other area Zip Codes
- 99.0 percent of patients reside within a 10-mile radius of the Braden Clinic

The applicant notes that a geographical analysis of the proposed service area reveals that the 10-mile radius surrounding the four Zip Codes within this radius do not cross into Hendry or Lee County.

The applicant expects a 70.0 percent capture of Zip Code 34143 (n.b. the applicant notes zip code 34143 is located within Zip Code 34142 which is the applicant's PSA), 10.0 percent capture of Zip Code 34141 and also 10.0 percent capture of Zip Code 34120 (CON application #10522, Page 36). BC states that 85.4 percent of inpatient discharges will come from Zip Code 34142 and the remaining 14.6 percent of discharges will come from 34143, 34120 and 34141.

BC provides descriptions of the population size and wealth distribution of Subdistrict 8-2, neighboring communities and its proposed service area. The applicant notes that while Collier County is one of the wealthiest counties in Florida there are significant regions of poverty, notably the 35-45 miles of rural communities along the coast. BC indicates that population growth within Collier County from 1995 – 2015 (2.8 percent per year, from 199,272 – 346,805 residents) exceeding the rate of growth across the United States and the State of Florida within the same time period. The applicant notes that the town of Immokalee accounts for 6.6 percent of the population in Collier County. The applicant describes Naples as an affluent coastal community and the urban heart of Collier County with a median income ($86,880) that exceeds the Florida median

income ($50,860). The applicant states that the median age within Collier County is 66.8 years while the median age across the State of Florida is 42.1. BC indicates that this elderly and wealthy population translates into a very needy and lucrative market for health care and the area provides many expensive physician practices and nursing homes. Per the US Census Bureau, the applicant notes that the population of the Naples-Immokalee-Marco Island, Florida metro area has increased 13.6 percent from 2010 – 2016. The applicant provides the following chart highlighting the differences between the targeted PSA and Collier County:

Census Field	Collier County	Immokalee CDP
Population, Census, April 1, 2010	321,520	24,154
Persons under 5 years, percent, April 1, 2010	5.2%	10.7%
Persons under 18 years, percent, April 1, 2010	19.5%	33.7%
Persons 65 years and over, percent, April 1, 2010	26.4%	5.4%
Foreign born persons, percent 2012 – 2016	23.8%	45.4%
Median value of owner-occupied housing units, 2012 – 2016	$291,900	$81,400
Language other than English spoken at home, percent of persons age 5 years+, 2012 – 2016	32.4%	81.2%
High school graduate or higher, percent of persons age 25 years+	85.7%	39.3%
Bachelor's degree or higher, percent of persons age 25 years+ 2012 - 2016	33.9%	4.8%

Source: CON application #10522, Page 39

BC asserts that there is no hospital located in the proposed PSA and no hospitals are located near the edge of the proposed service area. In addition to the absence of hospitals within the PSA, the applicant notes that residents of the PSA must drive 40 to 70 minutes, pay for transportation, or take a long ambulance ride to get to a hospital. In review of the health care usage by patients within Zip Code 34142, BC states that 98.0 percent of patients receive emergency care from hospitals in Naples, Fort Myers, Lehigh Acres and Clewiston.

The applicant describes Ave Maria as a newly planned master community established in 2007. BC underscores rapid population growth within the community, the addition of Ave Maria University, a medical device plant (Arthrex) and seasonal residents who all reside within the proposed service area. The applicant notes that other than the Braden Clinic, the community does not have medical services or a pharmacy. The applicant describes how residents of the area who are not patients of the clinic must drive at least 27 miles to the nearest hospital and approximately 12 miles to the nearest pharmacy in

Immokalee. Since Ave Maria is a new community, BC indicates that census data is not available for the population but the population is estimated to be ~7,600 – 8,000 including the resident university students.

BC describes Immokalee as an unincorporated community seven miles from Ave Maria with a population of 24,154 (2010). From October – May, the applicant notes that the migrant population expands the population to ~60,000. BC indicates that the Immokalee/Everglades service area has been designated as a Health Professional Shortage Area (HPSA) and the low-income migrant farmworker community has been designated as a Medically Underserved Population. BC maintains that the health care needs of the Seminole Tribe would also benefit from the addition of a local hospital. Outside of a small clinic with no diagnostic equipment operated from a trailer, the applicant discusses the lack of health care resources of the Seminole Tribe in Immokalee.

The applicant notes that Florida State University (FSU) and the Healthcare Network of Southwest Florida (HNSF) have partnered to operate a clinic in Immokalee that accepts insured and uninsured patients. The applicant references HNSF's support for the proposal.

Population Size and Growth

BC provides a table summarizing the anticipated growth within its proposed service area and indicates that population growth is derived from population changes of the master planned communities, Rural Lands West and Ave Maria, along with the Immokalee community. The following table demonstrates the applicant's forecasted population changes within its proposed service area:

Braden Clinic Service Area Forecasted Population Changes					
Year	**PSA**	**SSA**	**Service Area Total Population**	**Subdistrict Population**	**District Population**
2017	33,093	31,559	64,652	363,945	1,751,234
2023	40,659	37,513	78,172	403,492	1,924,277
Population Growth	7,566	5,954	13,520	39,547	173,043
Percent Growth	**23%**	**19%**	**21%**	**11%**	**10%**

Source: CON application #10522, Page 44

BC reiterates the targeted service area's status as a medically underserved community and Immokalee/Everglades status as a HPSA. For primary care physicians, the applicant notes that the Braden Clinic in Ave Maria is on Florida Department of Health's (FDOH) list of Facilities Approved as Areas of Need since September 18, 2015.

The applicant additionally provides maps of the 15-mile radius surrounding Ave Maria, Florida and Immokalee, Florida. The applicant notes that the nearest hospital (NCH North) is located 23 miles from the proposed hospital. BC also provides a table of the hospitals that are closest to the centroids of population within the proposed service area which is reproduced below:

Distance and Ideal Time from Three Nearest Hospitals to Centroids of Service Area Zip Codes				
Hospital Name	**Centroid 34142 Miles (Min)**	**Centroid 34143 Miles (Min)**	**Centroid 34120 Miles (Min)**	**Centroid 34141 Miles (Min)**
NCH North Hospital	31.3 (45)	34.0 (46)	14.6 (22)	-
Physicians Regional Medical Center – Pine Ridge	32.5 (45)	35.6 (44)	15.4 (23)	41.3 (48)
Lehigh Regional Medical Center	38.3 (51)	24.2 (33)	-	-
Physicians Regional Medical Center – Collier Blvd	-	-	19.9 (29)	31 (36)
NCH Downtown Hospital	-	-	-	36.9 (46)

Source: CON application #10522, Page 47

Using the National Academies report, *Access to Healthcare in America,* definition for access as: "the timely use of personal health services to achieve the best possible health outcomes" and the 2-14 RUPRI Health Panel Report on rural health care access definition: people (age, education, occupation, cultural difference from provider), place (travel burden), provider (hours, cultural competence, patient-centeredness) and payment (out-of-pocket costs, pre-authorization requirements) the applicant provides the following analysis of access issues within its PSA:

People	Place	Provider	Payment
Emergency Room utilization below national average	Travel time to health care more than reasonable at 40 – 70 minutes	Low primary care professional availability	Number of patients on Medicaid is rising
Utilization rate of preventative services low	Mobility challenged population in Immokalee	Shift to concierge medicine has reduced poorer patient access to relevant services	Percentage of uninsured Hispanics is 39.2 percent in Collier County; Immokalee is 74.6 percent Hispanic
Migrant farmworker population in 34142 is a designated Medically Underserved Population	Electronic Health Information Exchanges not interconnected fragmented care	Long wait times for appointments especially in season	In 2014 the uninsured Collier County population with less than a high school education was 52.6 percent. In Immokalee 62.4 percent of the population has a less than a high school diploma
Culturally sensitive care lacking (e.g. language, different norms, embarrassment, misunderstanding of financial responsibility, lack of education	Health Professional Shortage Area	Limited access to women's health/no birthing center in 34142	In 2016, 46.7 percent of residents were living below the poverty line (Florida average 20 percent)

Source: CON application #10522, Page 48

BC provides a summary of comments from a Survey on Health and Healthcare for Collier County from the Collier County Health Assessment 2013 in Appendix Q of CON application #10522.

The applicant notes that there are currently zero beds per 1,000 persons within the proposed service area. Based on current trends in population growth, BC anticipates that there will continue to be zero beds per 1,000 persons in 2023 in the absence of implementation of the proposed hospital. The applicant identifies a disparity and concludes that the lack of beds within a reasonable distance (within 20 minutes) shows that there is a geographic barrier to access within the proposed service area. BC describes the disparity in access as a function of the licensed acute care beds per 1,000 population as of December 31, 2017, noting that within the proposed service area, subdistrict, district and state, the following trends:

- Zero acute care beds per 1,000 within the proposed service area
- 2.25 acute care beds per 1,000 within Subdistrict 8-2
- 2.39 acute care beds per 1,000 within District 8
- 2.54 acute care beds per 1,000 within the State of Florida

The applicant provides an analysis of the bed supply per 1,000 of the proposed service area in comparison to other developing countries in order to demonstrate the disparity in access and insufficient bed supply that prevents residents of the proposed service area from accessing needed care. BC notes that in opposition to CON application #10185, Naples Community Hospital North provided a written opposition statement stating that 20 to 30 minutes was a reasonable travel time standard for accessing general acute care hospital services, with 30 minutes being outside the accepted range. The applicant indicates that the nearest hospital to the proposed service area is 23.0 miles away which requires 40 to 70 minutes driving time. BC states that the proposed facility is approximately 23.0 miles from Naples Community Hospital-North Naples.

In reference to access standards for critical access hospitals defined by the Centers for Medicare and Medicaid Services pursuant to 1886 (d)2(D) and 1886(d)(8)(E), Section 1861(e) of the Social Security Act, the applicant evaluates the driving distance from Ave Maria to NCH –North Naples using secondary roads and from Immokalee to NCH – North Naples using secondary roads. BC determines that from Ave Maria to the nearest hospital the total travel time is between 55.5 minutes and 70 minutes and from Immokalee to the nearest hospital the total travel time is between 59.5 minutes and 73 minutes. The applicant maintains that both travel times are dependent upon traffic, traffic signals and time of day. From Immokalee to Lehigh Regional Medical Center, the applicant determines that the total travel time is between 47.3 minutes and 60 minutes depending on the same variables in the previous scenario.

BC provides a Google Maps Study of the distance and driving times from BC, Downtown Immokalee and the nearest emergency rooms and hospitals (NCH Stand-Alone ER, NCH North Hospital, Physicians Regional Medical Center – Pine Ridge, Lehigh Regional Medical Center, NCH Downtown Hospital, Physicians Regional Medical Center – Collier and Cleveland Clinic Weston). All of the applicant's analyses demonstrate the distances and drive times from various points within the applicant's proposed service area to the nearest hospitals and emergency rooms, are greater than 20 to 30 minutes and beyond 30 minutes.

The applicant notes that significant geographic access problems exist within the PSA and that driving conditions such as two-lane roads and a number of other variable travel constraints present a significant access barrier as well as obstacles to quality care in time-sensitive emergencies resulting in patients being deterred from seeking care.

BC states that Google Maps provides a low estimate of time that does not account for many normal obstacles that prolong the drive between the PSA and existing hospitals. The applicant references sentiments expressed in letters of support as evidence of actual drive times which exceed Google Maps estimates. The following table is provided in the application to reflect drive times provided via Google Maps analysis:

	34142 Zip Code Centroid	Immokalee	Braden Clinic or Ave Maria Town Center
Drive time to current closest acute care hospital NCH North	51 min (Google Maps)	40 min (Google Maps) 59.5 – 73 min (Travel study)	38 min (Google Maps) 55.5 – 70 min (Travel study)
Drive time to new Braden Clinic Hospital	21 min (Google Maps)	15 min (Google Maps) 17 min (Travel study)	9 min (Google Maps) 10 min (Travel study)
Drive Enhancement (savings in time from previous closest acute care hospital to new facility)	28 min (Google Maps)	25 min (Google Maps) 42 – 56 min (Travel study)	29 min (Google Maps) 45.5 – 60 min (Travel study)

Source: CON application #10522, Page 73

The applicant anticipates that the proposed facility will reduce the drive time from the two major communities of Immokalee and Ave Maria from approximately 30 to 60 minutes to nine to 17 minutes—a reasonable drive time to access health care.

BC analyzes barriers to emergency medical services (EMS) along with the potential time savings implementation of the proposal would offer. The applicant indicates that there are three EMS stations within the PSA (34142), two stations in Immokalee, one within Ave Maria and two EMS stations within the SSA. BC states that ambulances take approximately two hours to transport patients from Zip Code 34142 to one of the closest hospitals and return. BC expects for the establishment of the proposal to reduce transport times.

The applicant also notes that EMS is also overused as a "taxi" for non-emergent medical problems due to travel constraints of residents which contributes to significant unnecessary costs for Collier County. A table provided by BC summarizes distances from EMS services to the proposed facility with anticipated reductions in time from existing emergency rooms. The applicant created another table summarizing EMS run times within the PSA and SSA from 2015 and 2016 using the FDOH EMSTARS data demonstrating that from within the PSA, the historic time from when the unit is notified to travel at the destination is 58 minutes. From within the applicant's SSA, the analysis provided reflects that the historic time from when the unit is notified to travel at the destination is 41 minutes. The applicant states that current EMS protocols dictate that once the patient is offloaded and the ambulance leaves, the ambulance is reported back in service and consequently the total time it takes to complete a single call for the PSA is 79 minutes and for the SSA is 61 minutes. BC states that in the event that an ambulance from the proposed service area returns back in service after leaving the hospital (but has not yet returned to the station), ambulances can be rerouted to local calls in Naples, depleting the service area of EMS resources.

The applicant provides the following table which reflects the percentage of cases that indicated "any kind of ambulance delay" by Zip Code and year within the proposed service area:

Percentage of Cases that Indicated any Kind of Delay by Zip Code and Year**			
Service Area	**Zip Code**	**2015**	**2016**
Primary Area	34142	6.44%	6.10%
	34143*	2.53%	9.72%
Secondary Area	34120	10.07%	11.66%
	34141*	38.89%	35.00%
Note: *The sample size for the marked zip code area is small ** Delay includes response delay, scene delay, transport delay and turn-around delay			

Source: CON application #10522, Page 80

Based on the results of this analysis, the applicant determines that EMSTARS data reflect significant barriers in emergency access for the proposed service area. An excerpt from the District Manager and Fire Chief Michael J. Choate's letter of support is provided as testimonial evidence of the analysis provided.

In reference to 2018 Collier County EMS/Fire Department Common Medical Protocols, patients with time sensitive conditions such as a heart attack, hazardous material exposure, obstetrical complaint, pediatric patients, stroke, traumatic injury, or any patient that might need to be admitted to the hospital are to continue to either one of the Physicians Regional Hospital locations or one of the Naples Community Hospital locations instead of the existing free-standing ER. The applicant states

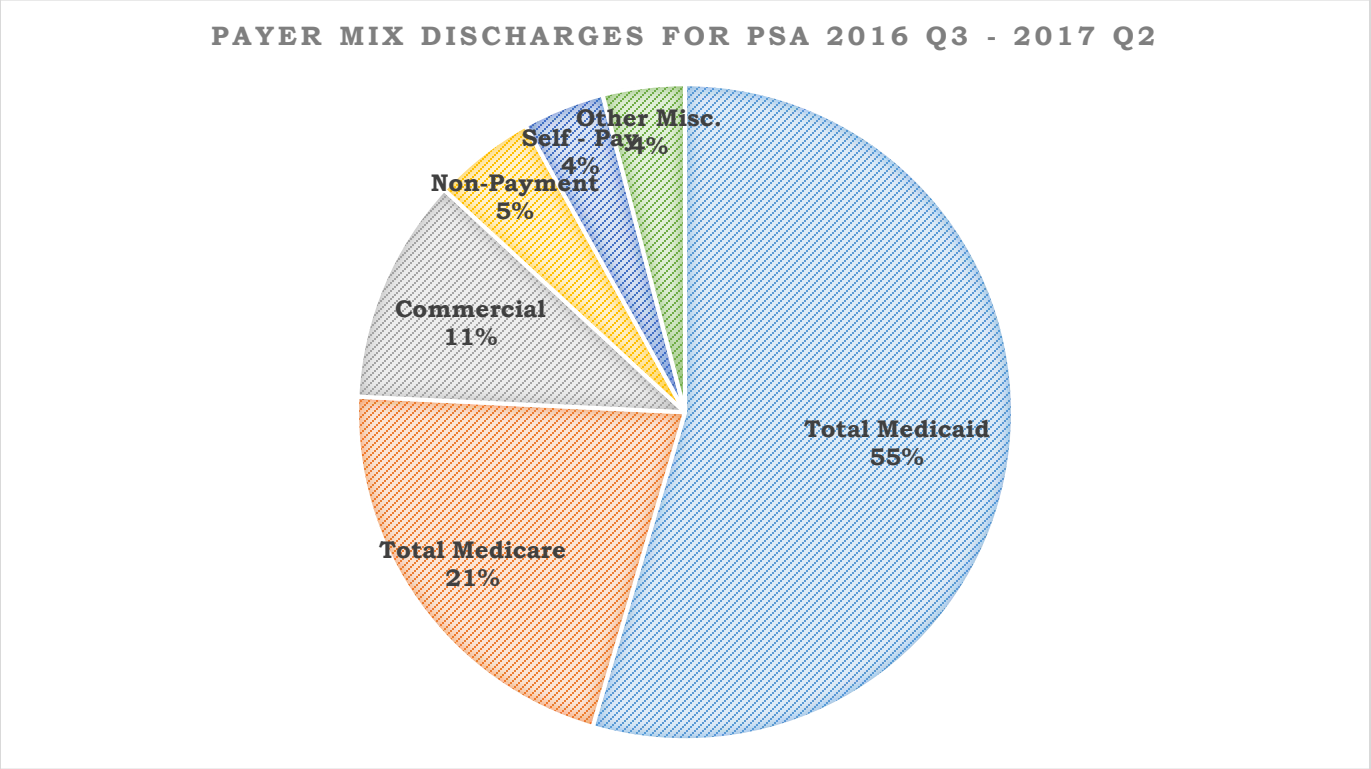
that this results in delays in life-saving care that can manifest in life-long disability and/or death.

Braden Clinic provides the following key findings about EMS in the proposed service area:

- The average time that it takes people in the proposed service area to arrive at a hospital is about one hour preventing acute care from taking place within the "golden hour" when life-saving care can be administered in critical situations
- It takes approximately two hours for an ambulance to transport patients and return to their station
- Ambulances can become "trapped" in Naples or Fort Myers and be away from their station for hours
- Ambulances are used as a taxi by people without transportation for non-emergent health care needs
- Sick individuals do not feel well enough to drive themselves 40 to 70 minutes and instead, will rely on EMS to transport them
- Large numbers of "non-standard" 911 calls (people not calling 911 on their cell phones or land lines)—an ambulance discovers someone laying on the side of the road or somebody comes to the ambulance station for emergency care
- The 34142 Zip Code is protected by only three paramedic units, meaning when one vehicle accident happens with multiple injuries, the district is left with no advanced life support units for upwards of an hour
- Due to the long travel/transport times, the ambulance has to send a third person in the medic unit to assist with patient care for all unstable patients

Economic Barriers to Access

Braden Clinic describes the large Medicaid and medically indigent population in the PSA, based on an analysis of payer mix discharges from the third quarter of 2016 through the second quarter of 2017 the applicant notes that 68.0 percent of the PSA was Medicaid, non-pay or self-pay. In 2016, BC notes that 46.7 percent of full-time residents were living below the poverty line. The applicant describes the poverty conditions of Immokalee migrant workers who are not accounted for in poverty estimates. BC states that the medical infrastructure in Naples is designed to serve the unique needs of the Naples population which is older and wealthier than the younger and poorer population of the proposed service area. The following table reflects the payer mix discharges for the applicant's PSA:



Source: CON application #10522, Page 82

Health Status of the Service Area

The applicant evaluates inpatient data in order to determine the health needs of the proposed service area. Overall, the applicant's review of inpatient data reveals that there are severe problems with the health status of its residents.

BC provides a table summarizing the total service area's "location of death" from 2014 – 2017 (CON application #10522, Page 84). The applicant's analysis reveals that the rate of people dying in hospice is not keeping up with the growth in the population—noting that the number of inpatient deaths has increased by 61.0 percent but the rate of deaths in hospice has increased by only 12.0 percent. Regarding hospice, the Agency states that the most recent hospice publication indicates no need for a new hospice program in hospice service area 8B (Collier County). BC states that this reflects that people who should be in hospice are not receiving hospice services. The reviewer notes that this shows a lack of availability of hospice services in the subdistrict, not necessarily hospital services. The applicant indicates that growth in deaths of people in "other specified place" (143.0 percent) reveals that individuals are dying in places where they can receive proper care. The reviewer notes that no other justification is provided for how this noted disparity reflects need for an additional hospital.

In analysis of the total service area deaths by location, BC references the disparity in skilled nursing facilities (SNFs) and assisted living facilities (ALFs) as evidenced by the reduction in deaths in SNFs within the service area. The applicant expresses the intent to collaborate with SNFs and ALFs for future health care development.

In analysis of the death rate across various age groups between the PSA and other Collier County Zip Codes with a hospital, BC notes that within Zip Code 34142 the rate of deaths is much higher in younger age groups than the rest of Collier County. Specifically, the applicant indicates that almost three times as many children under the age of one die in 34142 than in the rest of Collier County Zip Codes with hospitals. The applicant states that while there are no detectable deaths in Collier County Zip Codes where hospitals are located between ages one through nine, there are a number of deaths in those age groups in Zip Code 34142. Moreover, within the 75+ age group the applicant notes that more people die in the 75+ age groups in the rest of the county in Zip Codes with a hospital than in the PSA, which demonstrates to the applicant that the presence of a hospital could extend life.

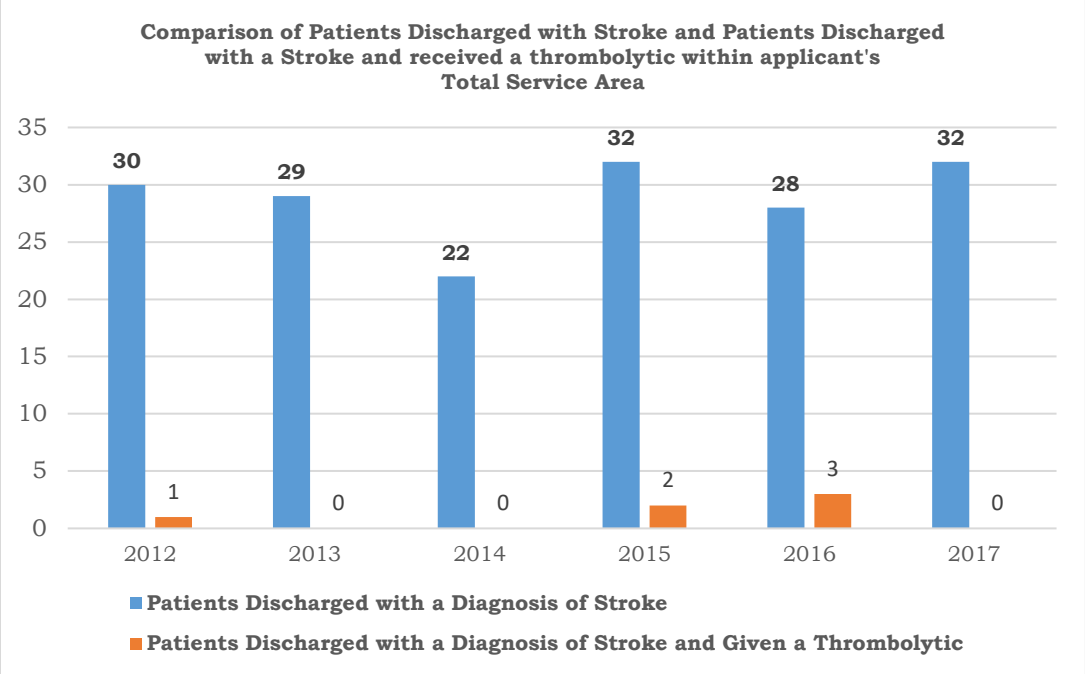
The applicant evaluates Florida Vital Statistics birth data from 2015 to 2017 revealing that 26.0 and 31.0 percent of births in Collier County occur within the proposed service area. From 2015 – 2017, BC notes that the crude infant death rate within the proposed service area has increased 12.0 percent while in the remainder of Collier County the crude infant death rate decreased by 31.0 percent. The applicant, in consultation with other health care providers, determines that the distance of health care services has contributed to an increased crude infant death rate in the proposed service area.

In analysis of Florida Vital Statistics data from 2015 – 2017, trends in live birth between the service area and the remainder of Collier County are noted by BC. The applicant states that from 2015 – 2017, the service area experienced a 14.2 percent increase in the number of live births within the proposed service area. BC indicates that the rate of children born prior to arrival at a hospital or emergency room per 100,000 from 2014 – 2017 had increased by 164.0 percent. The applicant provides a patient testimonial documenting the constraints of the obstetric health infrastructure in the community.

From 2014 – 2017 the applicant provides an analysis of stroke deaths for Zip Codes 34142 and 34143 per 100,000. Within this time period, BC notes that the rate of stroke death has surged from 2015 to 2017 within Zip Codes 34142 and 34143. The applicant attributes the increase to potential barriers to care. In order to evaluate this assertion, the applicant evaluated patients who were admitted to the hospital after receiving a thrombolytic, non-specific strokes and patients who are

admitted with a stroke and have received a thrombolytic agent. From this analysis BC determined that since 2012, the residents of the proposed service area are being admitted to the hospital for strokes are not reaching the greater than 50.0 percent threshold as recommended by the American Heart Association (AHA). Per AHA guidelines, the applicant notes "IV tPA should be administered to all eligible stroke patients within 3 hours of last known normal and to a more selective group of eligible acute stroke patients (based on ECASS III exclusion criteria) within 4.5 hours of last known normal. Centers should attempt to achieve door-to-needle times of <60 minutes in ≥50 percent of stroke patients treated with IV tPA[1]". [2]

The applicant provides the following chart reflecting the comparison of patients discharged with a diagnosis of stroke and patients discharged with a diagnosis of stroke and given thrombolytics:



Source: CON application #10522, Page 95. The applicant describes utilizing the inpatient database for MS-DRGs: 61, 62, 63, 64, 65, 66, 67 and 68 (CON application #10522, Page 94 – 95). 2017 data based on minimum average projection given 16 strokes Q1 2017 and 2017 Q2 with no stroke given a thrombolytic recorded

[1] tPA stands for tissue plasminogen activator, a thrombolytic agent
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124916/
[2] http://www.acc.org/latest-in-cardiology/ten-points-to-remember/2018/01/29/12/45/2018-guidelines-for-the-early-management-of-stroke

Nationally, the applicant notes that strokes are the leading cause of permanent disability and 34.0 percent of individuals who experience a stroke are under the age of 65. BC anticipates that within the proposed service area chronic illness and other risk factors will pose a burden to the long-term costs for residents who suffer a stroke and are permanently disabled. BC contends that in the PSA from 2012 – 2017, if 80.0 percent of strokes were prevented per AHA guidelines the service area would have saved $12,807,378.40.

From the third quarter of 2016 to the second quarter of 2017, the applicant notes that 25.0 percent of patients were discharged after suffering a stroke were able to be discharged home, 18.0 percent of patients who suffered a stroke were discharged to a rehabilitation facility and 57.0 percent of stroke patients were discharged to a long-term care hospital, SNF or hospice. The applicant states that the proportion of permanently disabled stroke victims is a preventable tragedy and the proposal is expected to allow strokes to be diagnosed and treated immediately and to reduce the numbers of patients who are disabled, live in long-term care facilities, enter hospice or die.

From 2013 – 2017 the applicant notes that the rate of acute myocardial infarctions from the PSA (MS-DRG 280 – 282) increased 102.0 percent. BC determined that this rate of increase within the PSA reflects the need to increase efforts to prevent coronary artery disease in the community. The applicant evaluated the volume of patients with STEMI and NSTEMI heart attacks within the PSA from the third quarter of 2016 through the second quarter of 2017. BC states that STEMI heart attacks require immediate cardiac intervention with a goal of 90 minutes from diagnosis to primary interventions.

Within the PSA, the applicant presents data that shows the following trends:

- Admitting diagnosis: 25.0 percent STEMI, 75.0 percent NSTEMI
- Principal diagnosis: 22.0 percent STEMI, 78.0 percent NSTEMI
- Secondary diagnosis: 100.0 percent NSTEMI

The applicant notes that NSTEMI heart attacks require a hospital-based emergency department with electrocardiography, a STAT laboratory and a radiology department. In consideration of the rate of increases of heart attacks within the proposed service area, the applicant maintains that the need for an emergency department is increasing.

Hospital Bed Utilization

BC provides an analysis of the acute care utilization of hospitals within a 50-mile radius from the centroid of Zip Code 34142 which is provided below:

Utilization of Acute Care Hospitals Serving Braden Clinic Hospital Residents July 1, 2016 - June 30, 2017				
Hospital	**Patient Days**	**Average Daily Census**	**Beds**	**Percent Occupancy**
Lee Memorial	74,708	205	336	60.9%
NCH	67,100	184	368	50.0%
Hendry Regional	1,426	4	25	15.6%
Lehigh Regional	9,626	26	88	30.0%
Gulf Coast	99,179	272	356	76.3%
Cape Coral	67,291	184	291	63.4%
Health Park	89,034	244	320	76.2%
NCH North Naples	48,121	132	249	53.0%
Physicians Regional Pine Ridge	24,259	66	101	65.8%
Physicians Regional Collier	13,154	36	100	36.0%

CON application #10522, Page 103

The applicant states that the yearly average occupancy rate of area acute care hospitals indicate that they are utilized, but have significant capacity if averaged over the entire year. In analysis of the occupancy rate of hospitals during the first quarter or winter seasons, BC notes that the service area has a tremendous surge of winter visitors. The applicant provides the following winter hospital occupancy rate of the three closest hospitals to the service area which is also provided below:

Winter Hospital Occupancy Rate of Three Closest Hospitals to Service Area						
	2015 Q1	**2016Q1**	**2017Q1**	**2018Q1***	**2019Q1***	**2020Q1***
NCH North	47%	62%	65%	76%	85%	94%
Physicians Regional - Pine Ridge	87%	80%	86%	83%	82%	81%
Physicians Regional – Collier Blvd.	45%	46%	60%	65%	73%	81%

Source: CON application #10522, Page 104. Projections based on AHCA Historical Data

Though occupancy rates are not forecasted to reach 100 percent, the applicant states that limited staffing contributes to excessive wait times and lowers the quality of care during the winter season. BC notes that past applications for certificates of need within the service area also reflect that need for acute care beds exists within the district and that the establishment of the proposed hospital will prevent north Collier County from running out of beds.

Projected Impact of Braden Clinic Hospital on Existing Providers

BC provides the following table which shows the total percentage of hospital admissions from area hospitals that historically come from the proposed PSA and the percent of hospital admissions that would be lost to area hospitals based on the estimated capture rate from the proposed service area. BC maintains that the proposal will serve as a bridge to connect people who need care to the medical facility that can best serve their needs patient losses are expected to be mitigated through this referral relationship. The applicant states that this percentage assumes

70.0 percent market capture from the pool of targeted DRGs that the proposed hospital will serve which is equal to 50.0 percent capture of the entire group of inpatients from the PSA. See the table below.

PSA (34142) Patient Losses for Local Hospital based on 70.0% Patient Capture and Target MS-DRG						
Facility Name	**Hospital Total**	**Discharges from 34142**	**Percent Discharges**	**Target MS-DRG**	**70.0 % Capture and Target MS-DRG**	**Percent Patient Loss**
NCH - North Naples	16,318	1,553	9.5%	1,322	925	5.7%
Lehigh Regional	2,795	86	3.1%	64	45	1.6%
Physicians Regional - PR	6,559	276	4.2%	133	93	1.4%
Health Park	25,082	298	1.2%	236	165	0.7%
NCH	13,828	263	1.9%	105	74	0.5%
Gulf Coast	22,595	155	0.7%	94	66	0.3%
Lee Memorial Hospital	16,162	92	0.6%	37	26	0.2%
Physicians Regional - CB.	3,323	20	0.6%	11	8	0.2%
Total	**106,662**	**2,743**	**2.6%**	**2,002**	**1,402**	**1.3%**

Source: CON application #10522, Page 107

The applicant notes that the inpatient utilization from PSA acute care inpatient beds is growing as evidenced from the analysis provided in the following chart:

Inpatient Discharges from PSA (34142) 2013 Q3 - 2017 Q2					
	Q1	**Q2**	**Q3**	**Q4**	**Year Total**
2013	**Not included**	**Not included**	561	582	1,143
2014	651	594	590	654	2,489
2015	661	634	644	653	2,592
2016	692	730	705	704	2,831
2017	789	714	N/A*	N/A*	1,503
Percent Growth	**22%**	**20%**	**26%**	**21%**	

Source: CON application #10522, Page 108. Data from 2013 Q1 and Q2 not included and data for 2017 Q3 and A4 not yet available

The applicant noted increases in emergency department utilization for Zip Code 34142 which are summarized in the following chart:

Total Emergency Department Visits for 34142					
	Q1	**Q2**	**Q3**	**Q4**	**Year Total**
2014	2,276	2,199	1,967	2,583	9,025
2015	2,461	2,276	1,995	2,354	9,086
2016	2,852	2,540	2,539	2,851	10,782
2017	3,019	2,565	N/A*	N/A*	
Percent Growth	**33%**	**17%**	**29%**	**10%**	

Source: CON application #10522, Page 110

BC provided the following table to reflect the total service area patient losses for local hospitals based on 70.0 percent capture for the PSA (Zip Code 34142), [3]10.0 percent capture for 34141 and 34120 of target MS-DRGs:

Total Service Area Patient Losses for Local Hospital based on 70.0 % Capture for 34142 and 34143, 10.0 % capture for 34141 and 34120 of Target MS-DRG

Facility Name	Hospital Total	Discharges from TSA	Percent Discharges	Target MS-DRG	Capture and Target MS-DRG	Percent Patient Loss
NCH - North Naples	16,319	2,841	17.4%	2,334	1,078	6.6%
Lehigh Regional	2,795	91	3.3%	69	48	1.7%
Physicians Regional - PR	6,559	766	11.7%	334	117	1.8%
Health Park	25,082	389	1.6%	296	179	0.7%
NCH	13,828	811	5.9%	254	93	0.7%
Gulf Coast	22,595	224	1.0%	118	78	0.3%
Lee Memorial Hospital	16,162	144	0.9%	44	28	0.2%
Physicians Regional - CB.	3,323	109	3.3%	39	11	0.3%
Total	**106,663**	**5,375**	**5.0%**	**3,488**	**1,632**	**1.5%**

Source: CON application #10522, Page 111

Based on patient losses to hospitals within the proposed service area, the applicant notes that the total loss of patients at NCH-North will be 6.6 percent (1,078 discharges). Based on population growth forecasts of 7.3 percent, the applicant expects for NCH-North volume to grow by 0.6 percent (98 discharges) more than the percentage of patients lost to BC. The reviewer notes that while the applicant expects for the rate of population growth to exceed the percentage of patient losses, the actual discharges derived from the population growth may not be commensurate with the forecasted patient losses from the proposed Braden Clinic Hospital.

The applicant contends that the following points indicate need for the proposed facility:

- Strong community support evidenced by over 650 unique letters of support. Many letters document poor health outcomes as a consequence of lack of access and give witness to the acute need for a local hospital. Almost every letter from a resident of the service area documents the fear residents have of experiencing an emergency and having a bad outcome as a consequence of excessive travel time.
- The service area is medically underserved with no acute care hospital and no outpatient services such as a radiology or laboratory. The service area also has a HPSA (Health Professional Shortage Area) federal designation.
- Over 90 percent of the targeted population live 40 to 70 minutes from the closest hospital or emergency room causing a significant geographic barrier to access.
- EMS are burdened by lack of proper access. EMS are overutilized as a method of transportation for non-emergent needs. Many extra costs and a lower quality of EMS care are a result.

[3] The reviewer notes that zip code 34143 is previously noted to be within zip code 34142

- The poor health status of the service area indicates poor medical access. This includes:
  - People die much younger in the PSA than the rest of Collier County.
  - High number of residents who die in an "other specified place" (not home or health care facility [like a bus stop or parking lot]) before they reach a health care facility.
  - A 12 percent increase in the infant death rate over the last three years compared to a 31 percent decrease in the infant death rate for the remainder of Collier County.
  - High and increasing rate of babies born before reaching a hospital.
  - Only three percent of stroke patients from the PSA received the lifesaving medicine needed to reverse a stroke that is currently the standard of care.
  - The number of heart attacks is rising faster than the population growth.
- Other current barriers to access health care include cultural barriers caused by different norms (embarrassment, misunderstanding of financial responsibility, lack of education).
- Significant population growth over the last few years in Ave Maria and Immokalee with plans for another master planned community (Rural Lands West) within the service area is creating an even bigger population in need of a local hospital.
- Data from the Zip Code 34142 shows that given the population, medical services including patient, ER and preventative medicine are underutilized illustrating prohibitive barriers to health care.

b. Will the proposed project foster competition to promote quality and cost-effectiveness? Please discuss the effect of the proposed project on any of the following:

- **applicant facility;**
- **current patient care costs and charges (if an existing facility);**
- **reduction in charges to patients; and**
- **extent to which proposed services will enhance access to health care for the residents of the service district.**
  ss. 408.035(1)(e) and (g), Florida Statutes.

The applicant states that the proposed hospital will operate as a micro-hospital which will promote competition by providing an efficient cost-effective model of health care delivery which is the most financially prudent.

BC states that the proposed project will help foster competition in southwest Florida since the proposed facility will not have a full complement of medical specialists but will send patients to local referral facilities for complex care. Due to the initial diagnosis and work up occurring at the proposed facility, the applicant indicates that patients will be empowered using relevant published outcome information and assist patients with choosing a facility for complex care.

The applicant describes its historical record of referring patients to a number of facilities including the Cleveland Clinic (Weston), University of Miami, University of Florida at Gainesville, Tampa General Hospital, NCH, Physicians Regional and Lee Memorial. BC notes commitment to providing the best outcome for patients indicating that centers of excellence are better referral centers than the closest facility for non-emergent cases.

BC states that the pared down model of the proposed hospital will form a bridge between people with little access to care and the medical centers that can best meet their needs. The applicant maintains that the proposal will not directly compete with existing medical centers in the area but will operate as a mutually beneficial collaborator providing timely emergency and critical care. BC states that partnerships with area medical centers is a necessity for the successful operation of the proposed hospital for seamless care along the patient care continuum. The applicant contends that the proposed facility will bring health care closer to people who need it most, stabilize them and refer them to centers for excellence for specialized services. The applicant maintains that opposition from existing hospitals demonstrates a lack of understanding for the intrinsic mutual benefits of collaboration between the proposed micro-hospital model and area medical centers.

BC discusses the proposed service area's designation as a HPSA. The applicant notes that approval of the hospital will attract providers to the area and allow for the procurement of equipment and space that providers need to practice in a rural area. BC states that people who live in the area often have no option for health care. The applicant maintains that the proposed hospital will provide residents in the proposed service area an option for health care and allow for others with a health care provider to have an alternative for outpatient testing. BC anticipates that the proposed facility will residents of the services area a choice. BC expects for population growth within the proposed service area to allow for a rural hospital in the district health plan.

The applicant notes that patients who arrive to a hospital and are admitted through an emergency department tend to be sicker and likely delayed seeking primary care or preventative health care. The applicant states that having a local hospital in the service area will allow local

physicians in the PSA to admit patients directly and save ER costs. The applicant provides an analysis of the discharge database which evaluates the difference between total charges for patients within the proposed service area who are admitted after an emergency department visit in order to evaluate the cost savings of inpatient utilization. The data analyzed evaluates the total discharges for the proposed service area documenting the percentage of patients from each Zip Code that were admitted through the emergency department.

PSA Cost Savings by Diverting Day Time Patients Who Are Admitted Through the Emergency Room 2016Q3 – 2017Q2				
Item	**34142**	**34143**	**34141**	**34120**
Hospitalizations	2,852	246	93	2,535
Number through ER	1,467	172	65	1,312
Percent through ER	51%	70%	70%	52%
Number Through ER During Day (9am - 5pm)	808	100	38	757
Percent Through ER During Day (9am - 5pm)	55%	58%	58%	58%
Average Admit Charges Not Through ER	$25,182	$37,365	$100,981	$46,432
Average Admit Charges Through Day ER Visit	$49,453	$39,850	$90,276	$54,853
Average Per Admit Potential Cost Savings	$24,271	$2,486	-$10,705	$8,421
Total Potential Cost Savings Per Zip Code	$19,610,832	$248,556	-$406,804	$6,374,405
Total Potential Cost Savings				**$25,826,989**

Source: CON application #10522, Page 117 * Applicant states: "We conducted a study of the discharge database evaluating the difference between total charges for patients in our service area who are admitted after an emergency department visit" (CON application #10522, Page 116).

The applicant contends that the chart above reflects that $25,826,989 worth of ER charges could be potentially avoided. BC notes that the proportion of patients from the proposed service area who utilize the emergency department during the day for admissions indicate a sicker population and a lack of local resources. The applicant states that unnecessary testing from physicians unfamiliar with patients will be reduced. BC expects for additional health care savings to be derived from patients seeking care earlier in their illness and from patients from the Immokalee area not using the EMS for transportation.

The applicant evaluates the number of patients who went to the emergency department and were sent home without any lab tests, radiology tests, medication administrations or pharmacy charges.

BC states that in order to evaluate the over-utilization of emergency services, the emergency department visit database for the service area from the third quarter of 2016 to the second quarter of 2017 was analyzed. The applicant states that the database was queried for all records where "0" was recorded for charges in items, 40 – Pharmacy Charges, 41 – Medical/Surgical Supply, 42 – Laboratory Charges and 43 – Radiology and other Imaging Charges. BC indicates that the data was grouped by CPT Service Code under Item 27 – Evaluation and Management and by Item 25 – Principle Payer. Lastly, the applicant

states that the "Total Charges" that were not associated with diagnostic testing, medication administration or complex medical decision making were totaled. The chart of this analysis is provided below:

Primary Service Area 2016Q3 - 2017Q2 Emergency Department Unique Visits by CPT Code Emergency Level and Payer Sans Pharmacy Charges Medication Charges, Laboratory Charges or Radiology Charges

Emergency Visit CPT Code	99281	99282	99283	99284	99285	Total Visits
Total Emergency Visits	206	663	992	88	17	1,966
Payer Name	99281	99282	99283	99284	99285	Total Charges
A - Medicare	$4,868	$10,542	$49,809	$4,604	$1,887	$71,710
B - Medicare Managed Care	$1,736	$8,869	$26,252	$3,014	$1,887	$41,758
C - Medicaid	$8,477	$12,693	$32,717	$12,051	$0	$65,938
D - Medicaid Managed Care	$85,796	$288,108	$520,777	$72,673	$17,615	$984,969
E - Commercial Health Insurance	$14,779	$63,347	$149,018	$43,807	$4,387	$275,338
H - Workers Compensation	$1,771	$3,975	$7,805	$2,862	$0	$16,413
I - Tricare or Other Federal	$0	$644	$2,212	$0	$0	$2,856
J - VA	$414	$0	$980	$0	$0	$1,394
K - Other State/ Local Government	$486	$2,824	$5,220	$0	$0	$8,530
L - Self Pay	$32,283	$69,185	$160,288	$46,929	$4,582	$313,267
M - Other	$0	$0	$6,802	$0	$474	$7,276
N - Non - Payment	$238	$13,841	$15,590	$4,250	$2,667	$36,586
O - Kidcare	$868	$9,607	$20,371	$1,805	$2,193	$34,844
Q - Commercial Liability Coverage	$582	$2,482	$16,731	$6,611	$2,667	$29,073
Total Savings in ER Visits	**$152,298**	**$486,117**	**$1,014,572**	**$198,606**	**$38,359**	**$1,889,952**

Source: CON application #10522, Page 118. CON application #10522 states "We evaluated the emergency department visit database for our service area from 2016Q3 to 2017Q2" (CON application #10522, Page 118).

The applicant maintains that diverting these patients from Zip Code 34142 out of the emergency department and into an outpatient physician's office would result in the savings enumerated in the table above, or $1,889,952 away from emergency medical care. BC maintains that the proposed hospital will decrease the number of patients from Zip Code 34142 who have emergency department visits without pharmacy, medical and surgical supply, laboratory, radiology or other imaging charges.

BC notes that though not depicted in the table, with the inclusion of the patient population who visit the emergency department and receive only a medication dose with a pharmacy charge of $101 from the Zip Code 34142, there is an increased cost savings of $3,037,120.

The applicant maintains that the proposed facility will result in less costly EMS services as well as fewer EMS trips with shorter transportation times resulting in decreased time per patient and downtime on the return from Naples. BC anticipates that these savings will be caused by decreased labor as there will be no need for a third person on the ambulance to care for patients because of the long travel time. The applicant also anticipates decreased fuel usage and wear and tear on vehicles.

BC states that improving timely access to testing and subacute services will have a long-term benefit on residents' health in the PSA and lead to lower long-term health costs as shown with the potential cost savings for potential strokes. The applicant states that the time investment required of rural patients driving to urban hospitals is often prohibitive and keeps many patients from performing lifesaving tests, like two-day cardiac stress tests. Moreover, BC argues that timely access to lifesaving tests and stroke care can prohibit future heart attacks, lead to lower long-term costs and definitive stroke care costs for people with permanent disabilities due to strokes.

BC indicates that it has partnered with electronic medical record (EMR) providers that connect to the Florida Health Information Exchange allowing for providers treating referral patients to view tests and results that patients have previously received. The applicant notes that some existing providers like NCH Healthcare System or Lee Memorial Healthcare System do not participate in an out of network health information exchange delaying the information exchanges and putting the health of patients at risk. The applicant notes that sharing data on information exchanges decreases health care costs. The applicant notes that per FloridaHealthFinder.gov for 2016, the charge of an average ER visit to Physicians Regional Medical Center on Pine Ridge (which does not participate in an open health information exchange) is $7,236 while the average charge for an ER visit at Cleveland Clinic Hospital (which does participate in an open health information exchange) is $1,965.

The applicant expects the proposed hospital to encourage health care development in the proposed service area as Eastern Collier County is a federally designated HPSA for primary care physicians. BC maintains that primary care physicians hesitate to practice without the support of a local acute care hospital. The applicant indicates that ALFs and SNFs do not desire to operate a facility without accessibility to acute care services. The applicant states that the establishment of a local acute care hospital will facilitate the growth of SNFs, ALFs and health care related services which are urgently needed in the proposed service area. BC anticipates an increase in the growth of such services within the proposed service area will result in a healthier and safer population.[4]

[4]The reviewer notes that there are 11 SNFs in Collier County. Eight SNFs in the adjacent subdistrict Charlotte County and one licensed SNF in the adjacent subdistrict, Desoto County. Four of the 11 facilities in Collier County are continuing care retirement communities (CCRCs) and one of these four facilities, The Arlington of Naples, Inc. exclusively serves life care contract holders. In District 8, the subdistricts with the largest number of licensed SNFs are located within Lee County (19) and Sarasota County (29) which also have the largest proportions of District 8's population. Across all facilities with SNF beds in Lee County, there are three CCRCs two of which exclusively serve life care contract holders. Within Sarasota County there are two licensed SNFs that are located on CCRCs, one of which exclusively serves life care contract holders.

BC describes how physicians within the proposed service area cannot join hospital staff in Naples because they live too far away from the hospital. The applicant maintains that a person must reside within 15 miles or be able to get to the hospital within 30 minutes in order to join medical staff. BC indicates that physicians residing in Zip Code 34142 will be able to join the medical staff of the proposed facility and will benefit from quality improvement feedback, meetings and the benefits of being part of an ever-learning medical community.

The applicant states that the proposed facility will provide the community with many educational opportunities and help the local population continue to learn and stay abreast of the latest advances in standard practices of health care.

BC provides a list of the proposed activities below:

- Pediatric Advanced Life Support, Advanced Cardiac Life Support, Basic Life Saving courses are taught at BC and will continue to be taught at the proposed facility.
- BC has a strong relationship with the local fire department and EMS. The proposed hospital will provide ongoing classes and support for these services.
- BC is partnered with Ave Maria University, NOVA Southeastern University, University of South Florida and Chamberlain University to be preceptor sites for their health professional students.
- BC currently accepts undergraduate student interns and provides guidance counseling for success in future health professions.
- Through a partnership with the technical school in Immokalee, nursing students will receive clinical training.
- BC interns have already been accepted to Medical Schools, Graduate Programs in Healthcare Administration at Johns Hopkins and PA School. The hospital would allow an even larger number of local residents and students to benefit from professional guidance and opportunities.

CON application #10522 includes a list of university affiliations in Appendix V of the application.

BC describes the infusion center as an outpatient clinic that allows for patients who need routine intravenous medications to have a means of receiving these medications from a registered nurse with a physician's standing order on a regular basis. The applicant asserts that the infusion center improves quality allowing outpatient infusion of medications, rapid diagnosis, discharge to prevent hospital-acquired infections, follow up with primary care and use of the infusion center as needed for ongoing antibiotics. BC states that its existing urgent care center operates an infusion center allowing patients who would normally

require observation or an inpatient stay to be seen. The applicant anticipates that an infusion center located at the proposed facility will allow for patients needing this form of care to be continuously seen. The applicant notes that currently the only infusion centers in Collier County are located at the hospitals and cancer centers in Naples. BC notes that due to travel times and dosing regimens some patients continue to be hospitalized longer than necessary. The reviewer notes that based on the applicant's description there are three infusion centers within Collier County, one located at the Braden Clinic and two located at a hospital and cancer center within Naples, respectively.

The applicant indicates that it currently is a quality provider that has elevated the quality of care within Collier County. The applicant references letters of support endorsing the proposal and lauding the services of BC as a health provider. As a multispeciality clinic providing the area with urgent care, primary care and specialty telemedicine services, the applicant states that BC does not currently offer acute care services and that patients will benefit from the implementation of the proposed hospital project. A table summarizing the proposed hospital target DRG usage is provided based on
2016 Q3 – 2017 Q2 data is reproduced below.

Proposed Historic Hospital Target DRG Usage if Hospital Was Open 2016Q3 - 2017Q2					
Payer	**Name**	**Discharges**	**Days**	**Weight**	**ALOS**
A	**Medicare**	175	788	788	4.5
B	**Medicare Managed Care**	97	386	386	4.0
C	**Medicaid**	659	1,648	1,648	2.5
D	**Medicaid Managed Care**	676	2,095	2,095	3.1
E	**Commercial Health Insurance**	227	808	808	3.6
H	**Workers Compensation**	4	16	16	4.0
I	**Tricare or Other Federal**	7	17	17	2.4
J	**VA**	2	15	15	7.5
K	**Other State/ Local Government**	18	159	159	8.8
L	**Self-Pay**	81	244	244	3
M	**Other**	7	24	24	3.4
N	**Non - Payment**	76	232	232	3.1
O	**Kidcare**	8	27	27	3.4
Q	**Commercial Liability Coverage**	8	38	38	4.8
Total		**2,045**	**6,497**	**6,497**	**3.2**

Source: CON application #10522, Page 130

BC contends that the proposed facility will enhance access to health care residents of the proposed service area in a number of ways, including:

- With an annual usage rate of over 10,500 ER visits and over 2,000 relevant inpatients, a significant number of residents would not have had to drive long distances to receive care and perhaps there would have been no child deaths for the one to nine age range in the proposed PSA.
- A local hospital will be a first and vital step in improving the poor health status of the proposed service area.
- Improve access to care so residents in the proposed service area die older commensurate with the rest of Collier County.
- Eliminate all deaths between the ages of one and nine years old.
- Reduce the number of residents who die in an "other specified place" (not home or health care facility).
- Reduce the high and increasing infant death rate.
- Reduce the high rate of babies born before reaching a hospital by providing a local obstetrical unit within a reasonable driving distance.
- The new hospital will be a "stroke ready" facility and will raise the outcomes from stroke patients by providing timely scans and initial stroke treatment. By rapidly diagnosing and treating stroke patients in the proposed service area residents can change the course of their lives, their family's lives and the costs to the health care system.
- Decrease the rate of heart attacks by providing outpatient testing and helping people stay healthier.
- There is no hospital in the proposed service area within reasonable driving distance. Patients must drive 45 – 60 minutes to receive care. The new hospital will cut drive times for residents by over 80 percent.
- There are many cases where "time is of the essence." Heart attack and traumatic accidents are emergent situations that would benefit from proximity to a hospital.
- Better outcomes in taking care of emergency patients when seen in a shorter time period.
- Safety will improve by patients not having to drive themselves long distances. This is true in many circumstances. Note especially patients fasting for labs.
- The time investment required of rural patients to drive into the urban hospital is prohibitive and keeps many patients from performing lifesaving tests.
- Family members being able to visit other family members who are in the hospital.
- Enhanced access to services. An infusion center for patients with complex infections requiring outpatient infusions.
- Patients from the Haitian and Hispanic communities in Immokalee have told the BC that they do not feel culturally understood or cared for by the urban hospitals in Collier County. While translator services are required, there are intangible benefits of being cared for by

someone from your own community. The new hospital would employ people from the Hispanic and Haitian communities and create an environment where patients are cared for by fellow members of their community.

The applicant outlines the following capacities in which approval of the proposal will foster competition to promote quality and cost-effectiveness:

- Foster competition by referring each patient to the best medical center to meet their needs for complex care.
- The new hospital will not be a feeder hospital for one particular hospital system, thereby it will have the freedom to make unbiased referral choices for its patients.
- The lean business model and pared down menu of services will allow the new hospital to provide the same service at a lower cost than a community hospital.
- Provide infrastructure to bring more providers to the area.
- BC has a strong history and culture of medical quality.
- Provide local providers with a medical community.
- Provide educational opportunities for educational partners including Ave Maria University, NOVA Southeastern University, University of South Florida, Chamberlain University and the Florida State University Rural Health Clinic.
- There will be reduction in charges to patients through EMS savings.
- Lower long-term health care costs associated with delaying care and outpatient testing.
- By treating strokes in a timely manner, the new hospital will decrease the $12,807,378 charged annually on preventable stroke care (from ZIP codes 34142 and 34143).
- Using local physicians to admit their own patients instead of sending patients 40 to 70 minutes away will reduce the $25,826,989 charged on admitting patients through the emergency department.
- Establishing a local Patient Centered Medical Home where patients see their primary care physician instead of traveling 40 to 70 minutes to use an emergency department as a primary care physician's office can save the $58,808,124 charged annually for non-emergent visits to the emergency room.
- Savings from information technology.
- The new hospital will reduce drive times by 30 to 60 minutes.
- Time sensitive emergencies will be taken care of within the critical window with lives saved and improved outcomes.
- Access to outpatient testing will help patients stay healthier.
- The new hospital will be a bridge from the people who need care that can best care for their complex needs.
- Burden on family members of patients will be alleviated.
- Many cultural and soft benefits of being cared for in your own community by your own community.

c. Does the applicant have a history of providing health services to Medicaid patients and the medically indigent? Does the applicant propose to provide health services to Medicaid patients and the medically indigent? ss. 408.035(1)(i), Florida Statutes.

The reviewer prepared a table displaying the Medicaid, Medicaid HMO and charity data for both the subdistrict and district for fiscal year 2016. See the table below.

Medicaid, Medicaid HMO and Charity Data: District 8 Providers FY 2016					
Area	**Medicaid/Medicaid HMO Patient Days**	**Charity Care Patient Days**	**Medicaid/Medicaid HMO (%)**	**Charity Care (%)**	**Total (%)**
Subdistrict 8-2	17,944	5,523	9.17%	2.82%	11.99%
District 8	127,001	26,864	12.18%	2.58%	14.76%

Source: Agency for Health Care Administration Florida Hospital Uniform Reporting System, FY 2016

The applicant is not an existing acute care provider within the Subdistrict 8-2, so data related to the historical provision of care to Medicaid patients and the medically indigent is not available. The applicant does indicate throughout the application that the proposal is intended to attend to the needs of the medically underserved.

BC maintains that its existing multispecialty clinic has been serving Medicaid and medically indigent patients since operations began in July 2014. The applicant intends to serve Medicaid and medically indigent patients upon licensure of the hospital and to provide charity care as needed. BC affirms that patients will not be discriminated against on the basis of their payer source or inability to pay. The applicant states that all patients are expected to contribute to the cost of their care, based upon their individual ability to pay and eligibility for government benefit programs.

The following chart provided in the application, provides a summary of the volume of discharges by payer for the PSA which represent the anticipated payer mix of patients to be served by the proposal:

Primary Service Area Medicaid, Self-Pay, Non-Payment Discharges and Patient Days 2016Q3 - 2017Q2					
Payer	**Name**	**Discharges**	**Days**	**% Discharges**	**% Days**
C	Medicaid	784	2,514	27%	22%
D	Medicaid Managed Care	768	2,885	27%	25%
L	Self-Pay	127	405	4%	3%
N	Non Payment	137	568	5%	5%
Total		**1,816**	**6,372**	**63%**	**55%**

Source: CON application #10522, Page 134

BC describes how the pared-down model of health care delivery that will be implemented at the proposed hospital will help facilitate cost-effective care for Medicaid and medically indigent patients as a result of the facility offering services at more affordable rates than at community hospitals. The applicant references an article titled "Are Micro-hospitals the answer for systems looking for low-cost expansion?" (2017) which reiterates that: "Micro-hospitals often choose areas with a higher volume [of Medicaid patients] where access is a problem. This is a contrast to typical satellite hospitals that often cherry-pick from the richer parts of town" (HealthcareFinanceNews.com, July 2017, CON application #10522, Page 135).

The applicant maintains that the proposed small, efficient model of the hospital is anticipated to provide the financial ability to serve the large Medicaid and medically indigent patient populations within the applicant's PSA. BC maintains that caring for Medicaid patients and the medically indigent will be a fundamental goal of the project. BC identifies the following policies that it maintains to support indigent patients:

- Discounted charges for qualifying uninsured patients' equivalent to Medicaid reimbursement rates
- Depending upon their income and assets eligible patients may qualify for up to a 100 percent charity care discount
- Extended payment plans for patients unable to pay for services at the time of care

BC indicates that the proposed project is intended to continue these programs in addition to providing financial counseling to evaluate eligibility for financial assistance programs. The applicant additionally describes how home visits are used as a special service for patients who are too ill to travel or who lack transportation. BC notes that it is registered as a dispensing practitioner so patients who lack transportation can receive their first doses of medications at night when they are unable to travel. The applicant indicates that for patients who are homebound and cannot ingest liquids medications or pills (who do not meet inpatient hospitalization criteria) are supplied home IV fluids and IV medications.

The applicant maintains that based on an analysis of its existing payer mix and the payer mix from the proposed service area, the proposed business model and revenue projections for the proposal will incorporate care for Medicaid and medically indigent patients. The applicant also intends to collaborate with HNSF in Immokalee to support the care of Medicaid and medically indigent patients.

d. Does the applicant include a detailed description of the proposed general hospital project and a statement of its purpose and the need it will meet? The proposed project's location, as well as its primary and secondary service areas, must be identified by zip code. Primary service area is defined as the zip codes from which the applicant projects that it will draw 75 percent of its discharges, with the remaining 25 percent of zip codes being secondary. Projected admissions by zip code are to be provided by each zip code from largest to smallest volumes. Existing hospitals in these zip codes should be clearly identified. ss. 408.037(2), Florida Statutes.

BC states that the PSA consists of Zip Code 34142 and the SSA consists of Zip Codes: 34143, 34141 and 34120. The applicant maintains that the purpose of the new hospital is to provide emergency services and the most essential outpatient and inpatient hospital services to the severely underserved residents of the proposed rural service area. BC indicates that the hospital will form a bridge between residents with little access to care and the medical center that can best meet their complex needs.

BC states that the proposed hospital will be built on a location designated for a hospital in the master plan of Ave Maria in Zip Code 34142. The applicant states that this location is on Arthrex Commerce Drive near Oil Well Road and the South entrance to the Ave Maria community. The applicant asserts that the location is ideal for a number of reasons:

- Distance from area hospitals
- There is a convenient road (Camp Keis Road) east of Ave Maria that bypasses the community but will allow Immokalee traffic to conveniently access the hospital
- The newly constructed space will provide an unusually attractive site for providers to practice
- The Ave Maria community has already attracted many health care professionals and is an attractive location for recruitment of staff
- The proposed site will be a safe neighborhood where patients from all communities I the service area will feel comfortable

The applicant notes that there are no acute care hospitals in the proposed service area with a stand-alone emergency department, NCH Northeast, located on the far west side of Zip Code of 34120. BC provides a map of the service area Zip Codes along with an outline of the Ave Maria community on page 141 of CON application #10522. The total projected admissions by proposed service area Zip Code are provided in the following charts as presented in the application:

Total Projected Percent Admissions by ZIP Code based on Historical Patient Volume		
Zip Code	**Admissions**	**Percent of Admissions**
Primary Service Area		
34142	1,432	85.4%
Secondary Service Area		
34120	138	8.2%
34143	102	6.1%
34141	5	0.3%

Source: CON application #10522, Page 141

Total Projected Admissions by Zip Code based on Historic Patient Volume										
Zip Code	**2021**		**2022**		**2023**		**2024**		**2025**	
	Admits	**% Admits**	**Admits**	**% Admits**	**Admits**	**% Admits**	**Admits**	**% Admits**	**Admits**	**% Admits**
Primary Service Area										
34142	1,539	85.4%	1,566	85.4%	1,592	85.4%	1,617	85.4%	1,643	85.4%
Secondary Service Area										
34120	149	8.3%	151	8.2%	154	8.3%	156	8.2%	159	8.3%
34143	109	6.0%	111	6.1%	113	6.1%	115	6.1%	116	6.0%
34141	6	0.3%	6	0.3%	6	0.3%	6	0.3%	6	0.3%
Total	**1,803**	**100.0%**	**1,834**	**100.0%**	**1,865**	**100.0%**	**1,894**	**100.0%**	**1,924**	**100.0%**

Source: CON application #10522, Page 141

BC states that all services, including each hospital MS-DRG code, were analyzed to achieve the highest value for patients while services were evaluated in light of their capacity to be provided at the highest value within the small hospital model. The applicant considered the cost-effectiveness of each service and the financial viability that could be supported by the local volume.

BC maintains that the new facility is to care for the emergency needs, key outpatient services and non-specialty/non-surgical inpatient hospital services. The applicant states that the goal with complex cases is to diagnose and stabilize the patient and direct them to a center of excellence to manage their complex care. BC indicates that an important focus of the hospital will be on diagnostic equipment and outpatient services necessary to diagnose patients.

The applicant provides the following list of outlined community needs that will be provided by the proposed facility:

- Twenty-four hour emergency care
- Acute care – medical inpatient care
- Swing bed care
- Pharmacy
- Infusion center

- Imaging
  - X-ray
  - Ultrasound
  - CT
  - MRI
  - Mammography
  - Nuclear medicine
- Laboratory
  - Hematology
  - Chemistry
  - Cardiac markers
  - Urinalysis
  - Blood gas analysis
  - Toxicology
  - Immunoassays
- Rehabilitation
  - Physical therapy
  - Occupation therapy
- Cardiorespiratory
  - Nebulizer treatment
  - Spirometry
  - Pulmonary function test
  - EKG
  - Graded exercise test
- Obstetrical care

BC indicates that the proposed service area needs a lean and efficient facility that is tailor-made to meet the needs of the area by facilitating the county health care delivery system. The applicant maintains that the proposal will operate as a "micro-hospital" and provide a streamlined model of health care that can be financially supported by the proposed service area. BC asserts that a traditional acute care hospital model is unsustainable in the proposed PSA and incompatible with the patient population of the service area. The applicant anticipates that a traditional hospital model would be underutilized and financially unsustainable in the service area. BC references a book titled "The Cleveland Clinic Way" summarizing the relationship between volume at facilities and procedural quality.

The applicant provides a narrative description of the micro-hospital model including benefits of the hospital model. BC describes how the increasing emergence of micro-hospitals providing mostly outpatient services point to the decreased need and financial viability of a full service hospital in every community. The applicant notes a trend in the hospital delivery system that shift away from inpatient to outpatient care.

The applicant indicates that these changes include:

- Advances in medical care and technology
- Changes in Medicaid and managed care reimbursement that focus on cost savings and efficiencies
- An increased understanding and awareness of infection control
- Patient comfort
- Overall health care cost control

BC maintains that micro-hospitals fit a "patient-centered medical home" model of health care delivery with primary care services as well as imaging and laboratory services to support testing. The applicant note that micro-hospitals offer an effective medical home model where patients are cared for by a team coordinated by the primary care practitioner. The applicant states that unnecessary hospitalizations will be minimized and patients will receive high quality personalized care resulting in better health care outcomes. BC notes that the micro-hospital model is endorsed by the American Hospital Association as a good health care delivery model for people in underserved areas. The applicant asserts that a patient-centered medical home delivery method integrates health care services in ways that eliminate inefficiencies and redundancies while promoting communication and integration of care. BC advances that the proposed model would not replace but supplement existing qualified health centers and rural health clinics. The applicant does not expect for benefits to be confined to improved population health but also includes significant cost reductions by eliminating unnecessary hospitalizations.

Using data obtained from the Emergency Medicine Database from the third quarter of 2016 through the second quarter of 2017, the applicant evaluates the time of arrival of patients that arrived between nine a.m. and five p.m. Based on the results of the analysis, the applicant determines that (by Zip Code) most patients from its proposed service area arrive at the emergency department during daylight hours. BC infers that these arrival times reflect that patients are using the emergency department instead of a local physician's office. The applicant expects for the proposed facility to create a patient-centered medical home which will allow the screening of patients while connecting them to primary care physicians within the PSA. From the analysis, BC determines that eliminating 52.0 percent of patients from the proposed service area who currently use the emergency department as primary care would divert 12,320 patient encounters away from the emergency department and result in $58,808,124.76 of potential charge savings.

BC states that the proposal's delivery model will effectively meet the need for local emergency, obstetric and acute inpatient care. BC states that the foundation of the business model of the proposal will center on a coordinated system of health care, an effective EMR, relevant diagnostic testing, telemedicine, hospital-at-home health care delivery and providers with a broad scope of practice. Narrative descriptions of each component of the business model are provided on pages 148 – 150 of CON application #10522.

As an existing provider of outpatient services within Collier County, the applicant maintains that it uniquely understands the needs of the community. BC states that its current practice focuses on technology and progressive care that will support the technology driven aspects of the micro-hospital model. The applicant indicates that the EMR platform, Athena EMR, will provide the proposed facility with the agility to provide the best quality and value to patients. BC maintains that the proposed hospital will connect residents to resources in the area and achieve a more balanced service delivery system in Collier County promoting a healthier population and cost-effectiveness in the service area.

BC states that the proposed hospital will operate as a rural hospital pursuant to the provisions of 395.602, Florida Statutes[5]. The applicant describes how the proposed service area meets the criteria for a rural hospital as the population density of the service area (for Zip Code 34142) is 46.6 persons per square mile. The applicant states that the service area's anticipated population growth will not exceed 58,643 persons as of the upcoming 2020 census. BC attests that the proposed hospital will receive funds under s.409.9116 for a quarter beginning no later than July 1, 2022, therefore qualifying the hospital as a rural hospital through June 30, 2031 (The proposal is anticipated to be completed in 2020).

The applicant indicates that per the Florida Department of Health Office of Rural Health, the proposed service area in Immokalee is within the Collier County Rural Health Network. BC states that the Florida Department of Health Office of Rural Health endorses the development of a hospital in Zip Code 34142. The applicant states that the introduction of the proposal is a vital and necessary part of the Collier County Rural Healthcare Network's health plan for the PSA and references a letter of support from Victoria Gauze, Executive Director of Collier County Rural Healthcare Network, endorsing this project (CON application #10522, Pages 27 and 154). The reviewer notes that the full letter of support from Victoria Gauze is not available in the letter of support volume, though Victoria Gauze is identified as Executive Director of Collier County Rural

Health Network in Appendix G of the application. BC provides a list of issues facing rural residents including being poorer, more likely to have chronic diseases and longer drive times which delay care. The applicant notes that Rural Health Networks are mandated to support rural hospitals pursuant to the provisions of 381.0406, Florida Statutes. BC states that the Collier County Rural Health Network promotes the health of rural inhabitants of PSA Zip Code 34142.

The applicant specifically references ss.381.0406 (12), Florida Statutes: *Networks, to the extent feasible, shall provide for a continuum of care for all patients served by the network. Each network shall include the following core services:*

- Disease prevention
- Health promotion
- Comprehensive primary care
- Emergency medical care
- Acute inpatient care
- Comprehensive maternity care, including prenatal, delivery, and postpartum care for uncomplicated pregnancies

BC determines that since there are currently zero acute care beds in the proposed service area and no emergency medical care, the Collier County Rural Health Network has had difficulty promoting high quality health care. The applicant notes that pursuant to the provisions of ss. 381.0406(12), Florida Statutes, basic emergency room services and prenatal postpartum for uncomplicated pregnancies should be available within 30 minutes and Level I obstetrical care, which is labor and delivery for low-risk patients should be available within 45 minutes travel time or less. The applicant additionally describes statutory mandates of ss. 395.602, Florida Statutes, and states that besides BC, the other substantial supplier of physician services in the proposed service area is HNSF which has endorsed support of the proposal through committing staff to support the physicians and midlevel providers for the proposal.

BC assert that the PSA lacks a health care infrastructure to adequately provide for a large and growing population and that approval of the proposal would promote health care services within the proposed service area.

The applicant expects for the proposal to provide core services pursuant to statutory guidelines enumerated in ss. 381.0406, Florida Statutes. BC indicates that having outpatient testing available locally will encourage residents to complete tests before life-threatening or critical situations arise. BC states that patients with these conditions will be diagnosed quickly and their providers can assist them with developing a health care plan to prevent the development of systemic disease. The

applicant states that health will be promoted through access to services as well as educational classes and training in care for chronic conditions.

BC maintains that the proposed facility in Zip Code 34142 will catalyze other important services in the continuum of patient care such as hospice care and assisted living. The applicant references its partnership with Avow Hospice and discussions with ALFs to facilitate important extensions of care in an immediate reality for the residents of the service area. BC states the proposal will ultimately raise the health status of residents in the PSA to a standard level.

BC provides an analysis comparing the distance of the proposed rural hospital to other hospitals listed on the Florida Hospital Rural Health Directory (excluding two rural hospitals in Monroe County). From this geographic analysis, the applicant finds that the average distance between a rural hospital and the next closest hospital was 23.0 miles, with the distance for the 25th percentile was 19.3 miles and the distance for the 75th percentile was 27.5 miles. BC states that the estimated distance from the proposed hospital to the next nearest hospital is 23.0 miles. The applicant contends that the geographic barrier to access that the proposed service area is experiencing is similar to other rural areas in the state. The applicant expects for the rural hospital to reduce geographic barriers in a similar capacity to other rural hospitals throughout the state.

The applicant provides a statistical analysis comparing the populations within the Zip Codes of the previous rural hospitals in comparison to the population within the proposed hospital's PSA. The population data used is from the 2016 US ACS Five-Year Population Estimate by the US Census Bureau. BC's analysis reflects that the average population within the Zip Code of a rural hospital is 26,033 persons with the population size for the 25th percentile is 25,847 persons and the population size for the 75th percentile is 26,291 persons. The applicant notes that the population size within the PSA is 29,287. The reviewer notes that based on the data provided the standard deviation of the data set would be 15,033 persons, the population size of the proposed SSA is 29,287, less than one standard deviation from the mean population size.

BC evaluates the utilization rate for rural hospitals included in the previous analysis using Agency data. Based on the data provided, the applicant indicates that the average utilization rate across rural hospitals in the State of Florida is 31.89 percent with the utilization rate for the 25th percentile was 23.43 percent and the utilization rate for the 75th percentile is 40.34 percent. The applicant states that from this analysis, rural hospitals are not well – utilized in comparison to urban hospitals.

BC indicates that due the importance of rural hospitals in health care delivery, they are not held to the typical 75.0 percent standard utilization rate for urban hospital projects.

The applicant provides a narrative description of the methodology and collaboration used to determine the targeted MS-DRG Codes for the proposed hospital. On page 162 of CON application #10522, BC provides a chart of the ICD-10 MS-DRG codes that will be targeted at the proposed hospital. The applicant notes that during the compilation of the list of MS-DRGs for inpatient services that would be provided at the hospital, the services proposed were compared against what the future medical staff identified as the hospital's core services, support services, equipment and other intangible items to ensure that there would be no waste and to maximize the utilization and benefit to the community. The applicant provides narratives of the methodologies used to determine surgery MS-DRG Codes for Centers of Excellence, the proposed hospital utilization for obstetric and infant services by MS-DRG including an analysis of the neonate utilization by MS-DRG Code within the PSA and SSA, stroke services and cardiac services by ICD-10 code on pages 163-170 of CON application #10522.

The applicant provides a narrative description of the operations of the proposed hospital which will include:

- Clinical services
- Pharmacy
- Laboratory
- Radiology
- Emergency services
- Physical therapy
- Respiratory/Cardiopulmonary therapy

BC identifies the following support services to be included:

- EMR and advanced information technology
- Medical staff services
- Continuing education
- Nutrition services
- Environmental services
- Plant operations and engineering
- Security
- Laundry and linen
- Human Resources
- Employee health
- Volunteer services
- Biomedical engineering
- Utilization review
- Quality assurance (QA)

- Discharge planning/social services
- Medical staff support
- Information technology/data processing
- Accounting/finance/billing/collections/registration
- Administration
- Central supply
- Marketing and public relations
- Gift shop/coffee shop
- Health professional development

The applicant provides factors that will positively contribute to health professional recruitment to the proposed facility in Ave Maria:

- Local residents who are health care providers have already committed to joining the medical staff at the proposed facility
- Past interns mentored at BC who are studying to become physicians, physician assistants, and nurse practitioners have indicated a desire to work at the future hospital
- The location of the hospital site in a pleasant family-friendly community in sunny Florida
- The progressive medical culture of the BC providers
- The modern design of the new hospitals as well as state-of-the-art technology and equipment
- The advanced and effective model of health care delivery
- The Critical Access Designation of the hospital will allow us to offer the following specialties for inpatient and outpatient care

The applicant states that providers have already agreed to join the following specialties for inpatient and outpatient care:

- Addiction medicine
- Adolescent and child psychiatry
- Adult psychiatry
- Anesthesia
- Emergency medicine
- Family medicine
- Internal medicine
- Medical toxicology
- Obstetrics and gynecology
- Pediatrics

The Braden Clinic states that the following specialty services will be provided via telemedicine:

- Cardiology
- Critical care
- Gastroenterology
- Infectious disease
- Nephrology
- Neurology
- Pulmonology

The applicant states that the proposed hospital will adjust its physician group in order to optimally meet the needs of the service area. Based on data obtained from the Florida Center for Health Information and Transparency, a table provided by the applicant summarizes the historical volume of discharges and patient days by payer mix across the applicant's proposed service area through the second quarter of 2017. From this analysis, BC concludes that Medicare accounted for 36.0 percent of patient days, Medicaid accounted for 33.0 percent of patient days and commercial insurance accounted for 19.0 percent of patient days.

Within the PSA, BC evaluates the historical volume of discharges and patient days by payer mix across the applicant's PSA through the second quarter of 2017. The applicant describes how Medicaid accounted for 47.0 percent of patient days and 54.0 percent of discharges, Medicare accounted for 21.0 percent of discharges and commercial insurance accounted for 11.0 percent of discharges. Within the SSA, the analysis provided reflects that Medicare accounted for 38.0 percent of discharges, commercial insurance accounted for 31.0 percent of discharges and Medicaid accounted for 20.0 percent of discharges.

Across the five-year period between the third quarter of 2013 and the second quarter of 2017, the applicant provides an analysis which reflects that the volume of inpatient discharges across the PSA has increased between 20.0 – 26.0 percent. From this data analysis, the applicant determines that the historical need for acute care hospital beds will continue to grow over the next several years alongside increases with the population. Due to the proportion of Medicaid and medically indigent, the applicant states that a unique health care model must be in place and the proposal will target the unique needs of the community.

BC provides a market share analysis and notes that the utilization data obtained from Zip Code 34142 obtained from the Agency does not include patients that are not full-time residents of the service area such as visitors, partial year residents, university students and the migrant worker population. The applicant states that based on BC's patient data and the migrant worker influx in Immokalee, an 8.0 percent "out of service area" factor was used in forecasting patient volume.

Based on data obtained from the National Center for Health Statistics, the applicant notes that emergency department visit patterns are related to proximity to patients' residences and patients within and outside of metropolitan statistical areas (MSA) drive an average of 6.8 miles to visit an Emergency Department. The applicant describes how 37.2 percent of patients receive care at the closest hospital to their home and 70.0 percent of patients residing outside of a MSA visit the nearest Emergency Department. In reference to this analysis, the applicant anticipates that the proposal will assume a 70.0 percent utilization rate of the ED for residents from the PSA.

In estimation of the inpatient market share, the applicant forecasts an average length of stay (ALOS) of 3.2 days. BC indicates that inpatient admissions from the emergency department and referring physicians from HNSF Clinic in Immokalee, BC in Ave Maria, the Seminole Nation Clinic and other credentialed physicians. BC expects that the proposed hospital will capture 50.0 percent of patients from the entire pool of inpatients from the PSA.

The applicant provides a table for the forecast of targeted admissions and discharges from 2021 – 2025 in which Medicaid and Medicaid Managed Care accounts for 61.0 percent of cases and 54.0 of total hospital days. BC indicates that during the first year of operations, time will be needed to streamline processes, work through efficiencies and complete the full credentialing process with DNV GL[6]. The appendices to the application provides a sample of a discussion with John D. Webster of DNV GL and a description of DNV GL's accreditation services.

[6] On Page 13 of CON application #10522, the applicant indicates that DNV GL is an international accreditation firm and world leading certification body that will provide training and consultation on a variety of hospital best practices and on-site inspections for national and international accreditation. The applicant additionally notes that DNV GL has been approved by the Centers of Medicaid and Medicare Services for deeming authority to determine health care organizations in compliance with the Conditions of Participation for Hospitals and Critical Access Hospitals since September 26, 2008 and December 23, 2010. The applicant additionally notes that DNV GL Healthcare National Integrated Accreditation for Healthcare Organizations Hospital Accreditation Program integrates ISO 9001 Quality Management System requirements with the Medicare Conditions of Participation for Hospitals or Critical Access Hospitals as applicable.

The following table reflects the forecasted utilization for the proposed hospital as presented in CON application #10522. The Braden Clinic indicates that an 80.0 percent start-up factor has been added to the first year of operations utilization.

Proposed Hospital Future Utilization					
Year	**2021**	**2022**	**2023**	**2024**	**2025**
Discharges	1,979	2,013	2,046	2,079	2,112
Utilization	56%	71%	72%	73%	74%

Source: CON application #10522, Page 192

BC determines that the demand forecast for the proposed hospital is appropriately sized to meet current service area needs and the future needs of the growing population. The applicant states that the projected utilization rate of 71.0 percent is high, but reflects the tremendous need in the proposed service area and that the proposal will be well utilized. BC provides the following charts reflecting the PSA (zip code 34142) and SSA targeted DRG days projected for 2021 – 2025 with 70.0 percent capture and an 8.0 percent out of service area factor. Within the SSA, BC notes that 70.0 percent capture is expected for Zip Code 34143 (located within Zip Code 34142) and 10.0 percent capture is expected for Zip Codes 34120 and 34141.

Primary Service Area (34142) Targeted DRG Days Projections 2021 - 2025 with 70.0 Percent Capture and 8.0% Out of Service Area Factor							
Payer	**Name**	**2021**	**2022**	**2023**	**2024**	**2025**	**% Days**
A	**Medicare**	661	672	683	694	705	12%
B	**Medicare Managed Care**	324	329	335	340	345	6%
C	**Medicaid**	1,382	1,406	1,429	1,452	1,475	25%
D	**Medicaid Managed Care**	1,757	1,787	1,817	1,846	1,875	32%
E	**Commercial Health Insurance**	678	689	701	712	723	12%
H	**Workers Compensation**	13	14	14	14	14	0%
I	**Tricare or Other Federal**	14	15	15	15	15	0%
J	**VA**	13	13	13	13	13	0%
K	**Other State/ Local Government**	133	136	138	140	142	2%
L	**Self-Pay**	205	208	212	215	218	4%
M	**Other**	20	20	21	21	21	0%
N	**Non - Payment**	195	198	201	204	208	4%
O	**Kidcare**	23	23	23	24	24	0%
Q	**Commercial Liability Coverage**	32	32	33	33	34	1%
Total		**5,449**	**5,543**	**5,635**	**5,725**	**5,815**	**100%**

Source: CON application #10522, Page 198. Shaded values are incorrect.

Secondary Service Area Targeted DRG Days Projections 2021 - 2025 with 70.0 Percent Capture for 34143, 10.0% capture for 34120 and 34141 and 8.0% Out of Service Area Factor							
Payer	**Name**	**2021**	**2022**	**2023**	**2024**	**2025**	**% Days**
A	**Medicare**	232	236	240	244	248	24%
B	**Medicare Managed Care**	91	93	94	96	97	9%
C	**Medicaid**	109	111	113	115	117	11%
D	**Medicaid Managed Care**	245	249	253	257	261	25%
E	**Commercial Health Insurance**	210	214	217	221	224	22%
H	**Workers Compensation**	1	1	1	1	1	0%
I	**Tricare or Other Federal**	15	16	16	16	16	2%
J	**VA**	3	3	3	3	3	0%
K	**Other State/ Local Government**	1	1	1	1	1	0%
L	**Self-Pay**	26	26	26	27	27	3%
M	**Other**	1	1	1	1	1	0%
N	**Non - Payment**	30	30	31	31	32	3%
O	**Kidcare**	1	1	1	1	1	0%
Q	**Commercial Liability Coverage**	3	3	3	3	3	0%
Total		**967**	**984**	**1,000**	**1,016**	**1,032**	**100%**

Source: CON application #10522, Page 204. Shaded values are incorrect.

f. Written Statement(s) of Opposition

Except for competing applicants, in order to be eligible to challenge the Agency decision on a general hospital application under review pursuant to paragraph (5)(c), existing hospitals must submit a detailed written statement of opposition to the Agency and to the applicant. The detailed written statement must be received by the Agency and the applicant within 21 days after the general hospital application is deemed complete and made available to the public. ss. 408.039(3)(c), Florida Statutes.

The Agency received one written statement of opposition (WSO) against the proposal on May 4, 2018 from Ausley McMullen, Attorneys and Counselors at Law on behalf of both facilities operated by Naples Community Hospital (NCH) in Collier County.

The reviewer notes that the opposition letter expresses collective criticism against all acute care proposals submitted in District 8. For instance, NCH opposes CON application #10522 and advances that this proposal and the other two proposals submitted for review in Lee County all fail to address any special or not normal circumstances, which the opposition determines invites serious criticism when alleging that residents experience impediments to access and availability to hospital-based care.

Opposition determines that all of the proposed projects are small hospitals without the capability to provide higher acuity services or address a myriad of medical conditions. Moreover, NCH maintains that the proposals offer nothing unique to the service area where multiple hospitals offer greater complexity and more services than any of the three applicants.

The opposition has determined that all three proposals share characteristics that overstate the size of the service area and the capabilities that small urban hospitals of 88 beds or less possess to render appropriate care. NCH identifies the following shortcomings to all of the proposals submitted in District 8:

- Service areas that overlap with existing hospitals in PSAs
- Redundancy and unnecessary duplication of existing services
- Selection of DRGs that stretch well beyond the capabilities that a small hospital can provide
- Negative impacts on existing hospitals
- Lack of evidence showing geographic barriers or impediments to current hospitals, notwithstanding drive times that do vary and would vary based on where residents reside
- Lack of any competitive advantages of location, service availability, demand, market rates or costs of charges
- Inability to justify any unique or special circumstances that arise to the level of justifying millions of dollars to create a small urban hospital in service areas that already have urban and suburban hospitals with higher case mix indices and established, broad-based medical staffs

NCH references conclusions and circumstances discussed in previous CON cases: Case Nos. 13-2508CON, 13-2558CON and 16-00112CON *et.al* (NCH WSO, Page 2). The opposition states that all three applications raise the issue regarding the highest and best use of resources. NCH expects for the proposals to essentially capture only a small percentage of a proposed service area that overlaps with existing hospitals that offer the same services—which is anticipated to result in market shift rather than market share. For this reason, the opposition states that sharing incremental growth within a new party does not confer benefits to residents and expects for implementation of the proposals to result in the fragmentation of existing low acuity services in a different location instead of support for existing relationships.

A 25-Bed Hospital and Its Service Area

The opposition maintains that the foremost rational in this proposal is the assertion that zip code 34142 and the Immokalee region are remote and distant to hospitals in Collier County, which necessitate a rural hospital. NCH maintains that the argument that need for a hospital is

evidenced by the absence of a hospital in Zip Code 34142 contradicts the Agency's policy as outlined in Rule 59C-1.008(2)(e), Florida Administrative Code. The reviewer notes that the opposition omits a few words from 59C-1.008, (2)(e)3. and reproduces it here (emphasis added): "*The existence of unmet need will not be based solely on the absence of a health services, health care facility, or beds in the district, subdistrict, region or proposed service area.*"

The opposition notes that Florida has 219 acute care hospitals ranging in size from critical access, rural and small to large medical centers with a variety of service levels. NCH indicates that only eight of 67 Florida counties lack a hospital due to small population sizes which have contributed to the closure of hospitals in Hamilton and Gilchrist Counties.

NCH reviews the substantial issues that rural hospitals face in staffing, financing, code compliance, mix of services, available and sustainable workforce and medical professionals and concludes that the Immokalee Zip Code 34142 faces perils. The opposition also maintains that while the Ave Maria community will grow, the area's designation as a medically underserved area for services and professionals will serve as a detriment to the success of the proposal.

Description of the Service Area and Issues that Arise

NCH notes the presence of extensive service area overlap between the proposals and existing providers and underscores that none of the proposals offer to serve an area that is not already served. In specific reference to the Braden Clinic's proposal, the opposition notes that the sole PSA Zip Code 34142 falls within the PSA of both NCH North and Physicians Regional-Pine Ridge.

The opposition provides tables and maps on pages 4-11 of the WSO which outline the service areas of Cape Coral Hospital, Gulf Coast Medical Center, Lee Memorial Hospital, Lehigh Regional Medical Center, Naples Community Hospital, NCH Healthcare System North Naples Campus, Physicians Regional Medical Center – Collier Boulevard, Physicians Regional Medical Center – Pine Ridge across all subdistricts in District 8. The reviewer notes that the tables show the coverage of District 8, the corresponding counties that existing hospitals serve and the applicant's proposed service area.

In description of the maps provided for NCH North and Physicians Regional-Pine Ridge, NCH notes the following:

- The first map shows the NCH North Hospital's PSA. Note that the reach extends into Zip Codes in Lee County. Its location affords access to Zip Code 34142, the PSA of Braden Clinic, LLC's proposed hospital.

- The second map shows the overlap of the applicant with that of NCH North, with Zip Code 34142 in red indicating that both hospitals would serve resident of that Zip Code as a PSA.
- The third map shows the PSA of Physicians Regional Medical Center – Pine Ridge and like NCH North, Zip Code 34142 falls within that hospital's PSA.
- The fourth map provides an illustration of the overlap of the proposed hospital PSA and that of Physicians Regional-Pine Ridge, with Zip Code 34142 shown in red.

The opposition's ultimate conclusions of the maps are that residents of Zip Code 34142 are neither unserved nor underserved, the locations of the existing hospitals do require travel and their locations reflect the development in past years for a preference in coastal living. NCH determines that no geographic impediments exist.

The Service Area

NCH describes the applicant's PSA, which consists of Zip Code 34142 and the applicant's SSA which consists of Zip Codes 34143 (located in Zip Code 34142), 34141 and 34120. The opposition notes that Zip Code 34143 is a PO Box address that lacks population. NCH's research of the AHCA hospital inpatient data file for July 2016 – June 2017 returned no cases associated with Zip Code 34143. The opposition notes that the applicant expects to capture only 10.0 percent of Zip Code 34120.

NCH indicates that Zip Code 34142 falls within the PSA of NCH North and Physicians Regional-Pine Ridge and the SSA of Cape Coral, Gulf Coast, Health Park, Lee Memorial, Lehigh Regional, Naples Community and Physicians Regional Collier Boulevard. The opposition states that Zip Code 34141 lies within the SSA of all four Collier County acute care hospitals and Zip Code 34120 lies within the PSA of both NCH North and Physicians Regional Pine Ridge and within the SSA of Gulf Coast, HealthPark and Lee Memorial (all four Collier County acute care hospitals are noted to lie within 15 miles or less of the centroid of Zip Code 34120).

Maps of the population centroids for Zip Codes 34120 and 34142 are provided on pages 13 -14 of the WSO. NCH explains that the maps have a circumference outlined around selected points in order to show the radius of a given size as indicated on the map. The opposition determines that the existing hospitals are accessible and fall within the circumference that denotes an approximate 15 and 23.5-mile radius respectively around Zip Codes 34120 and 34142 with the closest hospital to Zip Code 34141 located 39.7 miles/50 minutes away (Physicians Regional Collier Boulevard).

NCH concludes that while some residents may live closer to the northern border of Zip Code 34142, the opposition does not anticipate residents would select a very small rural hospital with limited services that lies farther away from Physicians Regional Collier Boulevard as anticipated with implementation of the proposal.

Travel Time Assessment Issues

The opposition provides a review of purported flaws of the travel time assessment provided in CON application #10522. NCH determines that the travel time assessment provided should not be considered as an adequate foundation to base any findings of fact. The opposition states that a technical review was undertaken of the materials provided in CON application #10522. The reviewer notes that the opposition does not attribute the source of the technical review.

NCH describes the following deficiencies in the time travel assessment:

- The travel time assessment does not provide an appendix to support the referenced data
- There is not enough information presented to track the quality of the data cited, making it difficult to determine if the data is in fact reliable
- Quality technical evaluations are able to be independently replicated toward reaching the same conclusion and the data provided by the applicant is insufficient to replicate the findings
- The Braden Travel Time Assessment does not appear to be authored by a licensed professional traffic engineer
- The casual use of technical terms without reference deviates from standardized traffic engineering protocol

The opposition itemizes a description of these issues on pages 55, 57, 60, 74 and 80 of CON application #10522 specifically.

In analysis of the drive-time assessment, NCH states that there are assumptions stated inferring population growth, traffic volumes and travel data and though related, does not have direct linear relationship to formulate conclusions. The reviewer notes that these assumptions are not directly itemized per the application but NCH maintains that the use of a regional travel demand model, traffic capacity simulation and calibrated drive time data would represent more standardized industry protocol for making these claims. The reviewer notes that again, NCH does not credit an expert or technical source for these conclusions.

NCH also determines that recent capacity updates that have reduced travel time were not reported in CON application #10522, nor does the report identify other programed and planned capacity improvements such as the programmed widening of SR 82 to a four lane road. The reviewer notes that the opposition does not provide documents attesting to these changes.

Description of the Services and Issues that Arise

The opposition restates the applicant's descriptions of the proposed service area as a medically underserved area lacking in support services and health care professionals. Areas of particular concern identified by the opposition are the staffing needs of the project and the proposal's feasible capacity to treat seriously ill stroke and heart attack patients. NCH notes the distribution of pharmaceutical and post-acute care services like SNFs which reflect that the service area lacks post-acute care services to allow the hospital to provide the services indicated in the proposal. The opposition states that the use of acute care beds as swing beds as described in the application will undercut the hospital's acute care mission and redoubles the argument of a lack of need for inpatient hospital care.

Using AHCA's hospital financial data, the opposition provides a table summarizing the mean case index for rural hospitals with 25 beds or less. NCH indicates that Florida Hospital Wauchula was removed because of a reported 10.0 day ALOS. See the following table:

Rural Hospitals with 25 or Fewer Acute Care Beds July 1, 2016 - June 30, 2017				
Hospital	**Cases**	**ALOS**	**Average CMH**	**Beds**
Calhoun - Liberty Hospital	304	3.8	0.9562	15
George E. Weems Memorial Hospital	149	3.9	0.8762	15
Shands Live Oak Regional Medical Center	1,078	3.3	0.8523	15
Sacred Heart Hospital on Gulf	425	3.7	1.061	17
Doctors Memorial Hospital	397	4.0	1.0103	18
Ed Fraser Memorial Hospital	239	2.8	0.9601	25
Hendry Regional Medical Center	515	3.0	1.0733	25
Lake Butler Hospital	24	2.7	0.8283	25
Madison County Memorial Hospital	400	3.8	0.9449	25
Northwest Florida Community Hospital	607	4.1	1.0643	25
Shands Starke Regional Medical Center	1,300	3.4	0.9311	25
Average	**494**	**3.5**	**0.9615**	**21**

Source: NCH WSO, Page 17

In review of the description of services provided on pages three and 143 of CON application #10522, NCH determines that there are discrepancies between the types of services the applicant states will be offered at the facility and the actual staffing and resources needed to provide full emergency care to an extent that the opposition determines reflect an overestimation of the proposal's capabilities.

NCH compares the applicant's list of DRGs on page 162 of CON application #10522 and computes an ALOS of 4.0 days and case mix index (CMI) of 1.2397. The opposition next compares the case mix index of the applicant with other hospitals for which bed sizes are also noted:

- Lehigh Regional (Lee County), 88 beds, CMI 1.2177
- St. Cloud Hospital (Osceola County), 84 beds, CMI of 1.1161

- Viera Hospital (Brevard County), 84 beds, CMI 1.2319

The ALOS derived from these hospitals was 3.7 days and the CMI derived was 1.2772. The opposition next reviewed the DRGs of the proposal and the proxy hospitals noted above. DRGs that were listed in the applicant's proposal but were not shared with the proxy hospitals were summarized in a table along with the calculated ALOS (6.7 days) and CMI 1.9267 (NCH WSO, Page 19). The opposition determines that the DRGs unique to the applicant in comparison to the proxy hospitals would require surgeons, specialists and other resources that conflict with statements made about the services to be offered in the proposal.

NCH evaluates the capacity for the proposal to treat stroke patients originating from the proposed service area. Using AHCA inpatient data, the opposition reviews the number of cases of patients from Zip Codes 34141 and 34142[7] with stroke or heart attack DRGs and provides the analysis in the following table:

Stroke and Heart Attack Patients from the Braden Clinic Service Area				
DRG	**34141**	**34142**	**Total**	**Average Case Mix**
064 Intracranial Hemorrhage or Cerebral Infarction w MCC	0	9	9	1.7518
065 Intracranial Hemorrhage or Cerebral Infarction w CC or tPA in 24 Hours	4	15	19	1.0431
066 Intracranial Hemorrhage or Cerebral Infarction w/o CC/MCC	0	4	4	0.7464
Subtotal	**4**	**28**	**32**	**1.2053**
280 Acute Myocardial Infarction, Discharged Alive w MCC	0	11	11	1.6748
281 Acute Myocardial Infarction, Discharged Alive w CC	2	9	11	0.9968
282 Acute Myocardial Infarction, Discharged Alive w/o CC/MCC	0	5	5	0.7463
283 Acute Myocardial Infarction, Expired w MCC	0	1	1	1.6925
Subtotal	**2**	**26**	**28**	**2.0477**
Total	**6**	**54**	**60**	**1.5985**

Source: NCH WSO, Page 20

In general, NCH determines that there were 60 persons from the two Zip Codes that fell into either the stroke or heart attack DRGs (strokes accounted for 32 cases and heart attacks accounted for 28) with 19 cases requiring the administration of tPA. Based on the derived case mix index of these cases (1.5985), the opposition does not anticipate that the staffing and resources of the proposal would adequately support treatment of these patients. In Appendix 1 of the WSO, STEMI and Stroke Guidelines are provided and the opposition concludes that EMS would not divert such patients to the proposed hospital.

NCH describes the freestanding emergency department operated by Naples North at the intersection of Immokalee Road and Collier Boulevard in Zip Code 34120 and states that the proposal would duplicate already existing emergency services. A map with drive times

[7] NCH notes that the applicant excluded zip code 34120 as a result of the small volume of cases

and distances between the Braden Clinic and the freestanding ED is provided on page 21 of the WSO. Annotations to the map indicate that the distance from the Braden Clinic to the Naples North ED is 20.2 miles, requiring a travel time of 20 minutes under normal driving conditions. The notes included under the table also indicate that guidelines from the American Heart Association indicate "local EMS should generally be used if available and 30-minute transport time to destination hospital."

Overstatement of Medicaid Cases

NCH reviews the applicant's Medicaid analysis and states that the application shows a complete hospital forecast by payer source and indicates that Medicaid and Medicaid Managed Care represent 61.0 percent of the proposed hospital's discharges. The opposition evaluates the reasonableness of the forecast, baseline from the AHCA inpatient data file by analyzing the Medicaid and Medicaid HMO cases for residents and hospitals within Collier County from July 2016 – June 2017. A consolidated reference to the table is reproduced below:

Medicaid and Medicaid Managed Care Cases for Residents and Hospitals within Collier County, July 1, 2016 - June 30, 2017

Hospital with Medicaid Payer	34120	34141	34142	Total Cases 3 Zip Codes	SA Total Cases with 10.0% of 34120
Naples Community Hospital					
∑Medicaid/Medicaid HMO	22	0	102	124	104
Hospital Total	394	1	237	632	277
NCH North Naples					
∑Medicaid/Medicaid HMO	96	0	295	391	305
Hospital Total	580	0	663	1,243	721
Physicians Regional - Collier Blvd.					
∑Medicaid/Medicaid HMO	6	0	5	11	6
Hospital Total	69	7	20	96	34
Physicians Regional - Pine Ridge					
∑Medicaid/Medicaid HMO	23	0	45	68	47
Hospital Total	400	3	272	675	315
Medicaid Total	147	0	447	594	462
Grand Total Hospitals	1,443	11	1,192	2,646	1,347
Medicaid as Percent of Total Cases	**10.2%**	**0.0%**	**37.5%**	**22.4%**	**34.3%**

Source: NCH WSO, Page 22

In comparison with the analysis presented in the table, the opposition notes that the applicant's projections for the year 2021 forecast 1,217 Medicaid and Medicaid Managed Care cases in comparison to 462 Medicaid and Medicaid Managed Care cases forecasted in the analysis above. The opposition forecasts 507 Medicaid and Medicaid Managed Care cases from a baseline of 462 cases when applying the anticipated population growth rate within the applicant's proposed service area (1.9 percent per year). With the inclusion of the applicant's 8.0 percent migration factor the opposition forecasts 548 total Medicaid and Medicaid Managed Care cases.

NCH includes all Collier County residents treated by any hospital in District 8 using the applicant's DRG list to yield 894 Medicaid and Medicaid Managed Care cases from the applicant's service area. With the inclusion of the compound annual growth rate and in-migration factor, the opposition forecasts 1,061 Medicaid and Medicaid Managed Care cases by 2021. NCH determines that it is unsupportable and unreasonable that the 25-bed proposal would support 1,217 Medicaid and Medicaid Managed Care cases.

Opposition provides the following table summarizing Collier County's enrollments in Medicaid HMO plans and the use of hospital services within health planning District 8 hospitals using the applicant's DRG list from July 2016 – June 2017:

Collier County's Enrollments in Medicaid Managed Care Plans and Use of Hospital Services within Health Planning District 8 Hospitals Using the Applicant's DRG List (July 1, 2016 - June 30, 2017)

Medicaid Managed Care	Number of Enrollees	Enrollees 1,000 Population
Molina	18,313	5.0%
Prestige	6,952	1.9%
Stay Well	5,254	1.4%
Sunshine State	4,670	1.3%
Subtotal	**35,189**	**9.6%**
Collier Total	**35,208**	**9.6%**
Collier County Population, 2017 (Claritas)	366,646	
Collier County Hospital Cases, Braden DRG List Medicaid Payer	1,044	
Collier County Hospital Cases, Braden DRG List Medicaid Managed Care Payer	1,156	
Enrollees Hospital Use Rate/1,000	32.8	
Enrollees MMC Rate/1,000 Population	3.2	

Source: NCH WSO, Page 24

Based on the hospital use rate for Medicaid Managed Care per 1,000 persons (3.2 per 1,000) and the future population estimated for Collier County in the year 2021 (396,111 persons), NCH computes 1,249 Medicaid HMO cases for the entire county.

Opposition determines that the foregoing comparisons provide a reliable test of the assumptions within the application regarding the experience of Collier County residents enrolled in Medicaid Managed Care plans and the use of hospital services denoted in the applicant's DRG list. NCH reiterates that the applicant's Medicaid forecasts are unreasonable and notes that the Braden Clinic, LLC, does not currently operate a hospital but operates a clinic which, per the Braden Clinic's website, does not accept Humana Medicaid or United Healthcare Medicaid and accepts Molina and Prestige.

Concern Regarding the Applicant, Braden Clinic, LLC

NCH reviews the assets included in audited financial statements submitted with the proposal and determines that the assets reflect little financial ability to secure adequate funding for the project. The opposition notes that though the overall financial feasibility of an acute care hospital is not directly at issue in this stage of review, the applicant has clearly raised the issue as to who will control the applicant entity if approved. Narrative critiques of the applicant's financial feasibility are included on page 25 of the NCH WSO.

Lack of Conditions Undercut the Proposal

In light of the previously enumerated deficiencies and critiques of the proposal in relation to the feasibility and reasonableness of the applicant's service mix, forecasted occupancy rate, proposed services to Medicaid/medically indigent, the proposed treatment of stroke and heart attack patients and the applicant's historical inexperience in operating or establishing a hospital—the absence of conditions is determined by the opposition to undercut the feasibility or practical implementation of the proposal.

Applicant's Forecast Produces an Adverse Impact on Collier County Hospitals

NCH expects for the forecasted patient load of the proposal to have an adverse impact on Collier County hospitals. The opposition does not expect for the applicant to capture the volume of forecasted cases indicated in the proposal without an adverse impact on Naples Community Hospital and Naples Community Hospital North. NCH provides the following table which reflects the existing market share within the applicant's DRG list:

Cases and Market Share for Collier County Hospitals in the Applicant's DRG List by Zip Code, July 1, 2016 - June 30, 2017

Collier County Hospitals	34120 Naples	34141 Ochopee	34142 Immokalee	Total	Market Share
Naples Community Hospital	39	1	237	277	15.7%
NCH Healthcare System North	58	0	663	721	40.7%
Physicians Regional Collier Blvd.	69	7	20	96	5.4%
Physicians Regional Pine Ridge	400	3	272	675	38.1%
Total	**566**	**11**	**1,192**	**1,769**	**100%**

Source: NCH WSO, Page 27

The opposition expects for the 1,769 forecasted cases to result in losses of 285 cases or $696,825 contribution margin in the first year (based on forecasts on page 141 of CON application #10522) and a loss of 384 cases or $938,880 contribution margin in the first year (based on the forecast provide on page 191 of CON application #10522). NCH states that the contribution margin calculation assumes the lost cases based on the applicant's service area description of Zip Code 34142 and 10.0 percent of 34120 with a greater financial impact should greater capture

of Zip Code 34120 occur. The reviewer notes that based on NCH's most recent FHURS report with a fiscal year end of September 30, 2017, NCH's net revenue was $467,295,330 with an operating margin of $35,429,068 (7.58 percent) and a total margin of $45,937,133 (9.83 percent). The reviewer calculates that the opposition identified contribution margin losses of $696,825 to $938,880 is equal to a 1.97 percent to 2.65 percent loss based on fiscal year 2017's operating margin—or representing 0.15 percent to 0.20 percent loss of total revenue to the proposed hospital.

NCH provides analysis which summarizes the forecasted losses to both hospitals based on the analyses presented on pages 141 and 191 of CON application #10522:

Impact of the Proposed Hospital on Hospitals in Collier County: Page 141 Forecast						
	2021	**2022**	**2023**	**2024**	**2025**	**Notes**
Service Area Cases	3,067	3,119	3,171	3,222	3,273	**Page 193**
Braden Hospital Cases	1,803	1,834	1,864	1,894	1,924	**Page 141**
ALOS	3.4	3.4	3.4	3.4	3.4	**Based on Braden DRG List, p. 162**
Days	6,152	6,257	6,360	6,462	6,564	
Occupancy	67.4%	68.6%	69.7%	70.8%	71.9%	**25 beds**
	Remaining Cases after Braden Hospital					
Subtract from Remaining	1,264	1,285	1,307	1,328	1,349	
Collier Hospitals Baseline Cases	1,769	1,769	1,769	1,769	1,769	
Cases Remaining after new hospital	**-505**	**-484**	**-462**	**-441**	**-420**	**Adjustment to 34120**
Naples Community Loss	-79	-76	-72	-69	-66	
NCH North Loss	-206	-197	-188	-180	-171	
Naples Health System Loss	**-285**	**-273**	**-261**	**-249**	**-237**	

Source: NCH WSO, Page 28

Impact of the Proposed Hospital on Hospitals in Collier County: Page 191 Forecast						
	2021	**2022**	**2023**	**2024**	**2025**	**Notes**
Service Area Cases	3,067	3,119	3,171	3,222	3,273	**Page 193**
Braden Hospital Cases	1,979	2,013	2,046	2,079	2,112	**Page 191**
ALOS	3.2	3.2	3.2	3.2	3.2	**Page 191**
Days	6,333	6,442	6,547	6,653	6,758	
Occupancy	69.4%	70.6%	71.8%	72.9%	74.1%	**25 beds**
	Remaining Cases after Braden Hospital					
Subtract from Remaining	1,088	1,106	1,125	1,143	1,161	
Collier Hospitals Baseline Cases	1,769	1,769	1,769	1,769	1,769	
Cases Remaining after new hospital	**-681**	**-663**	**-644**	**-626**	**-608**	**Adjustment to 34120**
Naples Community Loss	-107	-104	-101	-98	-95	
NCH North Loss	-278	-270	-263	-255	-248	
Naples Health System Loss	**-384**	**-374**	**-364**	**-353**	**-343**	

Source: NCH WSO, Page 28

The opposition states that the applicant's forecast exceeds the baseline 1,769 cases and hence adverse impact occurs. In the above analysis, the opposition notes that the 1,769 baseline cases represent only those cases from Braden's proposed service area.

Conclusion
NCH concludes that the foregoing analyses demonstrate that the applicant's proposal uses over-reach and the opposition expects for the effective impact amounts to result in a significant loss of cases that adversely affect the NCH Health System's ability to remain financially viable. The opposition concedes that doubt exists on the applicant's capacity to draw patients away from existing hospital.

NCH determines that denial of the proposal is warranted due to the lack of current sustainable growth and development to achieve projections and the lack of inpatient surgery which the opposition states is contradicted by the applicant's own DRG list that highlights a possibly well-intentioned but misguided proposal.

G. Applicant Response to Written Statement(s) of Opposition

In those cases where a written statement of opposition has been timely filed regarding a certificate of need application for a general hospital, the applicant for the general hospital may submit a written response to the Agency. Such response must be received by the Agency within 10 days of the written statement due date. ss. 408.039(3)(d), Florida Statutes.

The applicant submitted a response to the WSO submitted by Naples Community Hospital on May 11, 2018. BC states that protecting the health and wellbeing of the rural communities in the service area is the purpose of the CON application and the proposed new micro-hospital that will be established in Zip Code 34142.

BC states that the opposition's two main arguments against the proposal are centered on NCH's ability to remain financially viable and a lack of sustainable growth and development to achieve projections forecasted in the application. The applicant maintains that these two main points are specious and false.

BC anticipates that NCH will experience a loss of less than 1.7 percent in profit margin (from $55.9 million to $55 million) which does not compromise the financial viability of the NCH Health System. BC critiques the methods the opposition uses to allege a loss, noting that the opposition states that the applicant's Medicaid forecast is overstated by means of an analysis which does not include all Medicaid cases from the service area. The applicant notes that NCH's data was limited to patients

in Collier County who received care at hospitals located in health planning District 8, which does not account for patients who received care on the east side of the state (Broward County). The applicant reasserts that the listing of Medicaid cases in the service area factually represents the total number of Medicaid cases in the service area as reported in the AHCA database. The applicant states that the opposition does not understand and feels threatened by the proposed project which intends to fully collaborate with NCH for the health and wellbeing of the county.

The methodology of NCH's opposition statement

BC states that NCH obfuscates facts and presents false and irrelevant arguments in the opposition statement. The applicant states that most of the arguments presented in the opposition statement are irrelevant to BC and are identical to opposition statements submitted against proposed hospital projects under review in Lee County. BC identifies vast differences between the other proposals presented for review in District 8 and states that the residents of rural communities residing in the proposed service area endure unique challenges and dire health conditions that are not addressed in the opposition statement. The applicant determines that NCH conducted little research and has little understanding of the rural communities that reside in the PSA and notes that based on the AHCA Discharge Database there were 1,725 discharges and 7,793 total hospitals days from the first quarter of 2012 to the third quarter of 2017 from residents in Zip Code 34143. BC notes that Zip Code 34143 is used by the Seminole Tribe and that the data NCH used to analyze the service area was limited to patients who received care at hospitals in Collier County and in some analyses Lee County. BC maintains that this error was either intentional or due to ignorance and fails to account for patients from the service area that seek care in Broward County. BC wholly questions the credibility of the NCH analysis.

BC comments on NCH's purported full awareness of the substandard medical conditions in Zip Code 34142 and references the opposition's descriptions of the service area on page 16 of the WSO. The applicant attests to the indisputable substandard health outcomes of residents living in Zip Code 34142. Despite NCH's acknowledgement of poor health conditions within the service area, the applicant notes that NCH states that there are no geographic access problems in Zip Code 34142 and the area is neither "unserved nor underserved" without substantiating these claims. BC determines that NCH accepts the status quo in the area as adequate for the residents of the PSA. In the absence of approval of the proposal, the applicant expects for residents of the Immokalee area to continue to suffer terrible medical outcomes at an extent that will affect thousands of rural residents in the PSA.

NCHs Strategic Decisions in the Healthcare Environment
BC discusses NCH's strategic business decisions which focus on the wealthy coastal population and ignore the needs and terrible health outcomes of less privileged patients, especially those in the PSA. Despite a growing infant mortality rate and other increasingly poor health outcomes, the applicant notes that NCH maintains that the PSA is well-served and the status quo should continue. BC discusses NCH's current plans to build a freestanding emergency department in Bonita Springs and determines that NCH does not focus on or invest in the needs of the applicant's proposed service area.

The applicant notes that NCH is the only local health care provider that has not supported the Braden Clinic Hospital project and acknowledges support from Physicians Regional and the HNSF.[8] BC states that NCH stands alone in opposition against the health and well-being of the people of Immokalee, the Seminole Tribe, Ave Maria and the surrounding communities.

Summary of Main Issues Raised by NCH
The applicant lists the following claims that NCH uses to oppose CON application #10522:
- Need (the claim the area is well served by current hospitals)
- Access (the claim there is no geographic access problem)

BC identifies the following points which are determined by the applicant to not be directly related to specific statutory requirements:
- Technicalities of the CON application
- Challenges faced by all rural hospitals (recruitment and financial health)
- The low standard of care achievable in rural hospitals and achievable in the PSA
- The proposed hospital project differs from other hospitals and this is a problem
- The ability of BC to produce what they promise
- The negative financial impact on NCH

The applicant reiterates that NCH provides no credible evidence to support the conclusions that there are no geographic access problems in the PSA or that the area is neither "unserved nor underserved" despite describing the area as a medically underserved area.

[8] The applicant states on page 22 of the response: "Physicians Regional has recognized the compelling need for a hospital in 34142 and supports the Braden Clinic Project as a positive step in furthering the health and well-being of residents in 34142. They do not seem concerned about the new hospital falling within their "primary service area" since they filed no statement of opposition."

In response to the opposition's analysis, BC notes that the map used in the opposition's WSO reflects that Zip Code 34142 falls within the PSA of both NCH campuses. BC determines that the current absence of a hospital in the PSA means that the closest acute care hospital to the PSA is NCH North located a 40 to 70-minute drive from Immokalee or Ave Maria. The applicant surmises that most residents drive to NCH North to access acute care services, but the opposition's analysis does not reflect that residents are adequately served by the hospitals they access. BC concludes that the location of the freestanding ED is irrelevant in the discussion of geographic access as the freestanding ED is not an acute care hospital and does not solve the major problems experienced by residents of the PSA. As a provider of outpatient services, BC acknowledges counseling patients against going to the freestanding ED in most emergencies as experience has shown that the level of service patients receive is equivalent to care received at an urgent care center.

After evaluating evidence provided in the NCH WSO, the applicant determines that the opposition has failed to provide evidence to discount significant geographic access issues originally presented in CON application #10522 such as:

- A 40-70-minute drive time from Immokalee and Ave Maria to the closest acute care hospital
- The mobility-challenged population of the service area
- The medical status of the area shows that the area is not receiving adequate medical care

The applicant identifies the following points in the NCH WSO:

- General statements about challenges in rural health without a single reference to medical literature or data
- General statements about the lack of resources in the PSA without reference to fact or data
- Statements regarding the adequacy of existing services for the PSA (NCH North) despite poor outcomes
- Contradicted their own statements by stating that the service area is a "medically underserved area"
- Took issue with technicalities of the BC travel study but provided no evidence to show that the results of the study were false
- Stated that the absence of SNFs in the region compromise the success of the proposed hospital ignoring that SNFs will not build without a nearby hospital
- Benchmarked the proposed hospital DRG list to "urban hospitals" and stated that the service mix is different and therefore the proposed hospital service mix is not practicable—ignoring the real needs and volume of the proposed service area

- Benchmarked a cannibalized analysis of "small urban hospital" and appendices from their statement of oppositions for CON application #10523 and CON application #10524 and incorrectly applied it to the proposed project
- Stated that the proposed hospital would not have the capability to care for caesarian sections although the resources necessary for this surgery were listed in CON application #10522
- Misrepresented and misquoted plans to evaluate and initiate treatment for heart attacks, stroke and other emergencies
- Calculated Medicaid cases based on patients from Collier County only and accused the applicant of false calculations
- Stated that the proposed hospital cannot be financed from revenue from the Braden Clinic Ave Maria—which was never proposed
- Stated that the financial feasibility of the project is doubtful without providing any evidence to the contrary
- Stated that the applicant did not provide any conditions for approval and might choose not to provide care for the population proposed to be served
- Stated that the proposed project will have an adverse impact on Collier County hospitals and provided a table to show NCH's loss, which were minor at best but come with huge costs in terms of health outcomes to the PSA
- Provided letters of opposition from three of their own physicians who had clearly not read CON application #10522

Rural Hospitals

BC states that NCH failed to recognize the special provisions that the proposal is entitled to under ss.408.031 – 408.045, Florida Statutes (Health Facility and Services Development Act). The Braden Clinic specifically notes ss. 408.043, Florida Statutes, and attests to meeting these special provisions by:

- Providing documentation as to our membership of the Collier County Rural Health Network and their letter of support that this hospital is for their network[9]

[9] In Volume II, Appendix G of CON application #10522, the applicant provides documentation of a directory of the Florida Rural Health Association's directory of rural hospitals and rural health networks in Florida. The map provided in Appendix G (and available here: http://floridaruralhealth.org/rural-hospital-health-networks/) reveals that Collier County, the subdistrict for the proposal and location of the outpatient clinic Braden Clinic, is within the Collier County Rural Health Network. A letter endorsing the proposal is authored by Mike Ellis, President/CEO of the Healthcare Network of South Florida, which is listed as a primary partner of the Collier County Rural Health Network here: http://www.healthcareswfl.org/about-us/ccrhn/. The reviewer notes that the applicant previously states that the proposal has been endorsed by Victoria Gauze, Executive Director of the Collier County Rural Health Network (CON application #10522, Pages 27 and 154), however a full letter of support from Collier County Health Network was not available in Appendix G of the application.

- Plan to strengthen health care services in our rural area through partnership with (1) The Health Care Network of Southwest Florida, (2) The Seminole Tribe and (3) Braden Clinic
- The proposed hospital will increase access to inpatient health care services for Medicaid recipients and other low-income persons who live in rural areas

The applicant notes that NCH's two main arguments against the proposal include the capacity for health care recruitment and financial viability in an environment with an unusually high Medicaid and indigent population. BC identifies these issues as potentially serious impediments to the success of rural hospital ventures and notes providing special considerations on page 151 of CON application #10522.

BC indicates that the physician letters submitted with the NCH WSO demonstrate little understanding of rural health and reflect ignorance for the quality of care achievable at a rural facility. BC cites the emergence of Ave Maria, a new and highly attractive master planned community in close proximity to Immokalee, which will serve as a practical location for the proposed micro-hospital. The applicant characterizes the recruitment of health care professionals from Immokalee as daunting and identifies a density of 70+ professors living in the Ave Maria as a testament to the ability of the area to attract significant human capital. BC references details of its recruitment activities and capacity as provided on page 182 of CON application #10522.

The applicant comments on the closure of rural hospitals nationally and the financial difficulties faced by rural hospitals. BC states that the changing health care landscape no longer allows for low-volume rural hospitals to provide a traditional breadth of services and remain financially viable. The applicant states that the micro-hospital model provides a mainly outpatient hospital model that optimizes financial success and that data reflects that the trend away from community hospitals that offer "a little bit of everything" is more financially viable leading to better health outcomes for patients. The applicant concludes that while centers of excellence perform better than low-volume community hospitals, the micro-hospital model offers a practical and compelling solution to meet the unmet needs of the PSA by establishing a sustainable health care infrastructure.

BC determines that NCH's WSO assumes that only a low standard of care is achievable in a rural hospital and that large hospitals with large staff and many specialists can always provide better care than smaller hospitals. The applicant determines that that this is contrary to ss. 395.602(e)-(f), Florida Statutes. BC reiterates that the proposal has been endorsed by Collier County Rural Healthcare Network, per ss. 381.0406, Florida Statutes.

The applicant maintains that NCH offers no evidence that driving 40 to 70 minutes to an urban hospital will provide rural residents with better health care than a local rural hospital. The applicant states that the proposal will follow criteria and guidelines set forth by the American Heart Association, the American Stroke Association, DNV GL and other reputable organizations with specific certification criteria to rural hospitals in order to provide a higher level of service than the freestanding emergency departments.

The Services Offered by the Proposal

BC states that the menu of services and proposed business model were designed to be successful in a contemporary health care environment and meet the needs of a specific service area. The applicant argues that the unique model of micro-hospitals arouse questions in traditional institutions as micro-hospitals challenge the norms of "big hospital medicine". In evaluation of the NCH WSO, BC notes that NCH lists specific DRGs included in the new hospitals menu of services that were not found in the "small urban" hospitals chosen by NCH to serve as benchmarks. The applicant counters NCH's DRG analysis and asserts that each DRG on the proposed menu of services was discussed and chosen by health care professionals/physician committee that ensured that the hospital would have the experience, staffing, equipment and financial resources to service every chosen DRG with the best possible outcome. BC asserts that the range of services will allow for the proposed hospital to be successful in today's health care environment and that a difference in the menu of services does not warrant denial of the CON project.

Negative Financial Impact on NCH

BC contends that the forecasted financial impact to NCH due to the proposal is small and an invalid reason to deny care to a needy population. The applicant provides the following table of the forecasted financial loss to NCH:

NCH Hospital Financial Summary 2017	
Total Revenue:	$538,723,520
Total functional expenses	$482,755,373
PROFIT:	**$55,968,147**
NCH Hospital Financial Summary if Braden Hospital was Open 2017	
Loss from Braden Hospital (reported by NCH)	$938,880
NCH Profit with Braden Hospital	**$55,029,267**

Source: Braden Clinic, LLC Response to WSO, Page 12

BC determines that NCH will experience a profit loss of less than 1.7 percent and reiterates conclusions provided on page 29 of the NCH WSO which state that "the effective impact amounts to a significant loss of cases that adversely affects the NCH Health System's ability to remain financially viable." The applicant maintains that NCH cannot and does

not attest to the capacity to provide the quality of care to patients from the PSA in a manner consistent with NCH's own standards in light of the poor health outcomes of the services outlined in CON application #10522. The applicant indicates that to bring in the relatively small financial impact a micro-hospital would cause the NCH System as an argument against providing standard care for a community that has suffered for years with a severe lack of access would reflect a callous disregard for the value of the largely under-privileged population residing in Immokalee.

The applicant argues that a new micro-hospital would serve the financial interest of NCH as many residents of the PSA never seek care and data shows an unusually high death rate of residents at an early age. BC expects for a local hospital to serve as a bridge for people with little access to care to a medical facility that can best meet their needs and for area hospitals to acquire complex cases that they might never have received—reducing less complex patients and increasing more complex cases and hospital margins.

In response to the opposition's criticism that the proposals (CON applications 10522, 10523 and 10524) share the following characteristics – "Failure to address any special or not normal circumstances and invite serious criticism when opining that residents experience impediments to access and availability to hospital-based care," the applicant states that it provided solid proof of the uniquely underserved circumstances of the service area on pages 19 – 112 of CON application #10522. The applicant notes that the opposition identifies the Immokalee area as a medically underserved area and acknowledges that impediments to access exist and that "special circumstances" exist in the PSA. BC maintains that the proposal more than adequately demonstrates that the PSA reflects "special circumstances", residents experience "impediments to access" and compelling need for a small hospital in the PSA.

BC states that the application has shown in detail that the current medical facilities of Collier County do not adequately provide for the medical needs of the service area and identifies the following unique services that residents will benefit from as a result of the proposal:

- The new hospital will provide timely access to a labor and delivery unit
- The new hospital will provide the administration of the life-saving drug necessary to reverse stroke
- The Braden Clinic CON application provided substantial evidence of the benefits the service area will enjoy from the new micro hospital

The applicant states that the proposed service area was carefully chosen based on the current patients of Braden Clinic and data on patient habits documented by the Centers for Disease Control (CDC), which are consistent with national patient flow patterns and small rural hospitals. BC states that the size of the service area chosen by NCH is overstated and uses the "Principle of Dilution" to make a large number of Zip Codes part of the NCH PSA and SSA. NCH North Hospital alone lists 65 Zip Codes across all six subdistricts within District 8. The applicant notes that Sarasota, included in the opposition's service area, is more than 100 miles away from NCH North.

BC maintains that NCH enjoys a double standard in pretending that their PSA and SSA, which are a function of statutory calculation, correspond to the group of patients targeted for services. The applicant states that the proposed service area in CON application #10522 was developed using realistic estimates that are consistent with the policies and by-laws that NCH uses to define the geographical boundaries of their hospital. As previously noted in CON application #10522, the applicant states that NCH's policies dictate that physicians must live and practice within certain boundaries and be able to get to the hospital within 30 minutes in order to join the medical staff. BC cites an email exchange between the applicant and Diane Martinez (NCHMD-Medical Staff Services) and provides a map outlining the distance of the Immokalee and Ave Maria communities in relation to the Downtown and North Naples Hospitals as evidence of this methodology.

The applicant enumerates the drawbacks provided in the NCH WSO with counterarguments listed below:

- **Service areas that overlap with existing hospital's PSAs**
  - In most areas of the United States, there is overlap in health care service areas—creating competition and fostering improvements in the quality of care.
  - Physicians Regional is not opposing CON application #10522, whose PSA overlaps with the proposed service area.
  - The fact that the proposed PSA is currently part of NCH's PSA does not prove that residents are targeted for care by NCH.
- **Redundancy and unnecessary duplication of existing services**
  - BC maintains that services will not be redundant or duplicated with this proposal as many of the residents of the PSA are currently not receiving any care and access to the services of the proposal will be the first of their kind.
- **Selection of DRGs that stretch well beyond the capabilities that a small hospital can provide**
  - The proposed hospital will have the resources to adequately provide for the chosen MS-DRGs and no service will be provided that cannot maintain quality of care.

- **Negative impact on existing hospitals**
  - Some patient volume will be diverted from area hospitals to the proposed facility and other specialized cases will be passed on to local hospitals—but many of these cases would not occur without the presence of the new local hospital to eliminate the barriers to accessing care.
- **Lack of evidence showing geographic barriers or impediments to current hospitals, notwithstanding drive times that do vary and would vary based on where residents reside**
  - CON application #10522 provides copious amounts of evidence documenting significant geographic barriers to access.
- **Lack of any competitive advantages of location, service availability, demand, market rates, cost or charges**
  - The location of the new hospital will provide access for the mobility-challenged population of Immokalee as well as residents of the PSA.
- **Inability to justify any unique or special circumstances**
  - The inability of existing hospitals to adequately care for the patients of the PSA which results in millions of dollars of unnecessary health care expenditures.

The applicant further develops these points within the response, which are summarized below.

BC summarizes the opposition's reference of historical conclusions surrounding the denials of past certificate of need applications, which include:

- Proposed service area was relatively small in population size
- There was no enhanced access for Medicaid and indigent patients
- The population growth and perceived access arguments did not matter given the absence of any substantial corroborative evidence of true impediments or barriers to access
- Additionally, if there is no need, any comparative review of the competing applications simply does not matter and is not necessary.

The applicant maintains that CON application #10522 addressed:

- The significant population that would benefit from increased access
- The large Medicaid and indigent population of the proposed service area that would benefit from proximity to care
- The compelling evidence of need based on the medical status of the service area—the young age of death, women giving birth before reaching a hospital and residents who do not receive definitive stroke treatment

- Multiple letters of support witnessing significant barriers to access to health care in the proposed service area

BC responds to NCH's suggestion that the PSA is "too underserved" and the rural conditions "too profound" to operate a successful hospital. The applicant asserts that challenges of rural hospitals listed by the opposition on page three of the WSO are addressed below:

- While it is true that rural hospitals face unique challenges, this is a degrading stereotype of rural health as a whole rather than a valid and thoughtful analysis of the real issues of the communities in the proposed service area.
- Rural residents require adequate access to health care just as much as urban residents and the unique challenges faced by rural hospitals is not an appropriate argument against the *existence* of rural hospitals.
- NCH's argument that the service area is "too needy" for a hospital reeks of "discounting the resources available in poorer less privileged communities".
- Certificate of Need is not about discussing the problems with rural America nor is it about degrading rural America with "hopeless stereotypes"—it is about the demonstration of need.

On page three of the NCH WSO, BC notes that the opposition claims that "none of the proposals offer to serve an area that is not already served" and "the area remains a medically underserved area" on page 16 of the NCH WSO. The applicant states that CON application #10522 provides evidence that the residents of the PSA are poorly served by current hospitals, which are too far away to provide adequate care. BC notes that many residents choose not to seek care at all.

With regard to the overlapping of the proposed PSA with the existing PSAs of both NCH North and Physicians Regional-Pine Ridge, BC addresses criticism with the following points:

- Physicians Regional has recognized the compelling need for the proposed hospital and supports it as a positive step in furthering the health and wellbeing of residents in the PSA. Physicians Regional does not seem concerned about the proposed hospital falling within its designated PSA since it filed no statement of opposition.
- Service areas are dynamic and based on population demands and the health and safety of residents. The inadequate care residents of the PSA currently have access to is a compelling argument for a change of the *status quo.*

- In most areas of the United States, there is overlap in health care service areas. This is also true in most industries. For example, there is usually more than one plumber available within a single service area. Overlapping service areas create competition and foster improvements in quality.

BC describes the maps delineating 65 Zip Codes within the service areas of NCH North and states that NCH does not document serving all residents living within these Zip Codes with adequate care. The applicant reiterates that CON application #10522 has documented that residents of the PSA are both unserved and underserved, noting that the federal government has designated the area as an area of critical need. The applicant questions the health planning standards NCH uses to conclude that "no geographic impediments" exist within the proposed service area.

The applicant advances that no hospital can provide equal geographic access to all patients that it serves. The applicant notes that Zip Code 34141 will account for 10.0 percent of patient volumes of the proposed facility. BC does not expect for the small percentage of patients derived from the Zip Code to undercut the substantial enhanced access for the patients who reside in the PSA.

In NCH's analysis of its service area, the applicant notes that NCH North identifies seven Zip Codes in Sarasota County listed as part of the SSA for NCH North with all except for one having one discharge and the remaining Sarasota County Zip Code has two discharges. The applicant notes that the opposition's table lists six discharges from one Zip Code in Williamsville, New York. BC notes that the Williamsville Zip Code is listed below the Sarasota Zip Codes which is misleading.

The applicant reiterates that Zip Code 34143 is used by the Seminole Tribe and that the assertion by the opposition of lack of population within the Zip Code reflects a lack of understanding of the community that NCH purports to serve. With an excerpt of data from the third quarter of 2017, BC provides an explanation of the navigation of the AHCA Hospital Discharge Database that reveals 43 unique discharges from Zip Code 34143. Based on the AHCA Discharge Database the applicant identifies 1,725 discharges and 7,793 total hospitals days from the first quarter of 2012 to the third quarter of 2017 from residents within Zip Code 34143 (Braden Clinic Response to WSO, Page 25). The applicant maintains that it is unclear if the opposition's assertion that there are no cases from Zip Code 34143 within the AHCA Hospital Inpatient Data File stems from incompetence or purposeful intent.

A screenshot of the Seminole Tribe's website with the address 506 South First Street Immokalee, Florida 34143 is provided on 26 of the applicant's response to the NCH WSO. The applicant additionally provides snapshots from FEMA's statement regarding the Seminole Tribe Zip Codes that were part of the Hurricane Irma Disaster Declaration on page 27 of the response. BC acknowledges that while the number of discharges or number of outpatient services that NCH has provided the Seminole Tribe might be small, it is insulting to state that the Seminole Tribe does not exist. The applicant maintains that the opposition's assertion that there is no population for Zip Code 34143 should be disregarded.

Regarding the opposition's data resources, the applicant notes that NCH used Microsoft Map Points, a computer application last updated in 2012 and discontinued in 2013, in order to produce maps and drive times. BC states that the travel study presented in CON application #10522 used up-to-date software (Google Maps), data from the Florida Department of Transportation database and real travel times that were personally driven numerous times at various times of day and seasons to confirm times. The applicant notes that the travel times presented in the analysis reflect the experiences documented in letters of support from community members.

In light of the constraints previously noted with NCH's analysis software, the applicant considers the explosion of growth in the service area, large changes in infrastructure, road signage, traffic lights and patterns to determine that the technology used by NCH cannot accurately predict the travel times of today. BC notes that NCH did not provide a traffic study or maps to show adequate access and determines that no software (no matter how defunct or inaccurate) could demonstrate that the PSA is within reasonable access (30 minutes or less). Overall, the applicant determines that the technical issues raised by NCH regarding the travel time study are largely irrelevant and the premises used to question the applicant's drive time analysis are flawed. BC does not agree that the opposition's travel time assessment demonstrated that the travel time assessment provided in the application is an inaccurate foundation upon which to base any findings of fact.

The Braden Clinic acknowledges that recruiting adequate staffing is a huge problem for many rural hospitals, as the cost involved in luring health care professionals to undesirable rural areas eats up margins and many rural facilities remain understaffed. The applicant does not anticipate significant difficulty in procuring qualified health care professionals as a result of the Ave Maria community's capacity to attract significant capital. The applicant provides a description of the unique aspects of the Ave Maria community and provides the following points in support of the recruitment potential of the community:

- A number of NCH's own staff choose to live in Ave Maria rather than Naples
- BC has received numerous job applications from health professionals over the past four years of operation and have received a surge of inquiries upon the announcement of the new hospital project
- Many health care professionals currently reside in Ave Maria—some commute to NCH others travel all over the country
- The Braden Clinic has successfully recruited health care professionals to the clinic in Ave Maria from Wisconsin and Pennsylvania

The applicant anticipates that the proposal will foster positive health care growth in the region and that the lack of a SNF in the service area is an unmet need. BC advances that no SNF will build without a neighboring hospital and notes that this was the case with the VA's research into building a SNF in the Ave Maria and Immokalee area. The applicant describes discussing the need for a local SNF and nearby parcels of land adjacent to the future hospital as potential sites for a future SNF. BC maintains that when a hospital is built in a proposed service area, a SNF will soon follow.

BC states that NCH was correct in identifying a footnote on page three of CON application #10522 as not properly qualified. The applicant references the footnote as follows: *"Relevant" meaning inpatients who could be serviced by the Braden Clinic Hospital. This excludes inpatients admitted for surgery and other services that will not be provided by the Braden Clinic Hospital"* (CON application #10522, page three). The applicant explains that the footnote should have been qualified to reflect the fact that the proposal would include inpatient surgery. BC notes that the reference brought up by NCH on page 143 of CON application #10522 which lists services the new hospital provide, includes obstetrical care (which includes surgery).

The applicant maintains that the proposed hospital will include surgeries such as caesarian section which are standard in rural hospitals with obstetrical services and notes that the DRG code for caesarian section was clearly listed in the list of DRGs included in the proposal. The applicant describes how an anesthesiologist and obstetrician are listed as full-time providers with labor, delivery rooms and operating rooms for obstetrical surgeons are detailed in Appendix D of CON application #10522. The applicant maintains that an obstetrical unit is an urgent need of the proposed service area but that the volume of birth in the PSA surpasses the industry standard for the breakeven point of a labor and delivery unit in a rural hospital. BC determines that NCH's assertion that the application contradicts itself on the basis of a single footnote is ridiculous, limited and specious. The applicant contends that both the infrastructure and the human resources necessary for obstetrical surgery have been fully described and planned.

In response to the opposition's analysis of the proposal's case mix index and ALOS in comparison to other "small urban hospitals", BC states that when planning for needs of the community the standard practice is to look at actual utilization by the inhabitants of the proposed service area. The applicant states that in order to correctly determine ALOS and case mix index, one should use the present and real published discharges—which is the process the applicant attests to utilizing.

The applicant contends that the fact that the ALOS and case mix index fall outside the norms for a small rural hospital in Florida is immaterial to what is needed in the proposed service area. BC states that the idea of testing the reasonableness of the actual utilization of health services in the proposed service area by comparing it against the utilization of a "small urban hospital" misrepresents the definition of a statistical test. The applicant maintains that when conducting a statistical test, one needs to compare two similar items or the test itself is not valid. BC notes that in this case, NCH is comparing dissimilar items which destroys the validity of their test, *a priori.*

BC describes NCH Northeast's freestanding ED as the first emergency access point for residents of the PSA. The applicant maintains that transport times will not be 20 minutes even when assuming that people have access to a car and can drive—noting that many residents lack personal transportation and rely on the ambulance which may take equally as much time and push critically ill patients (e.g. stroke) beyond the one-hour critical period. BC contends that any patients who arrive at NCH Northeast freestanding ED must be transferred and the concern that NCH expresses is one that NCH practices. The applicant reiterates NCH's ongoing construction of a freestanding ED in Bonita Springs.

The applicant states that NCH dramatically understates Medicaid cases and discharges by using only some of the Zip Codes within the applicant's proposed service area and those residents that used hospitals located in Collier County. From these points, BC determines that the artificial constraints chosen for the analysis misrepresent the true Medicaid and Medicaid HMO cases in the proposed service area. The applicant indicates that the summation of historical discharges for Medicaid and Medicaid Managed Care from within the applicant's defined service area from July 1, 2016 – June 30, 2017 account for 61.0 percent of the Braden Clinic's proposed hospital discharges.

The applicant notes the methodology which counted discharges by payer from the applicant's targeted MS-DRG and capture percentage within the proposed service area. BC states that NCH did not account for discharges that were not cared for by a hospital in Collier County or Florida residents with Zip Code 34142 or 34143 who reside in Hendry

County. The applicant states that NCH used the "baseline data for the four hospitals above" (only Collier County Hospitals) as the denominator they chose to analyze, which does not reflect complete projections. BC provided the following table constructed from the AHCA discharge database:

Total Medicaid and Medicaid Managed Care Discharges: July 1, 2016 – June 30, 2017			
Zip Code	**Medicaid Discharges**	**Medicaid Managed Care Discharges**	**Total**
34141	1	3	**4**
34142	784	768	**1,552**
34143	37	64	**101**
34120	122	341	**463**
Total	**944**	**1,176**	**2,120**

Source: Braden Clinic Response to WSO, Page 40

The applicant notes that the Seminole Tribe has their own EMS services and transport protocols. BC states that accounting for hospitals east of the service area and utilizing state-level data and an analysis of all hospitals utilized by members of the community, individuals move freely throughout counties for health care services for a variety of reasons and that without accurate data, it is impossible to conduct health care planning for the community.

In response to questions surrounding the financial feasibility of the project, the applicant notes that these concerns are not applicable at this stage of the review pursuant to ss.408.035 (2), Florida Statutes.

In rebuttal to criticisms of the applicant's capacity and intent to provide care for the population targeted in the service area, in particular the applicant's choice to not propose conditions for approval, BC notes the following points:

- BC is currently operating in the proposed service area and providing care to an underserved population—the idea that the proposed micro-hospital would turn around and refuse care to service area residents is preposterous.
- The service mix of the new micro-hospital has been developed based on the AHCA database of all patients from the PSA. The menu of chosen services was developed to meet the needs of all patients within the service area without regard for their individual payer source.
- The planned obstetrical unit for the new micro-hospital would not have the necessary volume without births from Medicaid enrollees.
- The micro-hospital business model has been chosen as the only viable financial model to adequately meet the needs of a service area with a significant Medicaid and indigent population and remain financially viable.
- The benefit of providing conditions is relevant to urban hospitals rather than rural hospitals—as urban hospitals have a tendency to

cherry-pick their patients to optimize their own profit and try to push less profitable patients on to other hospitals.

- A good example of the sort of patient cherry-picking common among hospital systems is NCH's recent investment in a freestanding ED in Bonita Springs, located half a mile from Lee Health's new outpatient center. There is clearly no urgent need for additional medical services in the area but NCH is cherry-picking from the wealthy Bonita Springs/Estero coastal patient population. NCH shows no desire to provide solutions for a truly needy population.
- The proposed hospital will be located in a small "rural" community. It will be the sole local hospital so patient migration patterns will be limited.
- Conditions for approval are not necessarily helpful in a fast-changing environment. The dynamics of the population of 34142 have changed dramatically over the last few years. Saddling the new micro-hospital with conditions based on the needs of today's population is not necessarily in the best interest of the future needs of the proposed service area.
- Conditions for approval are not statutorily necessary and therefore not a valid reason to deny a CON application.

BC notes that there are no micro-hospitals in Florida but an opportunity is being created for them with an ever-increasing number of freestanding emergency departments. The applicant notes similarities between micro-hospitals and freestanding EDs and maintains that micro-hospitals offer a few inpatient beds to meet the needs of the populations they serve and offer mainly outpatient services. The applicant maintains that micro-hospitals are consistent with contemporary health care trends towards increased outpatient care.

The applicant reviews the forecasted contribution margin loss in the opposition's analyses: $696,825 and $938,880. BC describes reviewing NCH's 990 tax forms and financial statements and notes that in 2017, NCH had over 2.1 billion dollars in gross charges, which was an increase in around $110 million dollars in a single year (2016 – 2017) and after adjustments, had an increase in revenue of $15,396,300. The applicant notes that based on these documents Medicare, Medicaid and Blue Cross/Blue Shield account for 83.0 percent of revenue for NCH and the remaining 17.0 percent in patient service revenue comes from other insurers, including 7.0 percent for charity care.

BC maintains that NCH provided inaccurate information and conclusions that in no way refute the statutory necessity of approving the proposed hospital. The applicant indicates that the opposition failed to offer valid arguments to support the claim that there is a "lack of sustainable growth and development at this point to achieve the projections." BC

states that the application has provided many facts to support the projected volume of patients which include:

- The complete AHCA database for the service area which included all patients residing in the PSA including those who sought care in Lee and Broward County
- The current population of the service area
- The rate of growth including the number of homes sold in Ave Maria alone and people per household
- Employment increases in Immokalee's agriculture industry
- The imminent construction of Rural Lands West

In response to letters of opposition submitted by physicians affiliated with NCH, the applicant states that the core business of NCH Northeast ED is to diagnose patients and transfer them to an inpatient hospital. BC notes that the freestanding ED does not provide inpatient services, obstetrical services, stroke services, cardiac services or pediatric services to any patient that presents to the stand-alone ED. The applicant states that it is hypocrisy for NCH to operate and expand into the market of freestanding EDs when the opposition argues against the proposed hospital on the basis of patients needing to be transferred for critical care.

The applicant states that contrary to the opinions of the physicians, published data shows that rural hospitals staffed by board-certified emergency physicians with teleneurology and telecardiology backup provide equivalent outcomes to urban hospitals. BC notes that both the American Heart Association and American Stroke Association have specified published outcomes that reflect the capacity for the proposal to provide excellent care and demonstrated improvements in the health of the proposed service area.

BC concludes that the presence of a hospital in the proposed service area is a necessary step to support the health of the county as a whole and provide all residents of the county with standard medical care. The applicant indicates that the state bears a special responsibility to adequately provide for underprivileged rural residents. BC asserts that NCH offered a poorly researched and superficial opposition to the proposal and notes that the overview to the opposition statement was copied from other opposition statements for additional projects submitted for review in the current batching cycle. The applicant maintains that NCH has lost sight of the grave responsibility of the CON process that will impact the health and safety of real people in real communities.

BC asserts that NCH's opposition statement did not provide a single valid argument to discount a specific regulatory statute that CON application #10522 satisfied. The applicant states that after careful study of the

needs of the proposed service area and experience working in small rural hospitals nationally, a practical and creative business model was developed in this proposal to address the health care crises of eastern Collier County. BC notes that NCH stands alone against CON application #10522 and the health/well-being of the people of Immokalee, the Seminole Tribe, Ave Maria and surrounding communities. The applicant expresses an aspiration to work with all health planning experts, professionals and medical facilities in order to provide the best possible care and access to residents of the county and will persist in collaborating with NCH (despite objections) in order to provide better health care for residents of rural Eastern Collier County.

The applicant reiterates factors supporting need and approval of the proposal and maintains that the proposal more than satisfies the applicable statutory review criteria ss. 408.035 (1)(a)(b)(e)(g)(i) and 408.037(2), Florida Statutes, and Rule 59C-1.008, Florida Administrative Code through demonstration of health planning data analytics in considerable detail as well as a detailed study of the proposed service area patient pathology. The applicant concludes by stating that some of these factors independently warrant approval and collectively present a profound picture of need to an extent that a new hospital in the proposed service area is an ethical necessity.

H. SUMMARY

Braden Clinic, LLC (CON application #10522) is seeking to establish a new general acute care hospital consisting of 25 beds in Ave Maria, Florida in Subdistrict 8-2. The proposal will be established as a private not-for-profit hospital operated by Braden Clinic, LLC. The applicant currently runs a multispecialty clinic within the service area.

BC indicates that the proposal will offer an efficient pared-down "micro-hospital" model which will meet the needs of the service area while maintaining cost-efficient and high quality care. BC maintains that the hospital will not directly compete with existing medical centers but serve as a mutually beneficial collaborator that partners with area medical centers in order to successfully sustain hospital operations and provide a seamless continuum of care, a model which will also further competition.

PSA:

- Zip Code 34142

SSA:

- Zip Code 34143 (located within Zip Code 34142)
- Zip Code 34141
- Zip Code 34120

The applicant expects 70.0 percent capture of Zip Code 34143 since Zip Code 34143 is located within Zip Code 34142, 10.0 percent capture of Zip Code 34141 and 10.0 percent capture of Zip Code 34120. BC states that 85.4 percent of inpatient discharges will come from Zip Code 34142 and the remaining 14.6 percent of discharges will come from 34143, 34120 and 34141.

With this proposal, the applicant seeks to provide emergency services and the most essential outpatient and inpatient hospital services to the severely underserved residents of the rural service area.

Braden Clinic maintains that there is an immediate and urgent need to provide a hospital for the residents of the PSA and notes that the population within Zip Code 34142 is a medically underserved community which lacks primary care physicians, an acute care hospital and outpatient services. BC notes that the lack of medical access adversely impacts health outcomes in the area as evidenced by the high rates of infant mortality within the targeted service area and the poor standard of care for stroke victims. BC maintains that residents must drive 40-70 minutes to the closest hospital and that rapid population growth in the PSA will contribute to greater need for adequate medical access.

The applicant does not indicate any Schedule C conditions in this proposal.

Need

For the 12 months ending on June 30, 2017, Subdistrict 8-2, Collier County had 818 licensed acute care beds and an acute care utilization rate of 51.12 percent. The utilization rate within the subdistrict was lower than the District 8 acute care utilization rate (54.00 percent) and the acute care utilization rate of all general acute care facilities within the State of Florida (57.82 percent). During this period, Physicians Regional Medical Center – Pine Ridge had the highest acute care utilization rate out of the other four facilities within the area (65.80 percent).

In District 8, Subdistrict 2, Collier County, Physicians Regional Medical Center – Pine Ridge is currently approved to add five acute care beds via notification #NF120011.

The applicant indicates that need for the proposal is evidenced by and merited for the following reasons:

- The poor health status of the service area indicates poor medical access.

- Within Zip Code 34142 the rate of deaths is much higher in younger age groups than the rest of Collier County--specifically, almost three times as many children under the age of one die in 34142 than in the rest of Collier County Zip Codes with hospitals.
- More than 90 percent of the population must drive 40 to 70 minutes to the closest acute care hospital exhibiting geographic inaccessibility.
- The poor and mobility-challenged population of the service area is particularly burdened by the long drive to a hospital and often do not go when they should.
- The proposed facility is supported by the Healthcare Network of Collier County, which is federally mandated to support the utilization of statutory rural hospitals for appropriate health care services and thereby protect the health and safety of rural residents.
- EMS is overutilized and burdened by the lack of proper access. Long drive times put ambulances out of service for the rest of the population with no advanced life support unit available to the district for several hours. Many extra costs and a lower quality of EMS care are a result.
- Data from Zip Code 34142 shows that given the population, medical services are underutilized showing that the barriers to health care are prohibitive.
- The quality of care for time-sensitive cases (such as stroke patients) is very low at area hospitals for residents from the PSA.
- The proposed hospital will reduce drive times by 30 to 60 minutes, thereby eliminating the severe geographic access problem.
- The proposed hospital will be a bridge between the people who need care and the medical facility that can best provide care for their complex needs.
- Time sensitive emergencies will be stabilized within the critical window, saving lives and improving outcomes.
- Access to outpatient testing will help patients stay healthier thereby reducing costly emergency services, costly unmanaged conditions, and the sequela of disabling conditions.
- Foster competition by referring each patient to the best medical center to meet their needs for complex care.
- The proposed hospital will not be a feeder hospital for one particular hospital system allowing it the freedom to make unbiased referral choices for its patients, thereby fostering competition.
- BC has a strong history and culture of medical quality.
- The lean business model of a micro-hospital and pared down menu of services will allow the new hospital to provide the same services at a lower cost than community hospitals.
- By treating strokes in a timely manner, the new hospital will decrease the $12,807,378 charged annually on preventable stroke care (for residents within Zip Codes 34142 and 34143).

- Having integrated information technologies will reduce repeat testing and result in cost-effectiveness.
- The proposed service area has a very high percentage of Medicaid and medically indigent patients.
- The proposed hospital location will provide special relief and dramatically improve access for the vulnerable population who lack transportation.
- The proposed hospital will work with the HNSF clinic in Immokalee to support the care of their Medicaid and medically indigent patients.
- Significant population growth over the last few years in Ave Maria and Immokalee with plans for another master planned community (Rural Lands West) within the service area is creating an even bigger population in need of a local hospital.
- The application should be given preference under the provisions of 408.043(3), Florida Statutes, as the BC met all requirements.

Written Statement of Opposition
The Agency received one WSO against the proposal on May 4, 2018, from Ausley McMullen, Attorneys and Counselors at Law on behalf of both facilities operated by NCH in Collier County. The opposition letter expresses collective criticism against all acute care proposals submitted in District 8.

NCH determines that all of the proposed projects are small hospitals without the capability to provide higher acuity services or address a myriad of medical conditions. NCH opposes CON application #10522 and advances that this proposal and the other two proposals submitted for review in Lee County all fail to address any special or not normal circumstances, which the opposition determines invites serious criticism when alleging that residents experience impediments to access and availability to hospital-based care. NCH identifies the following shortcomings to all of the proposals submitted in District 8:

- Service areas that overlap with existing hospitals in primary service areas
- Redundancy and unnecessary duplication of existing services
- Selection of DRGs that stretch well beyond the capabilities that a small hospital can provide

- Negative impacts on existing hospitals
- Lack of evidence showing geographic barriers or impediments to current hospitals, notwithstanding drive times that do vary
- Lack of any competitive advantages of location, service availability, demand, market rates or costs of charges
- Inability to justify any unique or special circumstances that arise to the level of justifying millions of dollars to create a small urban hospital in service areas that already have urban and suburban hospitals with higher case mix indices and established, broad-based medical staffs

NCH states that all three applications raise issues regarding the highest and best use of resources. NCH expects for the proposals to essentially capture only a small percentage of a proposed service area that overlaps with existing hospitals that offer the same services—which is anticipated to result in market shift rather than market share. For this reason, the opposition states that sharing incremental growth within a new party does not confer benefits to residents and expects for implementation of the proposals to result in the fragmentation of already existing low acuity services in a different location instead of support for existing relationships.

NCH concludes that the foregoing analyses demonstrate that the applicant's proposal uses over-reach that affords more than is practical and consequently the opposition expects for the effective impact amounts to result in a significant loss of cases that adversely affect the NCH Health System's ability to remain financially viable. The reviewer notes that based on NCH's most recent FHURS report with a fiscal year end of September 30, 2017, NCH's net revenue was $467,295,330 with an operating margin of $35,429,068 (7.58 percent) and a total margin of $45,937,133 (9.83 percent). The reviewer calculates that the opposition identified contribution margin losses to the proposed facility of $696,825 to $938,880 is equal to a 1.97 percent to 2.65 percent total loss to NCH based on fiscal year 2017's operating margin—or representing 0.15 percent to 0.20 percent loss of total revenue to the proposed hospital.

NCH determines that denial of the proposal is warranted due to the lack of current sustainable growth and development to achieve projections in the proposal and determines that the proposal is possibly well-intentioned but misguided.

The reviewer notes that based on NCH's most recent FHURS report with a fiscal year end of September 30, 2017, NCH's net revenue was $467,295,330 with an operating margin of $35,429,068 (7.58 percent) and a total margin of $45,937,133 (9.83 percent). The reviewer calculates that the opposition identified contribution margin losses of $696,825 to $938,880 is equal to a 1.97 percent to 2.65 percent loss based on fiscal year 2017's operating margin—or representing 0.15 percent to 0.20 percent loss of total revenue to the proposed hospital.

The Agency finds that the applicant met the criteria specified in Section 408.035 (2), Florida Statutes, for a general acute hospital. The Agency has determined that based on a balanced consideration of all applicable criteria including need for the proposed facility, the application merits approval of the proposal. The Agency particularly notes the identification of data regarding poor health outcomes in the identified service area--specifically for the transportation-challenged population as well as higher mortality rates for the pediatric population--identifies need for more accessible and available inpatient services to enhance health care for a vulnerable population with minimal impact to NCH (less than a 2.75 percent loss to NCH's total operating margin and less than 0.25 percent loss of NCH's total revenue—based on NCH's own data).

Competition

BC asserts that approval of the proposal will foster competition to promote quality and cost-effectiveness for the following reasons:

- Foster competition by referring each patient to the best medical center to meet their needs for complex care.
- The new hospital will not be a feeder hospital for one particular hospital system, thereby it will have the freedom to make unbiased referral choices for its patients.
- The lean business-model and pared down menu of services will allow the new hospital to provide the same service at a lower cost than a community hospital.
- Provide infrastructure to bring more providers to the area.
- The applicant has a strong history and culture of medical quality.
- Provide local providers with a medical community.
- Provide educational opportunities for educational partners including Ave Maria University, NOVA Southeastern University, University of South Florida, Chamberlain University and the Florida State University Rural Health Clinic.
- There will be reduction in charges to patients through EMS savings. The distance to the nearest hospital creates many extra costs and a lower quality of EMS care.
- Lower long-term health care costs associated with delaying care and outpatient testing.

- Estimated savings from the $58,808,124 charged annually (to the service area) for non-emergent visits to the emergency room.
- Savings from information technology.
- Access to outpatient testing will help patients stay healthier.
- Many cultural and soft benefits of being cared for in your own community by your own community.

Medicaid/charity care

Braden Clinic, LLC, is not an existing acute care hospital provider within the subdistrict. Therefore, data related to the applicant's historical provision of care to Medicaid patients and the medically indigent is not available to discuss for this application. Throughout the application, the applicant indicates that the proposal is intended to attend to the needs of the medically underserved throughout the application. The applicant intends to serve Medicaid and medically indigent patients upon completion of the hospital and to provide charity care as needed.

BC affirms that patients will not be discriminated against on the basis of their payer source or inability to pay. The applicant states that all patients are expected to contribute to the cost of their care, based upon their individual ability to pay and eligibility for government benefit programs. The applicant also intends to collaborate with HNSF in Immokalee to support the care of Medicaid and medically indigent patients.

The small efficient model of the hospital is anticipated to provide the applicant with the financial ability to serve the large Medicaid and medically indigent patient populations within the applicant's PSA. BC maintains that caring for Medicaid patients and the medically indigent will be a fundamental goal of the project.

The applicant indicates that the proposed project will support the care of Medicaid and medically indigent patients in the following capacities:

- The proposed service area has a very high percentage of Medicaid and medically indigent patients.
- BC currently provides care for all Medicaid and medically indigent patients who come to the clinic.
- The lean, pared down model of the proposed hospital has been specifically developed to care for the large Medicaid and medically indigent population of the service area and stay cost-effective.

- The new hospital qualifies as a rural hospital as well as a high Medicaid outlier facility due to more than 50 percent of historic discharges coming from Medicaid and Medicaid Managed Care.
- The new hospital will provide special relief and dramatically improve access for the vulnerable population who lack transportation.

The reviewer notes that the applicant offers no Medicaid or charity care condition upon approval of CON application #10522.

I. RECOMMENDATION:

Approve CON #10522 to establish a new 25-bed acute care hospital in District 8, Subdistrict 2, Collier County.

AUTHORIZATION FOR AGENCY ACTION

Authorized representatives of the Agency for Health Care Administration adopted the recommendation contained herein and released the State Agency Action Report.

DATE: _____

_____
Marisol Fitch
Health Administration Services Manager
Certificate of Need