#### STATE AGENCY ACTION REPORT

#### **ON APPLICATION FOR CERTIFICATE OF NEED**

#### A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital on the Emerald Coast/CON #10567 7800 Hwy 98 West Miramar Beach, Florida 32550

Authorized Representative: Mr. Roger Hall, President (850) 278-3001

2. Service District/Subdistrict

District 1 (Escambia, Okaloosa, Santa Rosa and Walton Counties)

#### **B. PUBLIC HEARING**

A public hearing was not requested or held regarding the project.

#### Letters of Support

Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital on the Emerald Coast (CON application #10567) provides letters of support from local emergency medical services, transportation partners and health care providers who identify a relationship with the applicant, and three former "Family Birth Place" patients.

Support for the proposal is presented in light of:

- The capacity to enhance continuity of care and reduce transfers of mothers and infants
- The capacity to initiate and operate services affordably
- The existing quality of staff and services at Sacred Heart Hospital on the Emerald Coast
- Growth in deliveries at Sacred Heart Hospital on the Emerald Coast which, with the exception of Sacred Heart Hospital Pensacola, is the largest in the district

Support letters are noted from:

- Jason Cotton, EMS Chief, South Walton Fire District
- Edward D. Crews, RN, BSN, CCRN, RRT, UF-CCP, EMT, Program Director, ShandsCair Critical Care Transport Program, UF Shands
- Anne-Marie Piatanida-Whitlock, MD, MPH, FACOG, Division Director, Obstetrics and Gynecology, Sacred Heart Medical Group, Sacred Heart Hospital on the Emerald Coast
- Kimberly P. Hood, MD, Obstetrics and Gynecology, Sacred Heart Medical Group
- Brent Tidwell, MD, Obstetrics and Gynecology, Sacred Heart Medical Group
- Robert Clark Sledge, MD, Obstetrics and Gynecology, Sacred Heart Medical Group
- Ellen Jennifer Esses, MD, Obstetrics and Gynecology, Private Practice
- Crystal Tidwell, MD, Pediatrician, Sacred Heart Medical Group
- Rickey Viator, MD, Pediatrician, Sacred Heart Medical Group
- Prahba Weiss, MD, Pediatrician, Sacred Heart Medical Group

#### Letter of Opposition

Mr. Mitch Mongell, Chief Executive Officer of Fort Walton Beach Medical Center (FWBMC) states that it is a full service facility offering specialist care for all people in the community which includes a 10-bed neonatal intensive care unit (NICU). He states that FWBMC's NICU operated at 43.23 percent occupancy during CY 2018 and has the ability to accommodate transfers of Level II neonates from the applicant's facility and has done so when Sacred Heart Pensacola "has been unable to accommodate a transfer".

Mr. Mongell cites the importance of treatment in the first hour of life for low birth weight babies and states that those born "at the highest level center have a much better outcome". Per Mr. Mongell, FWBMC "practices evidence based family led care and incorporates many initiatives, such as the Florida Perinatal Quality Collaborative for Neonatal Abstinence Syndrome, which minimizes the length of stay for NICU babies' drug exposed in utero but provides essential care recognition and treatment as required". He cites FWBMC's "rooming in" service to NICU families which allows them "to care for their own baby 24/7 under NICU guidance".

Opposition maintains that FWBMC is the "experienced established facility" and "transferring between tertiary centers may increase risk of mortality". Mr. Mongell indicates that "FWBMC has trained NICU nurses who are experienced in Level III nursing and have the capability to care for very pre-term babies". He concludes that it is difficult to recruit neonatal nurses and that "opening a unit at Sacred Heart would detrimentally impact our staffing as they would likely try to recruit staff away from Fort Walton Beach".

#### C. PROJECT SUMMARY

Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital on the Emerald Coast (CON application #10567), also referenced as SHHEC or the applicant, is a Florida not for-profit corporation and a subsidiary of Ascension Health, also referenced as Ascension (the parent). The applicant proposes to establish a new 10-bed level II NICU at SHHEC in District 1, Walton County, Florida. The applicant notes that Ascension operates seven hospitals in Florida and three (one in District 1 and two in District 4) of these have NICU level II beds.<sup>1</sup>

SHHEC is a licensed Class 1 Rural Hospital with a total of 76 acute care beds. SHHEC has one non-CON regulated program—Level I adult cardiovascular services.

The project involves 4,440 gross square feet (GSF) of renovation and "no construction is anticipated as the 10-bed NICU as construction is already complete". Total project cost is \$394,364.<sup>2</sup> Project cost includes building, project development and start-up costs.

The applicant anticipates issuance of license in December 2019 and initiation of service in January 2020.<sup>3</sup>

Sacred Heart Health System, Inc. states the following on Schedule C conditions:

The applicant includes an agreement in Tab 12 of CON application #10567, signed by SHHEC President Robert Hall and Sacred Heart Hospital (Pensacola) President Carol Schmidt, indicating Sacred Heart Hospital Pensacola accepts patient transfers from SHHEC when medically indicated. SHHEC indicates this will apply to Level II NICU transfers to Level III NICU services.

<sup>&</sup>lt;sup>1</sup> The reviewer notes Ascension's Sacred Heart Hospital (Pensacola) has 28 level II and 39 level III NICU beds. The District 4 hospitals—St. Vincent's Medical Center Riverside and St. Vincent's Medical Center Southside both have 10-bed level II NICUs. St. Vincent's Medical Center Southside has CON #10543 approved January 3, 2019, to establish a four-bed level III NICU.

<sup>&</sup>lt;sup>2</sup> The project cost subject to fee is \$388,536. The applicant cites total project cost as \$394,436 (\$72.00 overpaid).

<sup>&</sup>lt;sup>3</sup> The applicant's Project Completion Forecast (Schedule 10) incorrectly cites December 2020 as the issuance of license with January 2020 as the initiation of service.

Reflective of its commitment to serve all neonates who meet the requirements for treatment in a Level II NICU, the applicant is willing to accept any such conditions based on any representations made throughout its CON application. Specific conditions to be met by SHHEC, if awarded a CON to establish a 10-bed Level II NICU, are as follows:

- 1) Greater than 55 percent of its total Level II NICU patient days will be provided to Medicaid and medically indigent patients which includes Medicaid, Medicaid managed care, KidCare, and self-pay patients.
- 2) The 10-bed Level II NICU proposed by this CON application will be located at SHHEC at 7800 US-98, Miramar Beach, FL 32550, Walton County, District 1.
- 3) SHHEC's NICU nursing staff will maintain a staff consisting of 100 percent registered nurses.
- 4) SHHEC (the applicant has SHECC here) will maintain breastfeeding and lactation support services consistent with standards set forth by the World Health Organization (WHO).

Should the proposed project be approved, the applicant's conditions 1, 3 and 4 would be reported in the annual condition compliance report, as required by Rule 59C-1.013(3), Florida Administrative Code. Condition 2 will be considered met when the applicant has the 10-bed Level II NICU added to its license.

Issuance of a CON is required prior to licensure of certain health care facilities and services. The review of a CON application and ultimate approval or denial of a proposed project is based upon the applicable statutory criteria in the Health Facility and Services Development Act (408.031-408.045, Florida Statutes) and applicable rule criteria within Chapters 59C-1 and 59C-2, Florida Administrative Code. An approved CON does not guarantee licensure of the proposed project. Meeting the applicable licensure requirements and licensure of the proposed project is the sole responsibility of the applicant.

#### D. REVIEW PROCEDURE

The evaluation process is structured by the certificate of need review criteria found in Section 408.035, 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 district, applications are comparatively reviewed to determine which applicant(s) best meets the review criteria.

Rule 59C-1.010 (3) (b), Florida Administrative Code, prohibits any amendments once an application has been deemed complete. 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, James B. McLemore, analyzed the application with consultation from the financial analyst, Everett "Butch" Broussard of the Bureau of Central Services, who reviewed the financial data and Scott Waltz of the Office of Plans and Construction, who reviewed the application for conformance with the architectural criteria.

#### E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

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

#### 1. Fixed Need Pool

## a. Does the project proposed respond to need as published by a fixed need pool? ss. 408.035(1) (a), Florida Statutes. Rule 59C-1.008(2), Florida Administrative Code and Rule 59C-1.039(5), Florida Administrative Code.

In Volume 45, Number 13, dated January 18, 2019 of the Florida Administrative Register, a fixed need pool of zero beds was published for level II NICU beds in District 1 for the July 2021 planning horizon.

District 1 has 38 licensed and eight approved Level II NICU beds, 28 of these are located in Escambia County and ten are in Santa Rosa County. The reviewer notes that Notification #NF160046 was issued to Sacred Heart Hospital (Escambia County) to add eight Level II NICU beds on October 24, 2016. District 1's level II NICU occupancy rate was 60.72 percent for the 12-month period ending on June 30, 2018. The table below shows the district's level II NICU licensed inventory and utilization during the reporting period.

12 Months Ending June 30, 2018				
Facility	# Beds	County	Percent Occupancy	
Sacred Heart Hospital	28	Escambia	70.05%	
Fort Walton Beach Medical Center	10	Santa Rosa	34.60%	
District 1 Total	38		60.72%	

District 1 Level II Neonatal Intensive Care Utilization 12 Months Ending June 30, 2018

Source: Florida Hospital Bed Need Projections and Service Utilizations by District, January 2019 Batching Cycle

SHHEC provides an analysis of the existing acute care providers, female population aged 15 to 44, and birth trend volumes in District 1. Specific to Okaloosa and Walton Counties, the applicant notes that there are five acute care hospitals and three provide obstetrics—FWBMC (level II NICU provider), North Okaloosa Medical Center and SHHEC. A map of the distribution of acute providers is shown on page 13 of CON application #10567.

The applicant notes that during the 12 months ending June 30, 2018 there were 8,248 babies delivered at District 1 hospitals, which was an increase of 1.6 percent from the 8,118 deliveries during 12 months ending June 30, 2016. SHHEC asserts that it delivered the second largest number of babies with 1,281 total or 15.5 percent of all volume-increasing by nearly 11 percent compared to FWBMC's decrease of almost 12.3 percent (from 1,022 deliveries during the 12 months ending June 2016 to 898 during the 12 months ending June 2018).

SHHEC presents a chart summarizing discharge trends from the 12 months ending June 30 of 2016, 2017, and 2018 by volume and percent change on page 15 of CON application #10567. The reviewer's consolidated reference to the applicant's table is produced below:

12 Months Ending June 30, 2016 & June 30, 2018					
Hospital/County	12 months ending June 30, 2016	12 months ending June 30, 2018	Percent Change		
Sacred Heart Hospital/Escambia	3,526	3,769	6.9%		
Sacred Heart Emerald Coast/Walton	1,158	1,281	10.6%		
Fort Walton Beach Med. Ctr./Okaloosa	1,022	896	(12.3%)		
Baptist Hospital/Escambia	985	898	(8.8%)		
West Florida Hospital/Escambia	604	564	(6.6%)		
North Okaloosa Medical Ctr./Okaloosa	465	472	1.5%		
Santa Rosa Medical Ctr./Santa Rosa	358	368	2.8%		
District 1 Total	8,118	8,248	<b>1.6</b> %		

#### District 1 Acute Care Hospitals Deliveries Discharge Trend 12 Months Ending June 30, 2016 & June 30, 2018

Source: CON application #10567, page 15

The applicant notes the following with respect to delivery trends:

- SHHEC's deliveries are growing at a greater rate than all other District 1 hospitals
- Sacred Heart Health System deliveries grew more than 7.8 percent compared to District 1's 1.6 percent
- SHHEC's delivery volume has exceeded 1,000 deliveries consistent with Rule 59C-1.042(6), Florida Administrative Code, for each of the past three years and an increasing trajectory presents a strong rationale for approval of the proposed Level II NICU

The applicant notes that District 1's 138,261 female population age 15 to 44 years as of July 2019 is projected to increase by 3,518 to 141,779 (2.5 percent) by July 2021. SHHEC indicates that Environics/Claritas population projections indicate District 1 will have 145,612 females and Walton and Okaloosa Counties combined will have 95,038 females in the 15-44 age cohort in 2021. The applicant notes District 1 has the highest fertility rate at 70.4 of the state's 11 health planning districts, Walton County (76.1) is the sixth highest and Okaloosa County (77.7) the fourth highest counties in Florida.

SHHEC provides a chart indicating that it had 72.7 percent of Walton County resident and 28.4 percent of Okaloosa County resident hospital obstetric (MDC 14) discharges in CY 2018—up from 71.8 percent of Walton County and 25.3 percent of Okaloosa County resident MDC 14 discharges in CY 2016. The applicant concludes this demonstrates its dominance in Walton County and gains of significant market share in Okaloosa County. SHHEC contends that FWBMC is not the provider of choice in obstetric services for Okaloosa and Walton County residents based on FWBMCs 4.8 percent decline in market share between 2016 and 2018.

Walton County's overall population is discussed with the applicant indicating a U.S. Census Bureau report states Walton County "gained nearly 3,000 new residents in 2017" making it the sixth fastest growing county in the nation. An overview of Walton County population factors leading to increased growth is briefly discussed. SHHEC states that Walton County will experience the greatest growth rate (5.5 percent) of the four District 1 counties, growing from 10,980 in July 2019 to 11,584 females ages 15 to 44 in July 2021.

The applicant states the following seven not normal circumstances for which approval of the proposal is warranted. Please note that the italicized words and the applicant's bold "Not Normal Circumstance" #s, with the exception of the reviewer adding "Not" to Normal Circumstance #5, are reproduced word for word. **Not Normal Circumstance #1** *SHHEC's most recent births on a trailing* 12-month were only 85 births shy of attaining the 1,500 birth threshold to qualify for a CON exemption to develop a Level II NICU of at least 10 beds. The upward trajectory indicates the applicant will reach the 1,500 birth minimum by the end of calendar year 2019.

The reviewer notes that the "trailing 12-month" reference above refers to the 12-months ending February 28, 2019, during which SHHEC indicates it delivered 1,415 babies. The applicant contends it will meet the 1,500 births required to establish a 10-bed Level II NICU by CON exemption contained in Rule 59C-1.008(6)(g) Florida Administrative Code, by the end of CY 2019. The applicant states that if it achieves the exemption minimum birth requirement by year end, recruitment and training along with other pre-opening activities would delay implementation "until sometime in the second quarter of 2020". However, SHHEC contends that there is a dire community need for NICU services and since the 10-bed NICU is already fully constructed and equipped, approval of this CON application will allow it to become "fully operational approximately four to six months sooner".

**Not Normal Circumstance #2** SHHEC is the only hospital in District 1, aside from SHHP (Sacred Heart Hospital Pensacola) that meets the minimum service volume of 1,000 live births per 12-month period required to apply for a Level II NICU per Rule 59C-1.042(6). SHHEC has the highest volume of births in Subdistrict 1-2 and second greatest number of births in District 1; second to only its sister facility which is the Level III NICU provider for the district.

As previously stated, the applicant meets the birth volume criteria in Rule 59C-1.042(6) Florida Administrative Code to establish a 10-bed level II NICU. Specific to the birth volume in this rule, the reviewer notes that SHHEC reported 1,285 births during the 12-month period ending June 30, 2018.

**Not Normal Circumstance #3** SHHEC's volume of neonate transfers to Level II NICU and high-risk maternal transfers prior to birthing alone could substantiate the need for a 10-bed Level II NICU at SHHEC.

The applicant states that between 2014 and 2018, SHHEC transferred 252 babies to NICUs—242 of these went to Level II mostly transferred to Sacred Heart Hospital Pensacola (SHHP). SHHEC provides a chart of NICU transfers for the last five years along with annualizing CY 2019 based on the month of January 2019. The applicant maintains that it is "on track" to transfer at least 64 babies this year—60 of which are expected to be Level II neonates. The reviewer prepared the following chart utilizing the data provided by the applicant.

CY 2014 through CY 2018					
Calendar Year	Transfers to Level II	Transfers to Level III	Total Transfers		
2014	29	0	29		
2015	38	1	39		
2016	66	2	68		
2017	61	3	64		
2018	48	4	52		
Total	242	10	252		

#### Sacred Heart Hospital on the Emerald Coast **Neonate Transfers to NICU Services**

Source: CON application #10567 based on applicant's table on page 30

As shown above, SHHEC transferred 29 neonates (all to Level II NICU) in CY 2014 and reached a high of 68 transfers (all but two to Level II NICU) in 2016—averaging approximately 48 (48.4) annual neonate transfers to Level II NICU services during the five-year period. The applicant's chart included annualized 2019 data based on the month of January 2019. SHECC notes that if it had a Level II NICU, the majority of these babies (and their mothers) would have the opportunity to remain within their facility rather than be transferred to SHHP.

The applicant provides a chart documenting maternal transfers—high risk mothers who require transfer to SHHP prior to delivery. As with neonatal transfers, the applicant annualized CY 2019 based on the month of January 2019—projecting 96 such transfers for CY 2019. The applicant averaged approximately 50 (49.6) annual maternal transfers during CY 2014-2018. See the table below.

#### **CY 2014 through CY 2018** Calendar Year **Number of Transfers** 2014 33 2015 69 2016 37 2017 48 2018 61 248 Total

### Sacred Heart Hospital on the Emerald Coast Maternal Transfers to Sacred Heart Hospital (Pensacola)

Source: CON application #10567 based on applicant's table on page 31

SHHEC indicates that combined NICU and maternal transfers will represent all year one NICU admits and account for 76 percent of year two's (146 of 192). The applicant presents the following table summarizing the forecasted utilization for the proposed Level II NICU.

Sacred Heart Hospital on the Emerald Coast Internal Demand for Level II NICU Forecasted Years One and Two				
	Year One	Year Two		
Forecasted Level II NICU Admissions	120	192		
NICU Transfers to SHHP, 2019 Annualized	60	60		
Maternal Transfers to SHHP, 2019 Annualized*	86	86		
Internal Demand, Total	146	146		
Internal Demand as Percent of Forecasted Admissions	121.7%	76.0%		
Additional NICU Admissions (Surplus)	(26)	46		

Source: CON application #10567, page 32

Note: (\*) Maternal transfers result in a greater number of births due to multiple births.

The applicant contends that the data above demonstrates that the project will "fulfill the overwhelming internal demand for its NICU". SHHEC notes that the project will allow obstetricians to maintain more high risk moms in-house with maternal fetal specialists on site and its 24/7 neonatologists will be able to maintain all Level II neonates who are presently transferred out. The applicant notes that Level III babies will still be transferred to SHHP.

**Not Normal Circumstance #4** The applicant's location on a barrier island creates geographic accessibility challenges for neonatal transfers from SHHEC, specifically given excessive travel time and distance to these NICUs and the many challenges posed by the system of bridges required to travel off the island.

SHHEC provides travel times to SHHP and FWBMC using various routes. The closest distance to SHHP is a 64-mile drive on U.S. Hwy 98 but involves one hour and 37 minutes travel time. An alternate route is cited to be nine minutes faster but 20 miles longer. SHHEC states that FWBMC is 24 miles west of its location using US Hwy 98 but is an average 45-minute drive and requires passing over three bridges. The most common alternative route is stated to be more than a 35-mile drive with a 49-minute average travel time. The applicant indicates that all routes from SHHEC to existing NICUs are slow due to traffic congestion and all require traversing bridges.

Further discussion of the various bridges and the collapse of the intrastructure is provided by the applicant. SHHEC notes that all existing bridges must shut down to traffic when winds reach a sustained 40 mph which occur virtually every afternoon during summer rains. The applicant does not provide actual dates/times these situations closed the bridges. Several bridges are stated to have low lying portions that hug the water's surface and become submerged in sand and debris. SHECC states that the third and most hazardous challenge with the bridge system is the structural integrity of several bridges resulting in the closure for repairs or replacement. The applicant specifically cites:

- Brooks Bridge: located on US Hwy 98 west of Choctawhatchee Bay between downtown Fort Walton Beach and Okaloosa Island currently in the replacement planning phase
- Mid-Bay Toll Bridge: a 3.6-mile two lane bridge in Okaloosa County closed for 21 days in January 2019 due to structural issues
- Choctawhatchee Bay Bridge (US 331)/Clyde B. Wells Bridge: built at Bay level where debris and sand can cover portions of these bridges, which are closed until debris can be removed
- Eastern Bridges: along County Road 30A, two miles east of SHHEC, have had problems due to soft ground and brackish waters
- Big Redfish Bridge: collapsed in 2017, making County Road 30A impassable

The applicant includes maps with its location and the series of bridges in Walton and Okaloosa Counties as well as photographs in CON application #10567 (pages 39, 40, 42 and 43). Supporting documents in Volume II, Tab 5 of CON application #10567 include Florida Department of Transportation press releases regarding Mid-Bay Toll Bridge structural integrity and resulting closure, Brooks Bridge Replacement Study and current state and the status of County Road 30A bridges. An article in Tab 5 indicates the Brooks Bridge replacement project will begin in 2022 and be completed about three years later. Tab 5 also included an article on one County Road 30A bridge—the Alligator Lake Bridge which closed briefly during March 2017, due to structural damage created by beavers.

**Not Normal Circumstance #5** *Ambulance transfers from SHHEC to SHHP are a four to five hour round trip for South Walton County Fire District's Emergency Medical Services, which is an enormous vulnerability for the patient but also for EMS and Walton County residents as the transfer takes one of the County's ambulances out of the county for an extended period of time. Additionally ShandsCair also is out of the area for four to five hours when transferring a neonate.* 

The applicant includes excerpts of letters from Jason Cotton, EMS Chief, South Walton Fire District and Edward D. Crews, Program Director, ShandsCair Critical Care Transport UF Health Shands which affirm the Not Normal Circumstance #5 statements. The applicant indicates that the complete letters are in Tab IV of Volume I of CON application #10567.

**Not Normal Circumstance #6** *Low cost to initiate the Level II NICU as it is already fully constructed and equipped.* 

The applicant states that as part of the "Family Birth Place" construction which was licensed in January 2018, space on the second floor was fully equipped, designed and constructed to meet all Level II NICU plans, construction and licensure guidelines. SHHEC states that the only costs associated with treating Level II NICU neonates is largely variable costs staffing, supplies, ancillaries, professional fees, etc.

**Not Normal Circumstance #7** *Quality and efficiency will be assured with 10 NICU beds.* 

SHHEC notes that the NICU has nine NICU bays and one isolation room, located proximate to labor and delivery on the second floor of the "Family Birth Place". The applicant indicates that Mednax, the neonatology group that works with SHHP will be contracted to cover SHHEC's Level II NICU, which will ensure neonatologists will maintain their competencies by covering NICUs at both hospitals.

The applicant discusses quality of care awards such as Baby-Friendly Hospital Designation<sup>4</sup>—one of 17 hospitals in Florida with this designation. SHHEC indicates its low Cesarean Section rates for first time mothers (22.99 percent), one of 20 Florida hospitals recognized by the Agency and Florida Department of Health to obtain rates of 23.9 percent or lower over a three year period. Various other accreditations, certification and quality awards are listed in this response.

SHHEC summarizes its need discussion by reiterating the "Not Normal Circumstances" it contends individually and in aggregate are sufficient to warrant approval of the project.

The applicant indicates that the projected opening date for the Level II NICU is January 1, 2020 and provides the following utilization forecast. See the table below.

Sacred Heart Hospital on the Emerald Coast Forecasted Level II NICU Utilization Years One and Two			
	CY 2020	CY 2021	
Forecasted Admissions	120	192	
Average Length of Stay (Days)	14.0	14.0	
Patient Days	1,680	2,688	
Occupancy Rate	46.0	73.6	
Average Daily Census	4.6	7.4	

Source: CON application #10567, page 57

<sup>4</sup> Baby-Friendly Hospital Initiative is a global effort launched in 1991 by WHO and UNICEF to implement practices that protect, promote and support breastfeeding per the web page - Baby-Friendly Hospital Initiative: Revised, Updated and Expanded for Integrated Care. Geneva WHO; 2009 at <a href="https://www.ncbi.nih.gov/books/NBK153471/">https://www.ncbi.nih.gov/books/NBK153471/</a>

b. Regardless of whether bed need is shown under the need formula, the establishment of new Level II neonatal intensive care services within a district shall not normally be approved unless the average occupancy rate for Level II beds in the district equals or exceeds 80 percent for the most recent 12-month period ending six months prior to the beginning date of the quarter of the publication of the fixed need pool.

District 1's Level II NICU occupancy rate was 60.72 percent for the 12-month period ending June 30, 2018.

#### 2. Agency Rule Criteria/Preferences

Please indicate how each applicable preference for the type of service proposed is met. Ch. 59C-1.042, Florida Administrative Code.

- a. Ch. 59C-1.042(3)(g), Florida Administrative Code Services to Medically Indigent and Medicaid Patients. In a comparative review, preference shall be given to hospitals which propose to provide neonatal intensive care services to Children's Medical Services patients, Medicaid patients, and non-Children's Medical Services patients who are defined as charity care patients. The applicant shall estimate, based on its historical patient data by type of payer, the percentage of neonatal intensive care services patient days that will be allocated to:
  - (1) Charity care patient;
  - (2) Medicaid patients;
  - (3) Private pay patients, including self-pay.

The reviewer notes that SHHEC is the only applicant. The applicant forecasts Medicaid/Medicaid HMO will account for 68.39 percent of patient days both years one and two. SHHEC's narrative indicates that charity care and self-pay patients will account for 0.55 percent of patient days in years one and two. The applicant's chart on page 77 of CON application #10567, indicates 0.55 percent of total annual NICU patient days will be provided to self-pay patients. The chart also includes an "all other payors" category at 31.07 percent in year one but has an error with year two—as the Medicaid/Medicaid HMO category remains constant at 68.39 percent, it evident that 31.07 percent would be the all other payor category for year two also. SHHEC proposes to condition CON approval to greater than 55 percent of the total annual Level II NICU patient days being provided to Medicaid, Medicaid managed care, KidCare, and self-pay patients.

 b. Ch. 59C-1.042(4), Florida Administrative Code - Level II Service Continuity. To help assure the continuity of services provided to neonatal intensive care services patients: Hospitals may be approved for Level II Neonatal Intensive Care Services without providing Level III services. Applicants proposing to establish Level II Neonatal Intensive Care Services shall ensure developmental follow up on patients after discharge to monitor the outcome of care and assure necessary referrals to community resources.

SHHEC indicates that it presently adheres to the Florida Newborn Screening Program to ensure infants receive appropriate confirmatory testing, counseling (parents/families), treatment, all infants are offered a Healthy Start Infant Risk Screening before leaving the birthplace and referral for intervention services as needed. The applicant states that "it is the responsibility of the St. Vincent's Family Birth Place staff nurse and unit secretary to assure all associate evaluation and tasks are carried out". SHHEC concludes its response by stating all high risk and normal newborns are referred to community pediatricians for follow-up post discharge.

c. Ch. 59C-1.042(5), Florida Administrative Code - Minimum Unit Size. Hospitals proposing the establishment of new Level II Neonatal Intensive Care Services only shall propose a Level II Neonatal Intensive Care Unit with a minimum of 10 beds. (NOTE: All references to Level III NICU services are deleted except where relevant).

SHHEC proposes a 10-bed level II NICU and therefore complies with this criterion.

d. Ch. 59C-1.042(6), Florida Administrative Code - Minimum Birth Volume Requirement. Hospitals applying for Level II Neonatal Intensive Care Services shall not normally be approved unless the hospital had a minimum service volume of 1,000 live births for the most recent 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.

The applicant begins its discussion on page 80 of the application and presents a detailed discussion with charts documenting 12-month periods ending February 2017, 2018 and 2019. SHHEC restates that it had 1,425 births during the 12 months ending February 2019 and cites its 18.7 percent growth from February 2017 to February 2019. The applicant's table on page 82 indicates that for the 12-months ending June 2018, the facility had 1,293 births. SHHEC's narrative response on page 83 to this criterion indicates that the facility had 1,281 births during the 12 months ending June 30, 2018. The applicant concludes

its discussion on page 84 of the application by representing the District 1 historical trend previously addressed in its response to Item E.1. A. of this report.

The reviewer notes that data obtained from the Florida Center for Health Information and Transparency indicates that the applicant had 1,285 live births during the 12-month period ending June 30, 2018. The applicant meets this criterion.

#### e. Ch. 59C-1.042(7), Florida Administrative Code - Geographic Access. Level II neonatal intensive care services shall be available within two hours ground travel time under normal traffic conditions for 90 percent of the population in a service district.

The applicant does not directly address this criterion but does provide a detailed description of drive times to the existing Level II NICU providers. The applicant indicates only one route takes close to two hours from SHHEC to SHHP, and the other NICU provider is less than 50 minutes from its facility. The fastest route from SHHEC to SHHP is approximately one hour and 28 minutes in usual traffic per the Google Maps page in the application's Volume III, Attachment 10. Level II NICU services are available to 90 percent of the population under normal traffic conditions.

#### f. Ch. 59C-1.042(8), Florida Administrative Code - Quality of Care Standards for Level II Neonatal Intensive Care Services.

(1) Physician Staffing. Level II Neonatal Intensive Care Services shall be directed by a neonatologist or a group of neonatologists who are on active staff of the hospital with unlimited privileges and provide 24 hours coverage, and who are either board certified or board eligible in neonatalperinatal medicine.

The applicant states that SHHEC's Level II NICU will be directed by Mednax Medical Group, which consists of a group of nine board certified neonatal-perinatal specialists on staff at SHHP, who with CON approval will become active staff at SHHEC, with unlimited privileges to provide 24-hour coverage. The applicant provides a list of these staff on page 85 of CON application #10567 in addition to copies of their credentials in the Supporting Documents Tab 17 of the application.

SHHEC notes that upon CON award, there will be a full time maternal fetal specialist at SHHEC, provided through the Sacred Heart Regional Perinatal Center—a group of board-certified maternal-fetal medicine specialists who work in collaboration with obstetricians and primary care providers to provide care for highrisk pregnant women through consultation, co-management and direction of care during and after pregnancy. The applicant provides a list of these Maternal-Fetal specialists and includes copies of their credentials in the Supporting Documents Volume III, Tab 17 of the application.

(2) Nursing Staff. The nursing staff in Level II Neonatal Intensive Care Units shall be under the supervision of a head nurse with experience and training in neonatal intensive care nursing. The head nurse shall be a registered professional nurse. At least one-half of the nursing personnel assigned to each work shift in Level II Neonatal Intensive Care Units must be registered nurses.

The applicant indicates that the Level II NICU will be under the supervision of Christa Allen, RN, MSN, nurse manager of Women's Services at SHHEC. Ms. Allen is stated to have ten years of experience and to have experience and training in NICU nursing.

SHHEC states that Barbara Jeanne Fontaine, RN, MSN, LHRM, IA, serves as Vice President of Nursing and is responsible for leading and directing nursing and ancillary services, which will include the NICU. Ms. Allen's and Ms. Fontaine's resumes are included in the Supporting Documents Tab 17 of the application.

The applicant states that all nurses assigned to the NICU will be registered nurses—the reviewer notes this is a proposed condition to CON approval. SHHEC maintains that Ms. Allen, along with her team of NICU nurses, will receive on-site training prior to the opening of the NICU.

(3) Special Skills of Nursing Staff. Nurses in Level II Neonatal Intensive Care Units shall be trained to administer cardiorespiratory monitoring, assist in ventilation, administer I.V. fluids, provide pre-operative and post-operative care of newborns requiring surgery, manage neonates being transported, and provide emergency treatment of conditions such as apnea, seizures, and respiratory distress.

The applicant asserts that one hundred percent of SHHEC NICU nurses will be trained to administer cardio-respiratory monitoring, assist in ventilation, administer I.V. fluids, provide pre-operative and post-operative care of newborns requiring surgery, manage neonates being transported, and provide emergency treatment of conditions such as apnea, seizures and respiratory distress. The applicant states that NICU nurses will have to prove their competencies as they relate to both the family birth place and the NICU at the time of orientation on the unit, including respiratory NICU orientation and ordering blood gases. A list of NICU competencies that are evaluated is provided on pages 88 – 89 of CON application #10567.

(4) Respiratory Therapy Technician Staffing. At least one certified respiratory care practitioner therapist with expertise in the care of neonates shall be available in hospitals with Level II neonatal intensive care services at all times. There shall be at least one respiratory therapist technician for every four infants receiving assisted ventilation.

The applicant states that upon initiation of Level II NICU operations, there will be at least one certified respiratory care practitioner therapist in-house at all times, with expertise in the care of neonates. SHHEC indicates that there will be at least one respiratory therapist technician for every four infants receiving assisted ventilation at all times.

#### (5) Blood Gas Determination. Blood gas determination shall be available and accessible on a 24-hour basis in all hospitals with Level II neonatal intensive care services.

The applicant indicates that blood gas determination is already available and accessible on a 24-hour basis within the "Family Birth Place" at SHHEC and the availability will extend to Level II NICU services.

(6) Ancillary Service Requirements. Hospitals providing Level II neonatal intensive care services shall provide on-site, on a 24hour basis, x-ray, obstetric ultrasound, and clinical laboratory services. Anesthesia shall be available on an on-call basis within 30 minutes. Clinical laboratory services shall have the capability to perform microstudies.

SHHEC notes that it already provides x-ray, obstetric ultrasound and clinical laboratory services 24 hours a day seven days a week. The applicant states that anesthesia is available on-site 24 hours a day with the capacity for clinical laboratory services to perform all necessary microstudies.

SHHEC indicates an intent to maintain a blood exchange transfusion policy and procedure for its Level II NICU by adopting the one used by SHHP. (7) Nutrition Services. Each hospital with Level II neonatal intensive care services shall have a dietician or nutritionist to provide information on patient dietary needs while in the hospital and to provide the patient's family instruction or counseling regarding the appropriate nutritional and dietary needs of the patient after discharge.

The applicant states it "will have a clinical nutrition manager who is a registered dietician responsible for the oversight of all nutrition services provided in the NICU". SHHEC notes that the clinical nutritionist is available through a 3<sup>rd</sup> party contract with Touchpoint. The applicant states that nutrition consultations will also be provided by NICU nursing staff and neonatologists and supported by the hospital's registered dieticians who provide information on patient dietary needs while in the hospital and post-discharge. SHHEC indicates that lactation consultants are also available to provide information and guidance on breastfeeding—their resumes are provided in Volume III, Tab 17, of the supporting documents section of the application.

(8) Social Services. Each hospital with Level II neonatal intensive care services shall make available the services of the hospital's social service department to patients' families which shall include, but not be limited to, family counseling and referral to appropriate agencies for services. Children potentially eligible for the Medicaid, Children's Medical Services, or Developmental Services Programs shall be referred to the appropriate eligibility worker for eligibility determination.

The applicant states it provides social services to families which include family counseling and referrals to appropriate agencies for services. SHHEC discusses referring children eligible for Medicaid, Children's Medical Services and/or developmental services programs for eligibility determination. The applicant states that Cheryl Stacy, a Licensed Clinic Social Worker (LCSW), is SHHEC's Pediatric Navigator and she and other SHHEC social workers will be responsible for performing assessments to identify NICU patient, family and infant needs. SHHEC maintains that when appropriate, case managers will assess and refer families and patients to various community resources. Ms. Stacy's resume is included the supporting documents section (Volume III, Tab 17) of the application. (9) Developmental Disabilities Intervention Services: Each hospital that provides Level II neonatal intensive care services shall provide in-hospital intervention services for infants identified as being at high-risk for developmental disabilities to include developmental assessment, intervention, and parental support and education.

SHHEC describes its healthy start risk screening policy and procedure which is in place. The applicant notes it conducts an "Infant Screening" program which is jointly administered by the Department of Children and Families Children's Medical Services Program Office and the State Health Office. The applicant states that the goals of the "Infant Screening" program are to assure that:

- All affected infants receive the appropriate confirmatory testing, counseling and treatment as soon as possible
- All infants born in Florida are offered a Healthy Start Infant Risk Screening before leaving the birthplace and are referred for intervention services as needed

SHHEC states that the Healthy Start Risk Screening is designed to identify infants who may be at increased risk for impairment of health, intellect or functional ability due to medical, environmental, nutritional or behavioral risk factors so that intervention efforts to reduce identified risks can be implemented as soon as possible. The applicant states that the SHHEC's "Family Birth Place" staff nurse and unit secretary are responsible for assuring all associated evaluations/tasks are carried out. SHHEC provides a list of risk factors outlined in the Healthy Start Risk Screening and describes the methodology of the evaluation on pages 93 – 95 of CON application #10567.

#### (10) Discharge Planning. Each hospital that provides Level II neonatal intensive care services shall have an interdisciplinary staff responsible for discharge planning. Each hospital shall designate a person responsible for discharge planning.

The applicant states that Cheryl Stacy, LCSW, is SHHEC's Pediatric Navigator and she and her staff will be responsible for discharge planning from the NICU. SHHEC maintains that this staff will be responsible for performing assessments to identify NICU patient, family/infant needs and will collaborate with patient, family and the healthcare team to develop discharge plans. Staff will assess and refer families and patients to various community resources. As previously stated, Ms. Stacy's resume is included the supporting documents section (Volume III, Tab 17) of the application.

- g. Ch. 59C-1.042(9), Florida Administrative Code Level II Neonatal Intensive Care Unit Standards: The following standards shall apply to Level II neonatal intensive care services:
  - (1) Nurse to Neonate Staffing Ratio. Hospitals shall have a nurse to neonate ratio of at least 1:4 in Level II neonatal intensive care units at all times. At least 50 percent of the nurses shall be registered nurses.

SHHEC indicates that it has forecasted that the Level II NICU will have a minimum nurse to neonate ratio of 1:4 at all times. The applicant states that all nurses in the Level II NICU will be registered nurses. SHHEC provides the proposed FTEs for the unit and states that it will exceed the minimum required by this rule.

- (2) Requirements for Level II NICU Patient Stations. Each patient station in a Level II NICU shall have, at a minimum:
  - a. Fifty square feet per infant;
  - b. Two wall-mounted suction outlets preferably equipped with a unit alarm to signal loss of vacuum;
  - c. Eight electrical outlets;
  - d. Two oxygen outlets and an equal number of compressed air outlets and adequate provisions for mixing these gases;
  - e. An incubator or radiant warmer;
  - f. One heated humidifier and oxyhood;
  - g. One respiration or heart rate monitor;
  - h. One resuscitation bag and mask;
  - i. One infusion pump;
  - j. At least one oxygen analyzer for every three beds;
  - k. At least one non-invasive blood pressure monitoring device for every three beds;
  - 1. At least one portable suction device; and
  - m. Not less than one ventilator for every three beds.

The applicant states that the 10-bed Level II NICU has been constructed and equipped and the unit exceeds the above requirements.

#### (3) Equipment Required in Each Level II NICU. Each Level II Neonatal Intensive Care Unit shall be equipped with:

- a. An EKG machine with print-out capacity;
- b. Transcutaneous oxygen monitoring equipment; and
- c. Availability of continuous blood pressure measurement.

SHHEC maintains that the proposed Level II NICU has been constructed, equipped and exceeds the requirements above.

- h. Ch. 59C-1.042(11), Florida Administrative Code Emergency Transportation Services: Each hospital providing Level II neonatal intensive care services shall have or participate in an emergency 24hour patient transportation system.
  - (1) Provision of Emergency Transportation. Hospitals providing Level II neonatal intensive care services must operate a 24hour emergency transportation system directly, or contract for this service, or participate through a written financial or non-financial agreement with a provider of emergency transportation services.
  - Requirements for Emergency Transportation System.
    Emergency transportation systems, as defined in paragraph (11) (a), shall conform to Rule 64J-1.006, Florida Administrative Code.

SHHEC describes its existing contractual arrangement with Shands Teaching Hospital and Clinics, Inc. d/b/a ShandsCair to provide transport and specialized care by way of fixed-wing aircraft, helicopter and ground ambulance 24 hours a day, seven days a week. Since October 2017, all neonates who require transport are transported by ShandsCair, according to the applicant. SHHEC notes the letter of support from Edward D. Crews, Program Director, ShandsCair Critical Care Transport Program and states that "recitals from the Sacred Heart/ShandsCair transport agreement are provided in supporting documents of the application". The reviewer notes the recitals from the transport agreement are in Volume III, Tab 20 of the application. This agreement is effective June 7, 2017 for a period of two years with automatic one year renewals unless revoked by either party in writing at least three days before expiration. i. Ch. 59C-1.042(12), Florida Administrative Code - Transfer Agreements. A hospital providing only Level II Neonatal Intensive Care Services shall provide documentation of a transfer agreement with a facility providing Level III Neonatal Intensive Care Services in the same or nearest service District for patients in need of Level III services. Facilities providing Level III Neonatal Intensive Care Services shall not unreasonably withhold consent to transfer agreements which provide for transfers based upon availability of service in the Level III facility, and which will be applied uniformly to all patients requiring transfer to Level III, as defined in subparagraph 2(e)2. An applicant for Level II Neonatal Intensive Care Services shall include, as part of the application, a written protocol governing the transfer of Neonatal Intensive Care Services patients to other inpatient facilities.

SHHEC details its policy and procedure protocols for its "Family Birth Place" and notes that all patients requiring NICU care are transferred to SHHP "unless the patient's parent or guardian requests transfer to another facility, which is rarely the case". The criteria for the neonate's transfer to Level III NICU care is provided on page 101 of CON application #10567. SHHEC includes the interhospital transfer agreement with SHHP in Volume III, Tab 12 of the application. The reviewer notes that the agreement commenced July 1, 2011, for a one year period and renewal was to be "upon mutual agreement of the parties, in writing". The written renewals were not included, although all the facilities are Ascension Health Alliance d/b/a Ascension affiliates.

j. Ch. 59C-1.042(13), Florida Administrative Code - Data Reporting Requirements: All hospitals with Level II Neonatal Intensive Care Services shall provide the Agency or its designee with patient utilization and data relating to patient utilization of Level II Neonatal Intensive Care Services. The following data shall be provided to the Agency or its designee: Utilization Data. Level II Neonatal Intensive Care Services providers shall report the number of admissions and patient days for Level II Neonatal Intensive Care Services. Data shall be reported to the Agency or its designee within 45 days after the end of each calendar quarter.

The applicant states that it will comply with this criterion.

#### 3. Statutory Review Criteria

#### a. Is need for the project evidenced by the availability, quality of care, 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.

The applicant briefly discusses the zero net need for Level II NICU beds in District 1 as published January 18, 2019. SHHEC restates its contention that not normal circumstances, individually and in aggregate, justify approval of the proposal.

The applicant indicates that a significant investment has been made to construct and design an area of the second floor of the hospital's "Family Birth Place" with a fully equipped 10-bed Level II NICU consisting of nine bays and one isolation room. This area is presently licensed as a nursery and will be quickly converted into the Level II NICU upon CON approval and would become fully operational by January 1, 2020.

The applicant restates the hospital's location on a barrier island "whereby residents are reliant on an often faulty bridge system and travel times are excessive to alternate NICUs". SHHEC contends that it is the provider of choice for residents for labor and delivery as evidenced by the historical utilization data and because of its superior nursing staff and quality programs and services, and its mission driven values it offers to the community. The applicant restates the seven not normal circumstances as follows:

- 1. SHHEC's most recent births on a trailing 12-months were only 85 births shy of attaining the 1,500 birth threshold to qualify for a CON exemption to develop a Level II NICU of at least 10 beds. The upward trajectory indicates the applicant will reach the 1,500 birth minimum by the end of calendar year 2019.
- SHHEC is the only hospital in District 1, aside from SHHP, that meets the minimum service volume of 1,000 live births per 12-month period required to apply for a Level II NICU per Rule 59C-1.042(6). SHHEC has the highest volume of births in Subdistrict 1-2 and second greatest number of births in District 1—second to only its sister facility which is the Level III NICU provider for the district.
- 3. SHHEC's volume of neonate transfers to Level II NICU and highrisk maternal transfers prior to birthing alone could substantiate the need for the proposed 10-bed Level II NICU.
- 4. The applicant's location on a barrier island creates geographic accessibility challenges for neonatal transfers from SHHEC, specifically given excessive travel time and distance to these NICUs and the many challenges posed by the system of bridges required to travel off the island.

- 5. Ambulance transfers from SHHEC to SHHP are a four to five hour round trip for South Walton County Fire District's EMS, which is an enormous vulnerability for the patient but also for EMS and Walton County residents as the transfer takes one of the county's ambulances out of the County for an extended period of time. Additionally ShandsCair is out of the area for four to five hours when transferring a neonate.
- 6. Low cost to initiate the Level II NICU as it is already fully constructed and equipped.
- 7. Quality and efficiency will be assured with 10 NICU beds.

SHHEC contends that need for the proposal is warranted for the above "not normal circumstances". The applicant restates that there is more than sufficient internal demand to support the 10 beds in the proposal. SHHEC provides a summary of the quality and efficiency of care arguments presented in response to Rule 59C-1.042 (4), (5) and (8), Florida Administrative Code and not normal circumstance #7 "quality and efficiency" statement.

#### b. Does the applicant have a history of providing quality of care and has the applicant demonstrated the ability of providing quality care? ss. 408.035(1)(c), Florida Statutes.

SHHEC describes its capacity to provide quality care as it pertains to the Catholic health ministry of the organization, which it states is dedicated to spiritually centered, holistic care which sustains and improves the health of individuals and communities. The applicant notes how its associates are called to: service of the poor, reverence, integrity, wisdom, creativity and dedication. Components of the church's ministry of healthcare are discussed on pages 107 – 109 of CON application #10567.

The applicant discusses its quality improvement and patient safety program and provides additional descriptions and measures of the program in the supporting documents section of the application. The applicant states that Sacred Heart Health System and Ascension have a common goal set for 2022—to eliminate preventable disparities in health care outcomes. SHHEC indicates that the culture of the organization is rooted in quality and cites six principles it uses to ensure quality of care. Ascension's "Quadruple Aim" is addressed and the applicant indicates this "is all about a personalized care". SHHEC states that "Quadruple Aim" is based on the idea that by designing care around the person, associates seek to deliver the best possible outcomes, an enhanced experience for the people served and at an affordable cost. SHHEC provides a list of quality honors, recognitions and achievements awarded to its organization on pages 109 – 112, and a list of continuing medical education courses made available to clinical staff on page 113 of CON application #10567.

The following table accounts for the three-year substantiated complaint history for the applicant and Ascension Health facilities for the period of March 1, 2016 through March 1, 2019. During this period, Ascension had seven hospitals with a total of 1,927 licensed beds. SHHEC had no substantiated complaints and Ascension facilities had seven substantiated complaints during these 36 months. A single complaint can encompass multiple complaint categories. The substantiated complaint categories for the parent are shown in the table below.

Ascension Health Substantiated Complaint History March 1, 2016 – March 1, 2019		
Admission, Transfer & Discharge Rights	1	
Billing/Refunds 1		
Quality of Care/Treatment 3		
Resident/Patient/Client Rights 1		
State Licensure 1		
Total 7		

Source: Agency Complaint Records report ran March 15, 2019

The applicant demonstrated the ability to provide quality care.

c. What resources, including health manpower, management personnel, and funds for capital and operating expenditures, are available for project accomplishment and operation? ss. 408.035(1)(d), Florida Statutes.

The purpose of our analysis for this section is to determine if the applicant has access to the funds necessary to fund this and all capital projects. Our review includes an analysis of the short and long-term position of the applicant, parent, or other related parties who will fund the project. The analysis of the short and long-term position is intended to provide some level of objective assurance on the likelihood that funding will be available. The stronger the short-term position, the more likely cash on hand or cash flows could be used to fund the project. The stronger the long-term position, the more likely that debt financing could be achieved if necessary to fund the project. We also calculate working capital (current assets less current liabilities) a measure of excess liquidity that could be used to fund capital projects.

Historically we have compared all applicant financial ratios regardless of type to bench marks established from financial ratios collected from Florida acute care hospitals. While not always a perfect match to a particular CON project it is a reasonable proxy for health care related entities. The below is an analysis of the audited financial statements of Sacred Heart Health System, where the short-term and long-term measures fall on the scale (highlighted in gray) for the most recent year. All figures except ratios are in thousands.

Sacred Heart Health System, Inc. (In Thousands)			
· · · · ·	Jun-18	Jun-17	
Current Assets	\$200,474	\$195,877	
Total Assets	\$662,253	\$600,117	
Current Liabilities	\$170,560	\$165,222	
Total Liabilities	\$324,251	\$337,641	
Net Assets	\$338,002	\$262,476	
Total Revenues	\$917,206	\$892,763	
Excess of Revenues Over Expenses	\$6,689	\$40,219	
Cash Flow from Operations			
Short-Term Analysis			
Current Ratio (CA/CL)	1.2	1.2	
Cash Flow to Current Liabilities (CFO/CL)	0.00%	0.00%	
Long-Term Analysis			
Long-Term Debt to Net Assets (TL-CL/NA)	45.5%	65.7%	
Total Margin (ER/TR)	0.73%	4.51%	
Measure of Available Funding			
Working Capital	\$29,914	\$30,655	

Position	Strong	Good	Adequate	Moderately Weak	Weak
Current Ratio	above 3	3 - 2.3	2.3 - 1.7	1.7 – 1.0	< 1.0
Cash Flow to Current Liabilities	>150%	150%-100%	100% - 50%	50% - 0%	< 0%
Debt to Equity	0% - 10%	10%-35%	35%-65%	65%-95%	> 95% or < 0%
Total Margin	> 12%	12% - 8.5%	8.5% - 5.5%	5.5% - 0%	< 0%

#### **Capital Requirements and Funding:**

The applicant indicates on Schedule 2 capital projects totaling \$9,824,894 which includes FY 2019 routine capital expenditures, FY 2020-2021 capital expenditures, and the CON currently under review (\$394,436). The applicant provided a copy of its June 30, 2017 and June 30, 2018 audited financial statements. These statements were analyzed for the purpose of evaluating the applicant's ability to provide the capital and operational funding necessary to implement the project. The applicant noted on Schedule 3 that the funds will be provided by cash flow from operations.

Staff notes that while the applicant states it intends to provide funding from cash flows, the audited financial statements provided for 2018 did not contain cash flow statements for either Sacred Heart Health System, Inc. (consolidated) or SHHEC. However, staff also notes that the 2018 cash and cash equivalent balance for Sacred Heart Health System consolidated and SHHEC are \$20,032 million and \$1,000

(one-thousand). The appellant's ultimate parent company, Ascension Health Alliance, posted 2018 cash flows from operations of \$630,480 and a total year-end cash and cash equivalent balance of \$850,958.

#### Staffing:

SHHEC provides brief biographies of key leadership personnel on pages 115-117 of CON application #10567 and includes resumes and curriculum vitae for these individuals, Mednax neonatologists, maternal fetal specialists and SHHEC obstetricians in the supporting materials (Tab 17) of the application. The applicant does not address personnel specific to the NICU in its response. However, the applicant's Schedule 6 indicates that the staffing schedule for the Level II NICU is based upon actual staffing patterns anticipated to operate the 10-bed unit, including exceeding the minimum staffing required by Rule 59C-1.042(9)(a) Florida Administrative Code. Staffing for the proposal includes 15.6 additional registered nurses FTEs—12.6 RNs, two nurse managers and one unit secretary, 4.2 FTEs for respiratory therapy and ¼ FTE for social services in year one and year two. Based on the applicant's statements in Schedule 6 narrative and Schedule 6A "Staffing Pattern" table, the unit secretary will be an RN.

#### **Conclusion**:

The applicant states on Schedule 3 that funding will be provided by operating cash flows. Given the cash resources of the applicant's parent and ultimate parent, funding for the entire capital budget should be available as needed. Staff further notes that construction and equipping of the anticipated NICU is complete and should not pose a significant concern for further funding contingency.

## d. What is the immediate and long-term financial feasibility of the proposal? ss. 408.035(1) (f), Florida Statutes.

Our comparison is of the applicant's estimates to its latest FHURs report.

Because the proposed NICU cannot operate without the support of the hospital, we have evaluated the reasonableness of the projections of the entire hospital including the project. Staff compared the applicant its latest AHCA filing, which was June 30, 2018. Inflation adjustments were based on the new CMS Market Basket, 3rd Quarter, 2018.

	PROJECTIONS PER	Actual Data Inflated to		
	Total	PPD	2021	
Net Revenues	144,741,161	7,422	9,076	
Total Expenses	122,447,693	6,279	7,450	
Operating Income	22,293,468	1,143	866	
Operating Margin	15.40%			
	Days	Percent	2021	
Occupancy	19,501	62.10%	60.01%	
Medicaid/MDCD HMO	4,407	22.60%	18.45%	
Medicare	8,140	41.74%	48.29%	

The NICU represents 2.66 percent of the hospital's total projected revenue and 2.55 percent of hospital's total projected expenses. Projections indicate a \$22,293,468 profit margin at the end of year two. Because the NICU is such a minor part of the hospital's overall operations, the hospital could easily support the project even if extended losses were projected.

The applicant is showing a significant difference between the projected per patient day data and the inflated actual data from the facility's most recent fiscal year. While the use of estimates and shifts in patient mix may account for some of the discrepancy, the projected per patient net revenue data of \$7,422 appears to be lower than even the most recent fiscal year inflated results of \$9,076. This suggests that normal economic forces (e.g. inflation) may not be being taken into proper consideration. Similarly, projected total expenses also appear slightly lower per patient day than would be anticipated.

#### **Conclusion:**

Given the very small impact the project will have on the hospital, the project appears financially feasible. However, the projections appear to indicate that revenues may be understated.

### e. Will the proposed project foster competition to promote quality and cost-effectiveness? ss. 408.035(1) (e) and (g), Florida Statutes.

Strictly from a financial perspective, the type of competition that would result in increased efficiencies, service, and quality is limited in health care. Cost-effectiveness through competition is typically achieved via a combination of competitive pricing that forces more efficient cost to remain profitable and offering higher quality and additional services to attract patients from competitors. In addition, competitive forces truly do not begin to take shape until existing business' market share is threatened. The existing health care system's barrier to price-based competition via fixed price payers limits any significant gains in cost-effectiveness and quality that would be generated from competition.

#### **Conclusion:**

This project is not likely to have a material impact on competition to promote quality and cost-effectiveness.

# f. Are the proposed costs and methods of construction reasonable? Do they comply with statutory and rule requirements? ss. 408.035(1)(h), Florida Statutes, Ch. 59A-3 or 59A-4, Florida Administrative Code.

The applicant has submitted all information and documentation necessary to demonstrate compliance with the architectural review criteria. The cost estimate for the proposed project provided in Schedule 9, Table A and the project completion forecast provided in Schedule 10 appear to be reasonable. A review of the architectural plans, narratives and other supporting documents did not reveal any deficiencies that are likely to a have significant impact on either construction costs or the proposed completion schedule.

The plans submitted with this application were schematic in detail with the expectation that they will be necessarily revised and refined prior to being submitted for full plan review. The architectural review of this application shall not be construed as an in-depth effort to determine complete compliance with all applicable codes and standards. The final responsibility for facility compliance ultimately rests with the applicant owner. Approval from the Agency for Health Care Administration's Office of Plans and Construction is required before the commencement of any construction.

#### g. 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.

SHHEC did not participate in the disproportionate share hospital (DSH) program in state fiscal year (SFY) 2018-2019. As of May 16, 2019, SHHEC had a scheduled annual low income pool (LIP) distribution of \$44,388 and \$22,194 had been requested or paid.

Per the Florida Hospital Uniform Reporting System (FHURS), statewide, for FY 2017, SHHEC provided 12.93 percent of its total patient days to Medicaid/Medicaid HMO and 4.47 percent of patient days to charity care. See the table below.

Sacred Heart Hospital on the Emerald Coast and District 1 Medicaid, Medicaid HMO and Charity Data FY 2017					
Medicaid  Medicaid  Percent    Applicant/Area  HMO Days  Percent  Care Days					
SHHEC	2,026	12.93%	700	4.47%	17.4%
District 1 Total	91,837	20.43%	11,543	2.57%	23.0%

Source: FHURS data for FY 2017.

Note: Includes all 11 general acute care facilities in District 1 as Baptist Hospital, Inc. includes Gulf Breeze Hospital in its FHURS reporting.

Among the 10 providers included in the analysis, the applicant provided:

- The fifth largest provision of Medicaid/Medicaid HMO by percentage
- The sixth largest provision of Medicaid/Medicaid HMO by volume of patient days
- The third largest provision of charity care by percentage
- The third largest provision of charity care by volume of patient days

The applicant indicates that 50 percent of the newborns delivered at SHHEC during the 12 months ending June 30, 2018, were Medicaid or medically indigent. This is an increase from 46.1 percent reported for the 12 months ending June 30, 2016 and 45.3 percent reported for the 12 months ending June 30, 2017. The reviewer notes that the applicant conditions to greater than 55 percent and projects 68.39 percent of the Level II NICU's annual total year one and year two patient days for these patients.

#### F. SUMMARY

Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital on the Emerald Coast (CON application #10567) proposes to establish a new 10-bed Level II NICU in District 1, Walton County, Florida. The applicant notes that Ascension operates seven hospitals in Florida—three with a total of 48 Level II NICU beds. Ascension's Sacred Heart Hospital Pensacola also has 39 Level III NICU beds and St. Vincent's Medical Center (District 4) has CON approval for a four-bed Level III NICU.

SHHEC is a licensed Class 1 Rural Hospital with a total of 76 acute care beds. SHHEC has one non-CON regulated program—Level I adult cardiovascular services.

The proposed project involves a total project cost of \$394,364. The applicant indicates that the project consists of 4,400 GSF of renovation and zero total construction cost as the NICU is already constructed.

The applicant includes the following conditions on Schedule C:

- Greater than 55 percent of its total Level II NICU patient days will be provided to Medicaid and medically indigent patients which includes Medicaid, Medicaid managed care, KidCare, and self-pay patients.
- The 10-bed Level II NICU proposed by this CON application will be located at 7800 US-98, Miramar Beach, FL 32550, Walton County, District 1.
- SHHEC's NICU nursing staff will maintain a staff consisting of 100 percent registered nurses.
- SHHEC will maintain breastfeeding and lactation support services consistent with standards set forth by the WHO.

The applicant includes an agreement in Tab 12 of CON application #10567, signed by SHHEC President Robert Hall and Sacred Heart Hospital (Pensacola) President Carol Schmidt, indicating Sacred Heart Hospital Pensacola accepts patient transfers from SHHEC when medically indicated. Sacred Heart Emerald Coast indicates this will apply to Level II NICU transfers to Level III NICU services.

#### Need

In Volume 45, Number 13, dated January 18, 2019 of the Florida Administrative Register, a fixed need pool of zero beds was published for Level II NICU services beds in District 1 for the July 2021 planning horizon.

District 1 has the State's highest fertility rate at 70.39 per 1,000 females population age 15-44 and the primary counties in the applicant's service area—Walton County at 76.06 and Okaloosa County at 77.74 are the fifth and third highest among Florida's 67 counties.

The reviewer notes SHHEC exceeds the 1,000 minimum birth volume requirement needed to establish 10-bed Level II NICU contained in Rule 59C-1.042 (6) Florida Administrative Code—reporting 1,285 births during the 12-months ending June 30, 2018. Should the facility reach the 1,500 live birth volume, it will be eligible to apply for an exemption to establish the 10-bed NICU pursuant to section 408.036(3)(k), Florida Statutes.

SHHEC had the second highest birth volume in District 1 while its sister facility (SHHP with Level II and III NICU services) had the highest birth volume during the 12 months ending June 30, 2018.

The applicant presents seven reasons it contends individually and in aggregate are not normal circumstances that merit approval of the project. These include:

(1) SHHEC's high birth rate (1,415) for the 12 months ending February 28, 2019, and the historical upward trajectory of births which it states will hit 1,500 by the end of 2019.

(2) SHHEC meets the minimum birth volume cited in rule (1,285) for the 12 months ending June 30, 2018.

(3) SHHEC's high volume of neonate and maternal transfers.

(4) SHHEC's geographic accessibility challenges due to its location on a barrier island with excessive travel time and challenges posed by the system of bridges required to travel off the island.

(5) Ambulance transfers from SHHEC to SHHP round trips take four to five hours.

(6) Low cost to initiate the NICU as it is already constructed and equipped.

(7) Quality and efficiency will be assured with the proposed 10-bed Level II NICU unit.

SHHEC determines that need for the proposal is warranted based on the above and its experience as a quality, value based, compassionate, mission driven provider of obstetric and newborn services.

The Agency states that the applicant has demonstrated a need through the demonstration of not normal circumstances for the proposed Level II NICU unit. The applicant presented data noting the significant live birth volume and high volume of neonate transfers. Specific geographic access issues were also demonstrated—illustrating that the proposed project would improve access, availability, quality outcomes and efficiency.

The Agency finds that, on balance, the applicant demonstrated the applicable statutory and rule criteria to merit approval of the proposed project.

#### **Quality of Care**

SHHEC demonstrated the ability to provide quality care.

During the three-year period of March 1, 2016 through March 1, 2019, SHHEC had zero and the seven facilities operated by Ascension Health had seven substantiated complaints.

#### **Cost/Financial Analysis**

Funding for this project and the entire capital budget should be available to the applicant as needed. Construction and equipping of the anticipated NICU is complete and should not pose a significant concern for further funding contingency.

Given the very small impact the project will have on the hospital, the project appears financially feasible. However, the projections appear to indicate that revenues may be understated.

The project is not likely to have a material impact on competition to promote quality and cost-effectiveness.

#### Medicaid/Indigent Care

During FY 2017, SHHEC provided 12.93 percent of its total patient days to Medicaid/Medicaid HMO and 4.47 percent of patient days to charity care.

The reviewer notes that the applicant conditions to greater than 55 percent of the Level II NICU's total annual patient days being provided to Medicaid and medically indigent patients. SHHEC's Schedule 7 shows 68.39 percent of the Level II NICU's annual total year one and year two patient days for Medicaid/Medicaid HMO patients.

#### **Architectural Analysis**

The cost estimate for the proposed project provided in Schedule 9, Table A and the project completion forecast provided in Schedule 10 appear to be reasonable. A review of the architectural plans, narratives and other supporting documents did not reveal any deficiencies that are likely to a have significant impact on either construction costs or the proposed completion schedule.

#### G. RECOMMENDATION

Approve CON #10567 to establish a 10-bed Level II NICU in District 1, Walton County. The total project cost is \$394,364. The project involves 4,400 GSF of renovation and no construction cost.

#### **CONDITIONS:**

- Greater than 55 percent of its total Level II NICU patient days will be provided to Medicaid and medically indigent patients which includes Medicaid, Medicaid managed care, KidCare, and self-pay patients.
- The 10-bed Level II NICU proposed by this CON application will be located at 7800 US-98, Miramar Beach, FL 32550, Walton County, District 1.
- SHHEC's NICU nursing staff will maintain a staff consisting of 100 percent registered nurses.
- SHHEC will maintain breastfeeding and lactation support services consistent with standards set forth by the WHO.

#### 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