

STATE AGENCY ACTION REPORT
ON APPLICATION FOR CERTIFICATE OF NEED

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

All Children's Hospital, Inc./CON #9609
801 Sixth Street South
St. Petersburg, Florida 33701

Authorized Representative: J. Dennis Sexton, President
(727) 892-4474

2. Service District/County

District 5 (Pinellas County)

B. PUBLIC HEARING

No public hearing was requested or held regarding the proposed project. Fifty-five letters of support from physicians were submitted by the applicant. The letters of support indicate that All Children's Hospital (ACH) serves as the principle hospital in the Tampa Bay area and the West Coast of Florida for the provision of neonatal intensive care services, that ACH is a Regional Perinatal Intensive Care Center (RPICC) and is chronically over-capacity, and that there is a need for additional Level III NICU beds due to population growth and the fact that the Neonatology Program at the University of South Florida is centered at ACH. Also, the letters state that ACH provides excellent quality of care, however, the shortage of Level III NICU beds limits the ability to accept transfers and admissions from other facilities, causes delays in treatment, and hampers the clinical care for extremely ill infants. Furthermore, several letters indicate that overcrowding can create the potential for infection control issues. The physicians opine that additional Level III NICU beds will improve quality of care at ACH.

C. PROJECT SUMMARY

All Children's Hospital, Inc. (ACH), proposes to add thirteen Level III Neonatal Intensive Care Unit (NICU) beds to ACH's existing 27 licensed and approved bed Level III NICU, creating a 40-bed unit. The 13 Level III NICU beds sought by this application are comprised of seven Level III NICU beds published in the fixed need pool and six converted Level II NICU beds. The applicant is one of two providers of Level III NICU services in District 5. The hospital, located in Pinellas County, is a 216-bed Class II specialty hospital licensed for 156 acute care beds, 24 Level III NICU beds, and 36 Level II NICU beds. The applicant also has an approved certificate of need (CON #9309), which authorizes the addition of three Level III NICU beds.

According to the *Certificate of Need Predicated on Conditions* page, the applicant is proposing that a minimum of 40 percent of the total Level III NICU patient days shall be provided to Medicaid and charity care patients. The applicant's proposed condition is consistent with CON #9309, which conditioned the 27-bed Level III NICU to a minimum of 40 percent of the total annual patient days being provided to Medicaid and charity care on a combined basis. ACH is a designated Medicaid Disproportionate Share Provider and a Regional Perinatal Intensive Care Center (RPICC).

The total project cost is estimated at \$1,766,543. Construction costs are projected at \$914,213 and the project will involve 4,338 gross square feet (GSF) of new construction.

D. REVIEW PROCEDURE

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

Section 59C-1.010(2)(b), Florida Administrative Code, allows no application amendment information subsequent to the application being 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, Richard Patterson, analyzed the application in its entirety with consultation from the Financial Analyst, Roger Bell, who evaluated the financial data, and the Architect, Joel Hill, who evaluated the architectural and the schematic drawings.

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 Sections 408.035 and 408.037, Florida Statutes; applicable rules of the State of Florida, Chapters 59C-1 and 59C-2, Florida Administrative Code; and Local Health Plans.

1. Fixed Need Pool

a. Does the project proposed respond to need as published by a fixed need pool? Ch. 59C-1.008 and Ch. 59C-1.042, Florida Administrative Code.

In Volume 28, Number 30, dated July 26, 2002, on pages 3318-3319 of the Florida Administrative Weekly, a fixed need pool of seven beds was published for Level III NICU beds in District 5 for the January 2005 planning horizon.

District 5 has 29 licensed Level III NICU beds and three approved Level III NICU beds¹ as of July 26, 2002. The Level III NICU beds in District 5 experienced an occupancy rate of 115.61 percent during the period January through December 2001 (see chart below).

b. Regardless of whether bed need is shown under the need formula, the establishment of new Level III neonatal intensive care unit beds within a district shall not normally be approved unless the average occupancy rate for Level III 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. Ch. 59C-1.042(3)(f), Florida Administrative Code.

¹ The CON awarding the three Level III NICU beds to All Children's was voided on December 5, 2002.

As stated above, District 5 Level III NICU beds experienced an occupancy rate of 115.61 percent for the most recent reporting period.

**Occupancy Rates in District 5 Level III NICU Beds
January through December 2001**

Hospital	#Beds	Occupancy
All Children's Hospital	24	127.52%
Mease Hospital Dunedin	5	58.41%
Total/Average	29	115.61%

Source: *Florida Hospital Bed & Service Utilization by District, July 2002 Batching Cycle.*

- c. **Special Circumstances for the Approval of Additional Neonatal Intensive Care Unit Beds at Existing Providers, Ch. 59C-1.042(3)(g), Florida Administrative Code - Need for additional Level III neonatal intensive care beds at hospitals with Level III neonatal intensive care services seeking additional Level III beds is demonstrated in the absence of need shown under the formula specified in paragraph (3)(e) of this rule if the occupancy rate for their Level III beds exceeded an average of 90 percent as computed by the agency for the same period specified in subparagraph (3)(e)2.**

Although the published need in the district is for seven Level III NICU beds, the applicant is requesting 13 beds. The applicant proposes a further expansion of its Level III NICU bed capacity through the conversion of six existing but underutilized Level II NICU beds. The applicant states that this further adjustment of the NICU bed resources at ACH is prompted by a facility-based need to match NICU beds more closely with current service demands and to manage the ongoing volume of Level III NICU patient days more effectively. The applicant meets the "special circumstances" defined in Rule.

All Children's Hospital is a specialty children's hospital, a pediatric research/teaching facility², a state-certified pediatric trauma center, and the designated RPICC in District 5, serving as a regional referral center for pediatric and neonatal services. The applicant states that during 2001, over 25 percent of patients discharged from ACH came from outside of District 5.

District 5 Level III NICU utilization for 2001 indicates that ACH exceeded 110 percent occupancy in its Level III NICU each quarter. Mease Hospital Dunedin experienced occupancy of above 80 percent only in the third quarter of 2001. The applicant notes that Mease Hospital's small NICU program is not equipped to address the complex medical needs of the severely ill neonates treated at ACH and therefore transferring overflow Level III neonates from ACH to Level III beds at Mease Hospital is not a realistic option in most cases.

² All Children's Hospital is not a statutorily defined teaching hospital.

The applicant states that the high occupancy of the Level III NICU beds at ACH has created many operational difficulties for ACH in terms of responding to patient demands. The applicant also points out that even if the three approved Level III NICU beds authorized by CON #9309 had been available in 2001, the occupancy would have exceeded 100, well over the 80 percent recommended occupancy as well as the occupancy threshold for facility-specific need.

The applicant indicates that over 25 percent of the newborns discharged from ACH were coded with the most serious illness classification (DRG 386). The average length of stay for patients classed in DRGs 386, 387, and 389 was 27.4 days at APH. The median length-of-stay at ACH was 11 days.

The primary service area for ACH is District 5, from where 76.3 percent of its neonatal discharges emanated (65.1 percent from Pinellas County and 11.2 percent from Pasco County). Over 40 percent of the district neonate discharges for DRG 386 received care at ACH and Level III bed capacity there is being pushed to the maximum limit in an effort to offer care to these sick infants, according to the applicant.

Utilization forecasts are presented for both Level III and Level II NICU beds at ACH. The applicant used the bed need formula in Ch. 59C-1.042(3), Florida Administrative Code, to project patient days for District 5 for the first two years of operation of the expanded NICU program proposed by ACH and, assuming a constant market share, for ACH. The applicant expects that ACH would provide 10,541 and 10,479 Level III NICU patient days respectively in years one and two (91.3 percent of the projected District 5 Level III NICU patient days), which is a slight decrease due to a slight decline in the district's population of females of childbearing age. However, the applicant notes that this estimate is conservative, since ACH is a regional provider of specialty care and many patients receiving care at ACH are from outside of the district. The applicant notes that it utilized the same formula to project growth to 2002 in CON #9309 and actual patient days exceeded those projected by 12 percent. Therefore, according to the applicant, the utilization projections in this application are conservative and it is anticipated that future patient day volumes at ACH will be higher because of the regional nature of the patient base as well as the continued growth of the program through increased clinical research activity and the national and international reputations of the neonatologists being recruited here, as indicated in the letter of support from Dr. Robert Christiansen, Chairman of the Department of Pediatrics at the University of South Florida College of Medicine.

The applicant presented several occupancy alternatives in Table 5 of the application based on the foregoing patient days projection.

ACH Level III NICU Bed Need and Occupancy

	2006	2007
Projected Patient Days	10,541	10,479
Bed Need at 80% Occupancy	36.1	35.9
Occupancy with 27 Beds	107.0%	106.3%
Occupancy with 40 Beds	72.2%	71.8%

Source: CON Application No. 9609

The applicant states that even though projected average annual occupancy with the requested thirteen beds is below 80 percent, seasonal fluctuation in NICU utilization indicates high monthly volumes in the third and fourth quarters. The applicant states that a total of 40 Level III NICU beds is most appropriate/advisable since only four months each year are predicted to exceed 80 percent but these are expected to remain under 90 percent and thus stay at more manageable levels.

Although the applicant included proposed occupancy with 34 beds, rather than 40 total Level III NICU beds, in Table 5 and elsewhere in the application, the proposal under review is for an additional 13 Level III NICU beds to total 40 beds when added to existing and CON approved beds and no identifiable portion of seven beds was applied for. See Ch. 59C-1.008(6), Florida Administrative Code.

The applicant submits that because the Level II NICU beds at ACH have historically been underutilized, converting six beds to Level III status is not expected to adversely impact ACH's ability to continue to meet the needs of the less seriously ill infants. According to the applicant, reducing the size of the Level II NICU from 36 to 30 beds is expected to produce occupancy levels of 68 percent and 67 percent for the first two years of operation of the new nursery.

ACH Level II NICU Bed Need and Occupancy

	2006	2007
Projected Patient Days	7,422	7,378
Bed Need at 70% Occupancy	29.0	28.9
Occupancy with 36 Beds	56.5%	56.2%
Occupancy with 30 Beds	67.8%	67.4%

Source: CON Application No. 9609

Following is a chart illustrating utilization in the Level II beds had there been 30, rather than 36 beds:

Historic ACH Level II NICU Bed Utilization

Calendar Year	Patient Days	Occupancy 36 Beds	Occupancy if only 30 beds
2001	7,866	59.86%	71.8%
2000	7,207	54.07%	65.8%
1999	9,447	71.89%	86.3%
1998	9,479	72.14%	86.6%
1997	9,189	69.93%	83.9%

Source: *Hospital Bed Need Projections, July Batching Cycle* for utilization years 1997 through 2001

As the chart above illustrates, utilization in the applicant’s Level II NICU beds would not have reached 90 percent within the past five years had there been 30, rather than 36, Level II beds.

2. Local Health Plan Preferences

Is need for the project supported by the applicable district plan? ss. 408.035(1) and 408.037(1), Florida Statutes, and Ch. 59C-1.030(2)(c), Florida Administrative Code.

The October 2000 District 5 CON Allocation Factors Report lists the following preferences relevant to all CON applicants:

- (a) Preference shall be given to an applicant who proposes to locate a new facility in an area that will improve access for Medicaid and indigent patients.**

The applicant is proposing to house the requested beds in a new building on the existing campus of ACH. The applicant is a Medicaid disproportionate share hospital.

- (b) In cases where an applicant is a corporation with previously awarded certificates of need, preference shall be given to those which follow through in a timely manner to construct and operate the additional facilities or beds, and do not use them for later negotiations with other organizations seeking to enter or expand the number of beds they own or control.**

The applicant states that it has never sought to obtain or use a certificate of need for the purpose of negotiating with other entities and that most of its CONs have been implemented in a timely manner. According to the applicant, the implementation of CON #9309 has been delayed due to land acquisition issues. It is noted

that, unless resolved, the applicant will have the same problem implementing this CON, should it be awarded.

The October 2000 District 5 CON Allocation Factors Report lists the following preferences relevant to CON applications for Level III Neonatal Intensive Care beds:

- (a) **Certificate of Need applications that provide the AHCA with documentation that they provide, or propose to provide, the largest percent of Medicaid and charity care patient days in relation to other hospitals in the district. The charity care definition shall be consistent with Section 409.911, Florida Statutes.**

The applicant states that ACH provides a significantly higher number and percentage of Medicaid/charity care patient days in relation to other hospitals in District 5. The application contains fiscal year (FY) 1999 data that indicates ACH provided almost 53 percent of its total patient days to Medicaid/charity care patients and greatly exceeds all of the district's hospitals in that provision. AHCA FY 2000 hospital data available to the agency confirms that ACH provided the largest amount of Medicaid/charity care patient days in the district and its provision of Medicaid and charity care is greater than the district average. The applicant is a designated Medicaid Disproportionate Share Provider. See Section E.4.i. for additional discussion.

- (b) **Certificate of Need applications that demonstrate intent to serve HIV infected persons.**

The applicant provides a range of inpatient and outpatient services to pediatric and neonatal HIV patients. Whenever an inpatient stay is required, the children are admitted to an appropriate unit at ACH based on their needs. During the most recent fiscal year, ACH reported 11 HIV inpatient cases with 10 cases the year before. For the 12 months ending September 2002, there were 608 outpatient visits. The applicant also provided a description of the specialized services, treatment, and care program for pediatric and neonatal HIV patients at ACH.

- (c) **Certificate of Need applications that propose to convert existing licensed unused beds.**

The applicant is proposing, in part, a reduction of underutilized Level II NICU beds through conversion to needed Level III NICU beds. As stated above, reducing the size of the Level II NICU from 36 to 30 beds is expected to produce occupancy levels of 68

percent and 67 percent for the first two years of operation of the new nursery as opposed to the projected 56 percent occupancy without the conversion of six beds.

- (d) Certificate of Need applications that submit written patient transfer agreements with the county health department for maternal and child health services.**

The applicant states that no such transfer agreements exist because no transfers are made directly to ACH. Instead, the Pinellas (or Pasco) County Health Department makes referrals to a physician/service at ACH.

- (e) Certificate of Need applications that commit to conduct Healthy Start screens on all infants born in their facility.**

ACH does not have an obstetrics program, however, all infants within the Level II and Level III NICU at ACH receive Early Intervention/Part C screenings related to developmental or other medical needs and ACH assumes follow-up responsibility for those children identified by Healthy Start screenings at area birth hospitals.

3. Agency Rule Criteria

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)(k), 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 according to the Health Care Board, Florida Hospital Uniform Reporting System Manual, Chapter III, Section 3223. 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; and**
 - (4) Regional Perinatal Intensive Care Center Program and Step Down Neonatal Special Care Unit patients.**

As stated above, the applicant commits to provide a minimum of 40 percent of its Level III NICU patient days to Medicaid and charity care patients. All Children's Hospital is a specialty children's hospital, a pediatric research/teaching³ facility, a state-certified pediatric trauma center, the designated RPICC in District 5, and a designated Medicaid Disproportionate Share Provider. The NICU at ACH extends and will continue to extend services to all patients in need of care regardless of the ability to pay or source of payment. ACH's estimates of utilization by payer class hospital-wide are contained in Schedule 7A of the application, which incorporates the patient days and payer mix anticipated for the NICU program, consistent with APH's historical NICU experience. Children's Medical Services-eligible patients requiring NICU services are included in the "Medicaid-sponsored" payer category.

Refer to E.4.i. below for further discussion.

b. Ch. 59C-1.042(4), Florida Administrative Code - Level II and Level III Service Continuity. To help assure the continuity of services provided to neonatal intensive care services patients:

- (1) The establishment of Level III neonatal intensive care services shall not normally be approved unless the hospital also provides Level II neonatal intensive care services.**

The applicant currently has 36 Level II and 24 Level III NICU beds and also has approved and voided CON #9309, which authorizes the addition of three Level III NICU beds.

- (2) Applicants proposing to provide Level III 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.**

The applicant states that developmental follow-up for its neonatal patients is provided by the Early Intervention Program, which consists of the Developmental Evaluation Program, the Individuals with Disabilities Education Act Part C program, and services provided under Chapter 393, Florida Statutes. The multi-disciplinary discharge planning team conducts follow-up checks on discharged infants to monitor outcomes and determine appropriate referrals for care.

³ Ibid.

c. Ch. 59C-1.042(5), Florida Administrative Code - Minimum Unit Size.

The applicant currently exceeds the minimum unit size for each level of service.

d. Ch. 59C-1.042(6) - Minimum Birth Volume Requirement. Hospitals applying for Level III neonatal intensive care services shall not normally be approved unless the hospital has a minimum service volume of 1,500 live births for the most recent 12-month period ending six months prior to the beginning date of the quarter of the publication of the fixed bed need pool. Specialty children's hospitals are exempt from these requirements.

ACH is a specialty children's hospital and therefore is exempt from these requirements.

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

Currently Level II and Level III NICU services are available and accessible within the two hours ground travel time to 90 percent of the residents of District 5.

f. Ch. 59C-1.042(8) - Quality of Care Standards.

(1) Physician Staffing. Level III 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-hour coverage, and who are either board-certified or board-eligible in neonatal-perinatal medicine. In addition, facilities with Level III neonatal intensive care services shall be required to maintain a maternal fetal medical specialist on active staff of the hospital with unlimited staff privileges. A maternal fetal specialist is defined as a board-certified obstetrician who is qualified by training, experience, or special competence certification in maternal fetal medicine. Specialty children's hospitals are exempt from this provision.

The applicant states that there are 12 neonatologists on staff providing 24-hour coverage at the hospital. A curriculum vita for each of the physicians is included in the application. A comprehensive program in maternal fetal medicine is provided in conjunction with Bayfront Medical Center. Since ACH is a specialty children's hospital, it is exempt from this requirement.

- (2) **Nursing Staff. The nursing staff in Level II and Level III 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 and Level III neonatal intensive care units must be registered nurses.**

The applicant states that Pamela Bremmer, A.R.N.P., is the acting nursing director of the NICU at ACH. Ms. Bremmer's resume is provided in the application. Schedule 6A of the application indicates that 96 percent of the nursing staff consists of registered nurses.

- (3) **Special Skills of Nursing Staff. Nurses in Level II and Level III neonatal intensive care units shall 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 all of the nurses in ACH's NICU are trained in the foregoing requirements and that extensive in-service training and continuing education are provided to the neonatal nursing staff.

- (4) **Respiratory Therapy Technician Staffing. At least one certified respiratory care practitioner therapist with expertise in the care of neonates shall be available in the hospitals with Level II or Level III 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 there are currently sufficient qualified respiratory care practitioners on staff to satisfy this standard and the hospital maintains an appropriate full time 24-hour in-house staff of respiratory therapists who are available to support the present NICU population as well as the proposed expansion.

- (5) **Blood Gases Determination and Ancillary Service Requirements. Blood gas determination shall be available and accessible on a 24-hour basis in all hospitals with Level II or Level III neonatal intensive care services. Hospitals providing Level II or Level III neonatal intensive care services shall provide on-site, on a 24-hour 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.**

The applicant states that it provides all of the foregoing requirements, except for obstetric ultrasound, including blood gas determination availability, with the blood gas lab located in the NICU, on-site x-ray, and clinical laboratory services, available 24 hours a day. Anesthesiology services are available on-site. Obstetric ultrasound is provided by Bayfront Medical Center.

- (6) **Nutritional Services. Each hospital with Level II or Level III 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.**

According to the applicant, ACH has designated registered and licensed dietitians assigned to the NICU. These dietitians assess their patients for nutritional risk and follow them according to diagnosis-based standards of practice.

- (7) **Social Services. Each hospital with Level II or Level III 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 describes the duties of the social work services department in assisting the patient's family, including counseling and referral to community agencies for services.

- (8) Developmental Disabilities Intervention Services. Each hospital that provides Level II or Level III 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.**

The applicant provides developmental care and assessment by a multi-disciplinary team, including ongoing education in developmental care to nurses and families, ongoing consideration of environmental issues and individualized care plans.

- (9) Discharge Planning. Each hospital that provides Level II or Level III neonatal intensive care services shall have an interdisciplinary staff responsible for discharge planning. Each hospital shall designate a person responsible for discharge planning.**

According to the applicant, the case management team is comprised of case management nurse specialists, social workers, and the patient's staff nurse and physician, with support by rehabilitative services, dietary services, the CMS nurse and the family. The two NICU case management nurse specialists are responsible for coordinating the team members in case management activities for each neonate.

- h. Ch. 59C-1.042(10), Florida Administrative Code - Level III Neonatal Intensive Care Unit Standards. The following standards shall apply to Level III neonatal intensive care services:**

- (1) Pediatric Cardiologist. A facility providing Level III neonatal intensive care services shall have a pediatric cardiologist, who is either board-certified or board-eligible in pediatric cardiology, available for consultation at all times.**

There are nine board-certified pediatric cardiologists on staff who offer 24-hour coverage.

- (2) Nurse to Neonate Staffing Ratio. Hospitals shall have a nurse to neonate ratio of at least 1:2 in Level III NICUs at all times. At least 50 percent of the nurses shall be registered nurses.**

The applicant states it meets this standard and will continue to do so in operating additional beds. The applicant also states that every nurse providing Level III NICU care at ACH is a registered nurse. Schedule 6A of the application indicates that the current NICU staff includes the NICU staff already required to exceed the minimum staffing ratios at all times.

(3) Requirements for Level III NICU Patient Stations. Each patient station in a Level III NICU shall have, at a minimum:

- a. **Eighty square feet per infant;**
- b. **Two wall mounted suction outlets preferably equipped with a unit alarm to signal loss of vacuum;**
- c. **Twelve 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 non-invasive blood pressure monitoring device for every three beds;**
- k. **At least one portable suction device; and**
- l. **Availability of devices capable of measuring continuous arteria; oxygenation in the patient**

The applicant indicates that the new NICU center will be designed in accordance with all governing rules, statutes, and building codes to ensure that the appropriate spaces for beds, equipment, and support spaces are provided. Refer to the architectural review below in E.4.h.

(4) Equipment Required in Each Level III Neonatal Intensive Care Unit. Each Level III neonatal intensive care unit shall be equipped with:

- a. **An EKG machine with printout capability;**
- b. **Portable suction equipment; and**
- c. **Not less than one ventilator for every three beds**

The applicant states that equipment listed above will be included in the new NICU Center.

i. Ch. 59C-1.042(11) - Emergency Transportation Services: Each hospital providing Level II neonatal intensive care services or Level III neonatal intensive care services shall have or participate in an emergency 24-hour patient transportation system.

(1) Provision of Emergency Transportation. Hospitals providing Level II or Level III neonatal intensive care services must operate a 24-hour 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.

(2) Requirements for Emergency Transportation System. Emergency transportation systems, as defined in paragraph (11)(a), shall conform to section 10D-66.52, Florida Administrative Code.

All Children's Hospital provides its own neonatal inter-facility emergency transportation services on a 24-hour basis. The applicant also states that all of the transportation services utilized and provided by All Children's Hospital conform to Rule 64E-2.006 (formerly Rule 10D-66.52).

j. Ch. 59C-1.042(12) - 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 or Level III 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.

See response to 3.i. above.

k. Ch. 59C-1.042(13) - Data Reporting Requirements: All hospitals with Level II or Level III neonatal intensive care services shall provide the agency or its designee with patient utilization and fiscal reports which contain data relating to patient utilization of Level II and Level III neonatal intensive care services.

The applicant states that it will continue to provide all data required by the agency in this section of the rule.

4. Statutory Review Criteria

- a. Is need for the project evidenced by the availability, efficiency, 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(2) and 408.035(7), Florida Statutes.**

With respect to availability, the applicant is one of only two providers in District 5 offering Level III NICU services. The other is Mease Hospital Dunedin, which has a five-bed Level III NICU. The applicant notes that Mease Hospital's NICU beds (Level II and Level III) have been approved for transfer to the Countryside campus (CON #9164 and CON #9165). All Children's Hospital is licensed for 24 Level III NICU beds. The utilization at ACH's Level III NICU also evidences need for the additional beds proposed in this application. For the 12 months ending December 31, 2001, the occupancy rate for the Level III NICU beds at ACH was 127.52 percent, and seasonal, monthly, and daily fluctuations exacerbate bed shortages. Furthermore, although Mease Hospital's Level III NICU beds were only at 58.4 percent occupancy for the same period, the applicant submits that Mease Hospital's small NICU program is not equipped to address the complex medical needs of the severely ill neonates treated at ACH, and therefore transferring overflow Level III neonates from ACH to Level III beds at Mease Hospital is not a realistic option in most cases. Moreover, since ACH is the designated RPICC in District 5, the approval of additional Level III NICU beds is necessary to ensure that infants in that district as well as in neighboring areas in west central Florida have adequate access to the highest levels of tertiary and quaternary neonatal care. Additional beds would also relieve capacity constraints and enhance efficiency by alleviating current operational difficulties described in the application.

The applicant has historically experienced high occupancy in its Level III NICU beds. As discussed above, its Level II beds have historically been underutilized in comparison. Following is a five-year history of Level III utilization in the 24 existing beds:

5-Year Utilization History for ACH Level III NICU

	1998	1999	2000	2001	2002
Total Bed Days	8,760	8,760	8,760	8,784	8,760
Total Patient Days	8,791	8,619	8,628	9,206	11,171
Occupancy %	100.35%	98.39%	98.49%	104.80%	127.52%

Source: Florida Hospital Bed & Service Utilization by District; July 1998-July 2002 Batching Cycle.

The addition of Level III beds through the delicensure of some of the applicant's underutilized Level II beds is a better use of the applicant's resources.

The applicant's facility is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Refer to E.4.b. below for more discussion on quality of care.

The availability, efficiency, quality of care, accessibility, and extent of utilization at All Children's Hospital will be improved with this project.

- b. Does the applicant have a history of providing quality of care? Has the applicant demonstrated the ability to provide quality care? ss. 408.035(3), Florida Statutes.**

All Children's Hospital is a specialty children's hospital, a pediatric research/teaching facility⁴, a state-certified pediatric trauma center, and the designated RPICC in District 5, serving as a regional referral center for pediatric and neonatal services. The facility is accredited by the Joint Commission on Accreditation of Healthcare Organizations. The applicant is also a designated Medicaid Disproportionate Share Provider.

Copies of the Quality Improvement Program, 2002 Executive Summary and Neonatal Indicators are included in the application. The applicant also provided a detailed description of hospital services, support services, and outreach and community service programs.

According to AHCA data, the applicant had two confirmed complaints (one without deficiency), during the last three years. The confirmed complaint was related to patient care.

⁴ Ibid.

- c. **Is the applicant proposing special health care services for its service area that are not reasonably and economically accessible in adjacent service areas? ss. 408.035(4), Florida Statutes.**

The applicant states that approximately 24 percent of its Level III NICU patients in 2001 were from outside of District 5. ACH is a regional referral center and a designated RPICC facility for the provision of pediatric and neonatal services to a large service area in west central Florida and beyond. The proposed project does not involve special health care services that are not reasonably or economically accessible in adjacent districts.

- d. **Is this project to be located in a research or teaching hospital? Will the program affect the clinical needs of health professional training programs in the service area? ss. 408.035(5), Florida Statutes.**

The proposed project will not be located in a statutorily defined teaching hospital. All Children's Hospital serves as a primary pediatric teaching facility for the University of South Florida College of Medicine and is a center for research and development in the care of children. The application also describes ACH's numerous research activities. The primary purpose of the project does not involve research or physician education.

- e. **What resources, including health manpower, management personnel, and funds for capital and operating expenditures, are available for project accomplishment and operation? ss. 408.035(6), Florida Statutes.**

The audited financial statements for the periods ending September 30, 2001 and 2000 were analyzed for the purpose of evaluating the applicant's ability to provide the capital and operational funding necessary to implement the project. The following is a list of accounts and ratios used in the analysis:

	09/30/2001	09/30/2000
Current Assets	\$ 58,111,661	\$ 51,305,148
Cash and Current Investment	\$ 20,081,335	\$ 10,239,876
Assets Restricted for Capital Projects	\$ 7,221,379	\$ 7,063,712
Total Assets	\$ 291,922,068	\$ 259,585,222
Current Liabilities	\$ 33,571,318	\$ 28,840,256
Total Liabilities	\$ 61,968,977	\$ 58,661,835
Total Equity	\$ 229,953,091	\$ 200,923,387
Net Operating Revenues	\$ 168,689,923	\$ 161,520,465
Interest Expense	\$ 1,710,340	\$ 1,884,788
Net Profit - Operations	\$ 4,241,705	\$ 6,100,224
Net Income	\$ 17,020,956	\$ 18,662,155
Cash Flow from Operations	\$ 33,988,222	\$ 36,196,124
Working Capital	\$ 24,540,343	\$ 22,464,892
Current Ratio (CA/CL)	1.7	1.8
Cash Flow to Current Liabilities (CFO/CL)	1.0	1.3
Long-Term Debt to Equity (TL-CL/TE)	0.1	0.1
Times Interest Earned (NPO+Int/Int)	3.5	4.2
Equity to Total Assets (TE/TA)	78.8%	77.4%
Operating Margin (NPO/NOR)	2.5%	3.8%
Total Margin (NI/NOR)	10.1%	11.6%
Return on Assets (NI/TA)	5.8%	7.2%
Operating Cash Flow to Assets (CFO/TA)	11.6%	13.9%

Short-term position:

The applicant's current ratio of 1.7 indicates current assets are less than twice that of short-term liabilities, a minimally adequate position. The working capital (current assets less current liabilities) of \$25 million is slightly weak in relation to its total financial size and structure. The ratio of cash flow to current liabilities of 1.0 is good. The applicant's short-term position is on the lower side of satisfactory.

Long-term position:

The long-term debt to equity of 0.1 means this debt is very low in relation to the net worth of the entity, an excellent position. The cash flow to assets of 11.6 percent depicts a satisfactory cash flow when compared to total assets. The most recent year had an operating profit of \$4.2 million resulting in a margin of 2.5 percent, a fair level. The total equity of \$230 million with the equity to assets of 78.8 percent is considered very good. The applicant has a strong long-term position.

Capital requirements:

Schedule 2 indicates the applicant had \$58 million in capital projects planned or underway. The audited financial statements disclosed long-term debt maturing through 2005 of \$14 million, which when added to the Schedule 2 amount would total \$72 million.

Available capital:

Schedule 2 indicates funding for these projects will come from cash in hand of \$27 million and cash flows of \$31 million. The applicant's audited financial statement for September 30, 2001 indicates cash and short-term investments of \$20 million and assets restricted but available for capital expenditures of \$7 million. The audit also shows cash flows for that year of \$34 million, which if continued through 2005 would result in \$136 million.

Conclusion:

With potentially over \$160 million available the applicant should be able to fund all capital requirements as needed.

f. What is the immediate and long-term financial feasibility of the proposal? ss. 408.035(8), Florida Statutes.

A comparison of the applicant's estimates to the control group values provides for an objective evaluation of financial feasibility (the likelihood that the services can be provided under the parameters and conditions contained in Schedules 7 and 8), and efficiency (the degree of economies achievable through the skill and management of the applicant). In general, projections that approximate the median are the most desirable, and balance the opposing forces of feasibility and efficiency. In other words, as estimates approach the highest in the group, it is more likely that the project is feasible, because fewer economies must be realized to achieve the desired outcome. Conversely, as estimates approach the lowest in the group, it is less likely that the project is feasible, because a much higher level of economies must be realized to achieve the desired outcome. These relationships hold true for a constant intensity of service through the relevant range of outcomes. As these relationships go beyond the relevant range of outcomes, revenues and expenses may either go beyond what the market will tolerate or may decrease to levels where activities are no longer sustainable.

Comparative data were derived from hospitals in peer groups that reported data in 2000; the applicant will be compared to the hospitals in group 14. Per diem rates are expected to increase by an average of 3.4 percent per year. Inflation adjustments were based on the most current Florida Hospital Input Price Index.

Gross revenues, net revenues, and costs were obtained from Schedules 7 and 8 in the financial section of the application. These were compared to the control group as a calculated amount per adjusted patient day. The adjustment is made to factor out the outpatient revenues in the per patient day computation.

Net revenue per adjusted patient day (NRAPD) of \$2,354 in year one and \$2,420 in year two is between the control group median and highest values of \$2,241 and \$3,827 in year one and \$2,308 and \$3,942 in year two. The highest level is generally viewed as the practical upper limit on economies of operation. With net revenues falling between the median and highest level, the facility is expected to consume health care resources in proportion to the services provided. (See Comparative Table). The 2001 actual NRAPD for this hospital was \$ 2,062.

Anticipated cost per adjusted patient day of \$2,326 in year one and \$2,388 in year two is between the group median and highest values of \$2,185 and \$4,657 in year one and \$2,251 and \$4,797 in year two. This application is considered cost-efficient when compared to the control group. (See Comparative Table). The 2001 actual CAPD for this hospital was \$2,079.

The year two operating profit for the hospital of \$2.5 million computes to an operating margin per adjusted patient day of \$32 which is between the peer group median and highest of \$-33 and \$72. The operating margin computes to 1.3 percent, which is a little low for Florida hospitals. For year two, the application indicated net non-operating revenues of \$21 million were expected. The forecasted total margin is \$23 million. The 2001 financial data submitted to the agency shows the hospital with a negative operating margin of \$-1.2 million and a total margin for 2001 after non-operating revenues of \$17 million.

Schedule 4 disclosed recent utilization of the existing NICU III beds in excess of 100 percent. The narrative indicated these excess patients are being shifted to NICU II beds. Because of the practice of treating the patient overload in other beds, no additional patient days are planned and no additional revenues are expected for the first two years of operations. The net effect of the addition of these beds is an incremental loss of \$-90,952 due to the costs of plant operations and property expenses.

The addition of these NICU III beds is more of a focus on future needs instead of the attraction of immediate additional patients and revenue. Obviously this is a long-range project and the two-year pro formas only measure a start-up period. Considering the structure of the hospital, its non-operating revenues, and the long-range mission, the application is felt to be financially feasible.

COMPARATIVE TABLE

All Children's 2000 DATA Peer Group 14	2007	YEAR 2	INFLATION ADJ. VALUES		
	YEAR 2	ACTIVITY	Highest	Median	Lowest
	ACTIVITY	PER DAY			
ROUTINE SERVICES	64,578,309	826	992	422	118
INPATIENT AMBULATORY	1,753,344	22	63	11	1
INPATIENT ANCILLARY SERVICES	180,285,670	2,305	2,935	1,717	532
OUTPATIENT SERVICES	118,573,659	1,516	7,845	2,032	756
OTHER OPERATING REVENUE	9,737,503	124	444	69	11
TOTAL REVENUE	374,928,485	4,793	8,969	4,714	3,485
DEDUCTIONS FROM REVENUE	185,643,500	2,373	*	*	*
NET REVENUES	189,284,985	2,420	3,942	2,308	1,322
EXPENSES					
ROUTINE	35,464,627	453	378	199	99
ANCILLARY	48,329,358	618	1,232	708	540
AMBULATORY	18,261,632				
OVERHEAD	84,703,511	1,083	2,847	1,061	672
OTHER	0	0			
TOTAL EXPENSES	186,759,128	2,388	4,797	2,251	1,507
OPERATING INCOME	2,525,857	32	72	-33	-434
		1.3%			
PATIENT DAYS	51,451		NOT INFLATION ADJUSTED		
ADJUSTED PATIENT DAYS	78,220				
TOTAL BED DAYS AVAILABLE	82,490				
ADJ. FACTOR	0.6578				
TOTAL NUMBER OF BEDS	226				
PERCENT OCCUPANCY	62.4%		61.4%	52.7%	3..46%
PAYER TYPE	PATIENT	% TOTAL			
	DAYS				
MEDICARE	340	0.7%	63.6%	30.9%	0.4%
COMMERCIAL	1,405	0.0%			
MEDICAID	23,608	45.9%	46.7%	7.4%	4.6%
PRIVATE	238	0.5%			
HMO/PPO	25,150	48.9%	47.4%	44.1%	21.9%
OTHER	710	1.4%			
TOTAL	51,451	100.0%			

- g. Will the proposal foster competition to promote quality and cost-effectiveness? ss. 408.035(9), Florida Statutes.

The applicant forecasts managed care to represent 48.9 percent of its patient days. This is just over the control group's highest level of 47.4 percent and is identical to the hospital's own 2001 managed care level of 48.9 percent. As a result of this project the applicant does not anticipate any additional NICU III patient days or revenues for the first two years. Since the addition of these NICU III beds will result in no change in the

level of managed care and no increase in patient days or revenues it will not have any significant impact on competition to promote quality and cost-effectiveness.

h. Are the proposed costs and methods of construction reasonable? Do they comply with statutory and rule requirements? ss. 408.035(10), Florida Statutes; Ch. 59A-3 or 59A-4, Florida Administrative Code.

This CON application is to increase the number of Level III NICU beds. The hospital was pursuing implementation of three previously approved Level III beds. However, as noted above, that CON was recently voided by the Agency. The hospital's intent is to locate all of its NICU beds in a new building that is in the planning stage. Occupancy is projected for 2006. According to the applicant, the proposed building plans are not at a point where they could be submitted to the AHCA Office of Plans and Construction, but a submission is projected for 2003.

A very schematic drawing was included in the application. The building is planned to be four stories high and linked at one end to the existing All Children's Hospital by a bridge on at least the third level. This level is the only one shown on the drawings. The building is basically one quadrant of a circle and the end opposite the bridge abuts the All Children's Hospital parking garage. The new building does not appear to allow pedestrian traffic to or from the garage at the third floor level. This avoids obvious security problems.

The layout shows a double-loaded corridor with four nursery areas of 16 beds each on the outer side of the arc of the building. Each area has its own nurse station and support spaces. A fifth area is an isolation nursery. It is located away from the curved side of the building and it too has support spaces.

The schematic drawings are not totally developed at this stage, but there appears to be enough space for the required ancillary spaces. It would be wise for the applicant and the design professional to closely follow the provisions of Chapter 59A-3 of the Florida Administrative Code and comparable portions of the Florida Building Code for the specific requirements for NICU areas. There are references and requirements for support spaces such as clean and soiled spaces of various types, staff lounges and locker areas, toilets and similar ancillary functions. Some of these spaces are required per suite, some per nursery, some per unit etc.

The codes referenced above are quite specific as to the requirements for these ancillary spaces, and the plans need to utilize the same space nomenclature as the codes so that the AHCA reviewers can determine if the necessary spaces have actually been provided.

The rationale for the curved configuration of the building is not evident from the plan information provided. The design decision may have been made to accommodate functions on the other three floors and possibly to provide covered access from the garage on other levels. Whatever the reason, the layout seems to be thought-out and although curved construction is usually more costly than rectangular, but for a project of this scope, the concept most likely would not increase the costs per square foot excessively.

Accommodations have been made not only for the patients and staff, but also for the parents, with several areas for family waiting, sleeping and there is a family resource area as well as other family-orientated spaces.

A list of codes does not appear to be in the application, but the existing codes are subject to change and this is a negligible issue. Cost data seem to be reasonable.

- i. 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(11), Florida Statutes.**

The applicant is a designated Medicaid Disproportionate Share Provider and has a history of providing Medicaid and charity care. All Children's Hospital is proposing a condition of at least 40 percent of the total Level III NICU patient days will be provided to Medicaid/charity care patients.

The following table provides an indication of the applicant's commitment to charity and Medicaid, with comparison to the district, based on Fiscal Year (FY) 2000 Actual Data prepared by AHCA.

**Medicaid and Charity Care of the Applicant
Compared to the District for Fiscal Year 2000**

Applicant Hospital	FY 00 Conventional Medicaid % of Pt. Days	FY 00 Charity % of Patient Days
All Children's Hospital	46.7%	1.6%
District 5 Average	6.9%	1.1%

Source: FY 2000 Actual Data/AHCA

As reflected in the table, All Children's Hospital's provision of Medicaid and charity care is greater than the district average. The applicant is a designated Medicaid Disproportionate Share Provider.

F. SUMMARY

The applicant proposes to add thirteen Level III NICU beds to the existing NICU at All Children's Hospital, located in Pinellas County. All Children's Hospital is a 216-bed Class II Specialty Hospital licensed for 156 acute care beds, 24 Level III NICU and 36 Level II NICU beds. The applicant had an approved certificate of need (CON #9309), which authorizes the addition of three Level III NICU beds that was recently voided.

The proposed project cost is estimated to be \$1,766,543 and involve construction costs of \$914,213 and GSF of 4,338.

Need/Other Special Circumstances:

A fixed need pool of seven beds was published for Level III NICU services in District 5 for the January 2005 planning horizon.

District 5 has 29 licensed Level III NICU beds as of July 26, 2002. The Level III NICU beds in District 5 experienced an occupancy rate of 115.61 percent during the period January through December 2001.

The applicant has shown that addition of Level III beds through the delicensure of six Level II NICU beds a better use of its resources. Need for additional NICU beds at the facility was demonstrated.

Quality of Care:

The applicant is JCAHO accredited and has a history as a quality care provider.

Medicaid/Indigent Care:

According to the *Certificate of Need Predicated on Conditions* page, the applicant is proposing a minimum of 40 percent of its total Level III NICU patient days to Medicaid and charity care patients. All Children's Hospital is a designated Medicaid Disproportionate Share Provider.

Financial/Cost:

The short-term position of the applicant is barely satisfactory and the applicant has a strong long-term position. Based on the financial position, the applicant should be able to fund all capital requirements as needed.

The applicant's level of managed care will have no significant impact on competition to promote quality and cost-effectiveness.

Architectural:

The new building where the proposed beds will be located is planned to be four stories high and linked at one end to the existing All Children's Hospital by a bridge on at least the third level. Although there appears to be enough space for the required ancillary spaces, the schematic drawings are not sufficiently developed to ascertain whether the necessary spaces have actually been provided.

Cost data appears to be reasonable.

RECOMMENDATION

Approve CON #9609 to add 13 Level III NICU beds to All Children's Hospital. The project cost is \$1,766,543 and involves construction costs of \$914,213 and GSF of 4,338.

CONDITIONS:

- (1) A minimum of 40 percent of the total Level III NICU patient days shall be provided to Medicaid and charity care patients.
- (2) Six Level II NICU beds shall be delicensed at the time the 13 Level III NICU beds are licensed.

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: _____

Karen Rivera
Health Services and Facilities Consultant Supervisor
Certificate of Need

Jeffrey N. Gregg
Chief, Bureau of Health Facility Regulation