STATE AGENCY ACTION REPORT

ON APPLICATION FOR CERTIFICATE OF NEED

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

Kendall Healthcare Group, Ltd d/b/a Kendall Medical Center/CON#9566
11750 Bird Road
Miami, Florida 33175

Authorized Representative: Gina C. Diaz
(305) 227-5500

2. Service District/County

District 11 (Dade County)

B. PUBLIC HEARING

No public hearing was requested or held regarding the proposed project. A letter of support from Dr. Jorge Pastoriza was submitted by the applicant. Dr. Pastoriza states that he has observed "tremendous growth" within Miami-Dade County and believes this project will allow patients more choice in providers.

C. PROJECT SUMMARY

The applicant operates Kendall Medical Center, a 412-bed general acute care private for-profit hospital located in Dade County. The applicant proposes to establish a 10-bed Level II Neonatal Intensive Care Unit (NICU) program in District 11 at that hospital through the conversion of 10 acute care beds.

According to the applicant's *Certificate of Need Predicated on Conditions* page, it will set aside a minimum of 20 percent of its Level II NICU patient days to Medicaid patients and a minimum of one percent of its Level II NICU patient days to charity care patients. The proposed project cost is estimated to be $2,008,680. Renovation costs are projected at $1,053,000 and the project will involve 5,400 gross square feet (GSF) of renovation.

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(s) with the criteria and application content requirements found in Florida Statutes, sections 408.035, and 408.037; 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 4, dated January 25, 2002, on page 374 of the Florida Administrative Weekly, a fixed need pool of zero beds was published for neonatal intensive care Level II beds in District 11 for the July 2004 planning horizon.

As of January 25, 2002, District 11 had164 licensed Level II NICU beds and 10 approved Level II NICU beds. The Level II NICU beds in District 11 experienced an occupancy rate of 73.98 percent during the period July 2000 through June 2001. The applicant is applying outside of the fixed need pool and indicates it is applying under special (not normal) circumstances.

b. Regardless of whether bed need is shown under the need formula, the establishment of new Level II neonatal intensive care unit beds 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 6 months prior to the beginning date of the quarter of the publication of the fixed need pool. Ch. 59C-1.042(3)(d), Florida Administrative Code.

As stated above, the 164 Level II NICU beds in District 11 experienced an occupancy rate of 73.98 percent for the most recent reporting period.

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 II neonatal intensive care beds at hospitals with Level II neonatal intensive care services seeking additional Level II beds is demonstrated in the absence of need shown under the formula specified in paragraph (3)(c) of this rule if the occupancy rate for their Level II beds exceeded an average of 90 percent as computed by the agency for the same time period specified in subparagraph (3)(e)(2).

Since the applicant currently has no Level II NICU beds, it does not meet the “special circumstances” defined in Rule. The applicant contends there are other not normal circumstances within the district that indicate the need for additional beds.

c. Other Special Circumstances:

The applicant states that need for the proposal is indicated by the annual growth in District 11 Level II NICU patient days over the last three years. Table 1-1 of the application depicts the three-year and annual growth rates for District 11 live births, fertile females, and Level II utilization.

District 11 Live Births, NICU Level II Utilization & Females Age 15-44 Percentage and Average Growth Rate between 1998 and 2001

Factor	1998	2001	Total Growth	Annual Growth
Births	31,784	31,859	0.24%	0.08%
Females Age 15-44	507,354	519,835	2.46%	0.81%
Level II Patient Days	42,712	47,412	11.00%	3.54%

Source: CON application

While the foregoing data suggest that District 11 Level II NICU patient days are increasing faster than births or population, need for a new Level II NICU program of 10 beds in the district is not demonstrated thereby. Further, the "Annual Growth" value is actually an average for the period. The following table portrays the actual annual growth in District 11 Level II NICU patient days for the last six years.

Annual NICU Level II Patient Day Growth Rate 1995-2001

Calendar Year	D11 Level II NICU Patient Days	Change
1995	40,620	
1996	38,332	-5.97%
1997	39,134	2.05%
1998	42,757	8.47%
1999	43,845	2.48%
2000	44,320	1.07%
2001	47,412*	6.52%

Source: ***Florida Hospital Bed and Service Utilization by District,*** **July 1996, 1997, 1998, 1999, 2000, and 2001 Batching Cycles; *AHCA preliminary data**

As indicated, no discernable growth trend can be found. The applicant notes that the Level II NICU bed need methodology in rule has not produced a numeric need for District 11 since January 1993. The applicant also points out that highly-utilized existing providers may add beds in the absence of published need. However, neither of these contentions constitutes not normal circumstances warranting application approval.

The applicant attempted to quantify the need for the proposed 10 beds by using the existing rule methodology. However, the applicant removed licensed beds from the calculation and also substituted a growth-inflated patient days variable in place of the rule mandated historical patient day total in its recalculation.

The applicant also deleted the 10 licensed Level II beds at Jackson Memorial (North) in displaying the utilization of District 11 Level II NICU beds for calendar year 2001 in Table 1-5 of the application. The correct utilization is shown below.

District 11 Level II NICU Occupancy CY 2001

Hospital	Level II Beds	Level II Patient Days	Occupancy
Baptist Hospital of Miami	12	5,973	136.37%
Hialeah Hospital	10	2,695	73.84%
Jackson Memorial Hospital	60	19,493	89.01%
Jackson Memorial (North)	10*	0	0.00%
Mercy Hospital	6	1,196	54.61%
Miami Children's Hospital	7	2,027	79.33%
Mount Sinai Medical Center	8	1,775	60.79%
North Shore Medical Center	8	2,134	73.08%
Palmetto General Hospital	10	3,289	90.11%
Parkway Regional Medical Center	10	2,980	81.64%
South Miami Hospital	23	5,850	69.68%
Total	**164**	**47,412**	**78.05%**

Source: District 11 local health council; *Q1 Total Bed Days is based on 19 beds.

The desired district average occupancy standard of 80 percent is not met in the service district.

Under the heading "Promote a Continuum of Care," the applicant argues that the birth volume at its facility lends support for the proposed Level II NICU. Although the applicant meets the minimum birth volume in rule, there are sufficient Level II NICU beds available in the service area and no access problems were demonstrated.

In the "Quality of Care and Enhanced Patient Satisfaction," section, the applicant states that approval of the application will allow choice (of Kendall Medical Center) and avoid transfers (from Kendall Medical Center). However, the foregoing does not constitute a "not normal" situation since the same can be said of any hospital with an obstetrics program that does not have a Level II NICU. The applicant did not state how many neonates were transferred to another facility with NICU services. AHCA Discharge Data Summary Report indicates that up to nine neonates were transferred, using DRG 385 category, to other hospitals during July 2000 – June 2001. The applicant did not indicate any access problems.

The applicant also states that a Level II NICU at its facility would "Promote and Enhance the Availability, Accessibility, and Distribution of Level II NICU Services." The applicant contends that the Level II NICU beds in the district are highly utilized. However, the utilization of the licensed Level II NICU beds in the district is not at the desired district average occupancy standard of 80 percent.

Further, although currently unavailable, the 10 Level II NICU beds at Jackson Memorial (North) are licensed and will either become available or removed from the inventory, as will the 10 approved beds for Baptist Hospital of Miami. These beds cannot be ignored in evaluating the need for an additional tertiary program in the district.

In the "Balancing Regionalization with Enhancements in Service Delivery" section, the applicant states that the proposal to establish 10 new Level II beds is necessary to accommodate institutional-specific need …" Need for 10 additional Level II NICU beds due to access denial or any other access problems was not demonstrated.

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 District 11 October 2000 CON Allocation Factors Report provides the following preferences in the review of applications pertaining to tertiary and neonatal intensive care services:

a. **Preference should be given to the following applicants for tertiary care services:**

Level One – Higher Priorities

(1) **Applicants who provided the highest proportion of charity care and Medicaid days during the past fiscal year for which reimbursement was received through Florida's "Disproportionate Share Program" of the Medical Assistance Trust Fund. "Charity care" is that care provided to persons below 150% of the federal poverty level and for which there was no compensation exclusive of adjustment allowances.**

The applicant is not a designated Medicaid Disproportionate Share Provider.

Level Two – Lower Priorities

(1) Applicants who include a plan to train personnel.

The applicant states that it has training programs in place to provide the necessary ongoing training and education required to establish and maintain a quality Level II NICU program.

b. Preference should be given to the following applicants for Level II neonatal intensive care services:

Level One – Higher Priority

(1) Applicants who provided the highest proportion of charity care and Medicaid days during the past fiscal year for which reimbursement was received from the State of Florida. "Charity care" is that care provided to persons below 150 percent of the federal poverty level and for which there was no compensation exclusive of adjustment allowances.

The applicant is not a designated Medicaid Disproportionate Share Provider.

(2) Applicants who demonstrate the highest ongoing commitment to serving Medicaid and indigent patients as well as patients from diverse minority backgrounds. "Medically indigent" refers to persons below 150 percent of the poverty level, uninsured and/or underinsured, as defined by the Health Council of South Florida.

Please refer to E.4.i. below.

(3) Applicants who provide onsite interpreters for Creole.

The applicant states that it has employees and volunteers on-site who speak and read Creole.

(4) Applicants who specify how their proposed program will contribute to the development of an organized district-wide neonatal program.

The applicant states that the establishment of a Level II NICU at its facility conforms to this preference. However, the proposed project does not add anything that does not already exist in the district.

Therefore, the proposed program will not contribute to the development of an organized district-wide neonatal program.

(5) **Applicants who convert a number of acute care beds as defined in Rule 59C-1.038, excluding specialty beds, which is equal to the number of Level II beds proposed, or who accurately project an occupancy rate of 75 percent for the applicable planning horizon for all acute care beds, excluding specialty beds.**

The applicant is proposing to convert 10 acute care beds to 10 Level II NICU beds.

(6) **Hospitals which propose to provide neonatal intensive care services to Children's Medical Services patients.**

The applicant states that it participates in the care of Children's Medical Services eligible patients. However, the applicant has not proposed to condition award of the CON upon providing services to this patient population.

(7) **Hospitals, which have both Level II and Level III NICU beds.**

The applicant does not currently have any NICU beds.

Level Two – Lower Priority

(1) **Applicants who demonstrate a commitment to quality of care as evidenced by the existence of a mechanism to assess and publicly report on quality.**

Please see E.4.b. below.

(2) **Commit to timely completion of CON projects that are approved.**

In Schedule 10 of the application, the applicant projects that the service would be initiated in January 2004.

3. Agency Rule 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)(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 is proposing a minimum of 20 percent of its Level II NICU patient days will be provided to Medicaid patients, and a minimum of 1 percent of its Level II NICU patient days will be provided to charity care patients.

Please 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) Hospitals may be approved for Level II neonatal intensive care services without providing Level III services. In a comparative review, preference for the approval of Level II beds shall be given to hospitals, which have both Level II neonatal intensive care unit beds and Level III neonatal intensive care unit beds.

The applicant does not currently have Level II or III NICU beds.

(2) Applicants proposing to provide Level II or 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 its discharge planning team will conduct follow-up checks on discharged patients to monitor outcomes of care and make appropriate referrals for care.

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

The applicant proposes to establish the minimum unit size of 10 beds as described in Rule.

d. Ch. 59C-1.042(6) - Minimum Birth Volume Requirement. Hospitals applying for Level II neonatal intensive care services shall not normally be approved unless the hospital has a minimum service volume of 1,000 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.

The hospital exceeds the minimum service volume of 1,000 live births for the most recent 12-month period.

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 time to 90 percent of the residents of District 11.

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

(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-hour coverage, and who are either board certified or board eligible in neonatal-perinatal medicine.

The applicant states that there is a board-certified perinatologist, Dr. Luis Izquierdo, six board-certified neonatologists, and 10 board-eligible neonatologists, on active staff at the hospital, providing 24-hour coverage.

A curriculum vitae for each of the 17 physicians is included in Exhibit 3-3 of the application. Schedule 6 of the application reflects 0.20 FTE new staff for a neonatologist/medical director and no perinatologist.

(2) **Nursing Staffing: 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.**

According to the applicant, the Director of Maternity and Women's Health Services at Kendall Medical Center, Maria Villa, R.N., who has experience in neonatal intensive care nursing, will be the head nurse. Exhibit 3-1 of the application contains the resume of Ms. Villa. Schedule 6 of the application indicates that all of the proposed nursing staff for the project are 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 the nurses in the Level II NICU program are trained in the foregoing requirements and that nurses assigned to the program either as new hires or as transfers from within will be required to have the technical skills to manage ill neonates and to provide the nursing interventions necessary to manage the intensive care that neonates receive.

(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 that the Respiratory Care Department is operated and staffed 24 hours, seven days a week, and that its director, Jose Miro, RRT, is qualified by training and experience to provide respiratory therapist services in the Level II NICU program. On Schedule 6 of the application, 6.3 FTEs are designated for respiratory therapists.

(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 the hospital has blood gas determinations available on a 24-hour basis. The applicant also provides on site x-ray, obstetric ultrasound, and clinical laboratory services with the ability to perform microstudies, 24 hours, seven days a week. In addition, anesthesia is available within 30 minutes, 24 hours a day.

(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.

The applicant states that the Clinical Nutrition Manager, Carmen T. Urrunaga, will participate as part of the interdisciplinary team in case planning and provide information and instructions to the parents at time of discharge in the discharge plan.

Exhibit 3-6 of the application provides a copy of Ms. Urrunaga's resume.

(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 indicates that it has social workers and case managers who are assigned to particular programs to ease patients' transitions at time of discharge. The case management director, Charlotte Price, is responsible for utilization review, including discharge planning. Maria Villa also participates in preparing the discharge plan, including the identification of required services and programs for which eligibility must be determined. Schedule 6 of the application indicates 0.5 FTE for social workers.

(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 states that it will provide in-hospital intervention services for infants identified as being high risk for developmental disabilities and will work with the parents and the assigned case manager to arrange for eligibility.

(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 clinical coordinator, newborn services, will direct the preparation of the discharge plan and in cooperation with the hospital's social services department and the assigned case manager, monitor the implementation of it. Table 3-5 of the application details the demonstrations required to be performed by the parents prior to discharge.

g. Ch. 59C-1.042(9) - 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.

The applicant states that the staffing exceeds the minimum requirement of one nurse to every four neonates in the Level II NICU but doesn't state if at least half of these nurses are registered nurses. Schedule 6 of the application shows 10.5 FTEs for registered nurses. However, Schedule 6 does not show the number of nurses per work shift.

(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;
l. At least one portable suction device; and
m. Not less than one ventilator for every three beds.

The applicant indicates that it is or will be in compliance with all of the requirements above. Refer to the architectural review below in E.4.h.

(3) Equipment Required to be Available to Each Level II NICU on demand:

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

The applicant indicates it will have all of the required equipment above available.

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 64E-2.003, Florida Administrative Code.

The applicant states that it participates with the Miami-Dade County Fire and Rescue emergency patient transportation system. No contract or other agreement was provided with the application. The applicant also states that it has a patient transfer agreement for the transport of neonates with Miami Children's Hospital, which provides the transport team. A copy of the transfer agreement in included as Exhibit 3-7 of the application.

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.**

The applicant indicates that its proposal is needed to enhance availability, quality of care, and accessibility, and to address the extent of utilization, in the service district. The applicant states that District 11 Level II NICU patient days have been increasing relative to births. There are currently 164 licensed Level II neonatal intensive care beds and 10 approved Level II NICU beds in District 11. The average occupancy in the Level II NICU beds in District 11 was 73.98 percent during the period July 2000 through June 2001, below the target of 80 percent occupancy.

The table below represents the period July 2000 through June 2001 utilization data for each Level II NICU provider in the district:

District 11 Level II NICU Occupancy
July 2000-June 2001

County	Hospital	Level II NICU Beds	Percent Occupancy
Dade	Baptist Hospital of Miami	12	122.44%
Dade	Hialeah Hospital	10	75.23%
Dade	Jackson Memorial Hospital	60	88.96%
Dade	Jackson Memorial (North)	10	0.00%
Dade	Mercy Hospital	6	55.21%
Dade	Miami Children's Hospital	7	75.23%
Dade	Mount Sinai Medical Center	8	70.10%
Dade	North Shore Medical Center	8	64.11%
Dade	South Miami Hospital	23	67.46%
Dade	Palmetto General Hospital	10	86.66%
Dade	Parkway Regional Medical Center	10	73.75%
Total		**164**	**73.98%**

Source: ***Florida Hospital Bed and Service Utilization by District,*** **January 2002 Batching Cycle**

The District 11 Level II NICU utilization for the last five years is as follows:

District 11 NICU Level II Occupancy 1997-2001

Calendar Year	Occupancy
1997	61.97%
1998	67.71%
1999	69.44%
2000	70.00%
2001	78.05%*

Source: ***Florida Hospital Bed and Service Utilization by District,*** **July 1998, 1999, 2000, and 2001 Batching Cycles; *AHCA preliminary data**

Although utilization of Level II NICU beds has been increasing annually, the district has yet to reach the desired district average occupancy standard of 80 percent. Further, the district's historical utilization and live births are factors considered in the rule need methodology. On average, at least 30 of the district's licensed Level II NICU beds are available. Moreover, there are 10 approved Level II NICU beds in the inventory (Baptist Hospital of Miami – CON #9460). Need for this project is not evidenced by utilization of existing area services and the applicant has not indicated the existence of any problems accessing the available beds in the district.

The applicant states that Kendall Medical Center is centrally located within Dade County in close proximity to a large portion of the district population. Table 4-2 of the application presents the hospital's primary service area population estimates by zip code for 2006 and indicates that approximately 43 percent of the county's population resides within the primary service area. As compared with 2000 census data, those population estimates show a six-year growth rate in the population of the primary service area of approximately 8.38 percent, or an average annual increase of 1.4 percent. Table 4-2 may actually understate the female age 15-44 population for the identified zip codes based on the 2000

census. The table has 205,533 estimated 2006 females age 15-44 for the primary service area. The 2000 census data shows 215,682 females in that age group for the zip codes identified in the table (although one zip code, 33122, had 0 in 2000, and another, 33199, could not be found in the census data).

The applicant also provided information showing that over 25 percent of the facility's births for the 12 months ending June 2001 was generated from within a five-mile radius of the hospital.

The applicant did not indicate that existing programs lacked quality of care; however, it indicated that the proposed Level II NICU program would provide a choice to patients and avoid patient transfers. High-risk infants (Level III) still would have to be transferred. The applicant's facility is accredited by the Joint Commission on Accreditation of Healthcare Organizations. Refer to E.4.b. below for more discussion on quality of care.

Need for the project is not demonstrated by the availability, quality of care, accessibility, and extent of utilization of existing health care facilities and services in the service district of the applicant.

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

The facility is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). A copy of the JCAHO accreditation is included in Exhibit 5-1 of the application. The application also includes detailed descriptions of the applicant's Organizational Performance Improvement Plan for 2002 and Case Management Plan. A copy of the guidelines and forms used in the Continuous Quality Improvement program is in Exhibit 5-2 of the application.

According to AHCA data, the applicant had 13 confirmed complaints (five (5) without deficiency), during the last three (3) years. Six of the confirmed complaints were related to billing and administrative concerns. The others concerned patient care, pressure sores, sanitation, patient rights, inappropriate discharge, and nursing service. As of April 19, 2002, two (2) complaints were referred to JCAHO and four (4) complaints were pending.

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 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 is not to be located in a research or teaching hospital nor will the primary purpose of the project involve research or physician education. The applicant provides in-service training for its employees, and sponsors community education and student programs. Application Exhibit 7-1 lists the Investigational Review Board Studies and Exhibit 7-2 contains the Continuing Medical Education calendar.

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 December 31, 2000 and 1999 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:

	12/31/2000	12/31/1999
Current Assets	$ 16,461,568	$ 15,155,658
Cash and Current Investment	$ 216,628	$ 0
Assets Restricted for Capital Projects	$ 0	$ 0
Total Assets	$ 62,330,006	$ 68,704,257
Current Liabilities	$ 16,435,231	$ 16,879,799
Total Liabilities	$ 19,067,692	$ 18,016,952
Total Equity	$ 43,262,314	$ 50,687,305
Net Operating Revenues	$ 134,952,583	$ 126,280,191
Interest Expense	$ 27,121	$ 34,569
Net Profit - Operations	$ 14,493,801	$ 11,733,899
Net Income	$ 14,980,317	$ 9,765,792
Cash Flow from Operations	$ 21,508,006	$ 21,379,916
Working Capital	$ 26,337	$ (1,724,141)
Current Ratio (CA/CL)	1.0	0.9
Cash Flow to Current Liabilities (CFO/CL)	1.3	1.3
Long-Term Debt to Equity (TL-CL/TE)	0.1	0.0
Times Interest Earned (NPO+Int/Int)	535.4	340.4
Equity to Total Assets (TE/TA)	69.4%	73.8%
Operating Margin (NPO/NOR)	10.7%	9.3%
Total Margin (NI/NOR)	11.1%	7.7%
Return on Assets (NI/TA)	23.3%	14.2%
Operating Cash Flow to Assets (CFO/TA)	34.5%	31.1%

Short-term position:
The applicant's current ratio of 1.0 indicates current assets are equal to short-term liabilities, a weak position. The working capital (current assets less current liabilities) is basically nonexistent. The ratio of cash flow to current liabilities of 1.3 is very strong. The applicant has a mixed short-term position. The poor ratios are the result of the centralized cash management of all HCA facilities. Surplus cash and short-term investments are held by the parent.

Long-term position:
The long-term debt to equity of 0.1 is low, indicating minimal debt, a good position. The cash flow to assets of 34.5 percent reflects a very high level of cash flows. The most recent year had an operating profit of $14.5 million, which resulted in a margin of 10.7 percent, a high level. The total equity of $43.3 million with the equity to assets of 69.4 percent is good. The applicant has a strong long-term position.

Capital requirements:
Schedule 2 indicates the applicant had $96.6 million in capital projects planned or underway. Long-term liabilities are relatively small and repayment was not discussed in the audit notes, indicating there are no significant scheduled repayments of this debt. The Schedule 2 amount of $96.6 million is the presumed total capital needed for this analysis.

Available capital:
Schedule 2 indicates funding for these projects will come from operations and the parent HCA. A letter from HCA indicates it will provide funding for 100 percent of the cost of this NICU unit as well as all other capital projects as needed. A copy of HCA's financial statements provided in the 10K report support its ability to provide this funding.

Conclusion:
When we consider the applicant's cash flows along with the strength and commitment from the parent, 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 5. Per diem rates are projected to increase by an average of 3.3 percent per year. Inflation adjustments were based on the most current Florida Hospital Input Price Index.

The application did not provide a Schedule 7 for the total facility. A statement of revenues and expenses for the total facility was provided; however, it did not include adequate detail for revenue types and the functional expense breakdown as suggested by Schedule 7. We were therefore unable to determine an adjustment factor for removing the effect of outpatient revenues from the patient day computations. The hospital has not filed its 2001 hospital financial report with the agency; therefore this review resorted to the adjustment factor calculated from the 2000 financial data submitted to the agency.

Net revenue per adjusted patient day (NRAPD) of $1,637 in year one and $1,693 in year two are both above the control group highest values of $1,579 and $1,627 respectively. The highest level is generally viewed as the practical upper limit on economies of operation. With net revenues falling above the highest level, the facility is expected to consume excess health care resources compared to the services provided. (See Comparative Table). The 2000 actual NRAPD for this hospital was $1,276, which was between the median and highest in that year. Without the NICU project the NRAPD for year one is $1,673 and for year two it is $1,731. Both years are above the highest value in the control group. Since the NRAPD is above the highest in the control group both with and without the NICU unit this project makes no discernable difference in net revenues per day.

Projected cost per adjusted patient day of $1,346 in year one and $1,401 in year two is slightly below the group highest values of $1,395 in year one and $1,437 in year two. The highest value is considered the upper limit of cost-efficiency. This application is not considered cost efficient when compared to the control group. (See Comparative Table). The 2000 actual CAPD for this hospital was $1,121, which was the median in that year. Without the NICU project the CAPD for year one is $1,372 and for year two it is $1,429. Both years are just below the highest value in the control group. Since the CAPD is just below the highest in the control group both with and without the NICU unit this project makes no discernable difference in costs per day.

The year two operating profit for the hospital of $32 million computes to an operating margin per adjusted patient day of $293 which is above the peer group highest of $246. The 2000 financial data submitted to the agency shows the hospital with an operating margin per adjusted patient day of $154. The projected margin is 17.3 percent. Without the NICU project the margin is 17.5 percent. In an industry where a 10 percent profit margin is considered high (approaching the 80th percentile) a 17 percent margin could indicate that either charges are too high or not enough is being spent on patient care. While there is no doubt in the applicant's ability to implement the project, the project represents a

costly and financially inefficient solution to providing neonatal intensive care services in the local market.

COMPARATIVE TABLE

CON # 9566					
Kendall Med Ctr	2005	YEAR 2			
2000 DATA Peer Group 5	YEAR 2	ACTIVITY	INFLATION ADJ. VALUES		
	ACTIVITY	PER DAY	Highest	Median	Lowest
ROUTINE SERVICES	0	0	976	553	274
INPATIENT AMBULATORY		0	129	44	16
INPATIENT ANCILLARY SERVICES	0	0	3,703	2,055	1,327
OUTPATIENT SERVICES	0	0	1,977	1,366	670
OTHER OPERATING REVENUE	0	0	65	11	1
TOTAL REVENUE	0	0	5,747	3,989	2,803
DEDUCTIONS FROM REVENUE	0	0	*	*	*
NET REVENUES	184,945,677	1,693	1,627	1,265	845
EXPENSES					
ROUTINE	0	0	293	214	161
ANCILLARY	0	0	598	438	314
AMBULATORY	0				
OVERHEAD	0	0	650	573	400
OTHER	0	0			
TOTAL EXPENSES	152,994,229	1,401	1,437	1,287	955
OPERATING INCOME	31,951,448	293	246	9	-374
		17.3%			
PATIENT DAYS	77,052		NOT INFLATION ADJUSTED		
ADJUSTED PATIENT DAYS	109,216				
TOTAL BED DAYS AVAILABLE	150,380				
ADJ. FACTOR	0.7055				
TOTAL NUMBER OF BEDS	412				
PERCENT OCCUPANCY	51.2%		90.6%	53.6%	23.0%
PAYER TYPE	PATIENT DAYS	% TOTAL			
MEDICARE	28,776	37.3%	68.2%	41.6%	19.4%
COMMERCIAL	0	0.0%			
MEDICAID	9,464	12.3%	22.8%	6.0%	0.7%
PRIVATE	6,127	8.0%			
HMO/PPO	32,686	42.4%	64.6%	36.0%	13.7%
OTHER	0	0.0%			
TOTAL	77,053	100.0%			

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

The applicant projects managed care to represent 42.4 percent of its patient days. This is between the control group median and highest levels of 36.0 percent and 64.6 percent and is similar to the hospital's own 2000 managed care level of 46.9 percent. The applicant's level of managed care will have no discernable impact on competition to promote quality assurance and cost-effectiveness. The high level of pricing as indicated by the hospital's ranking of net revenue per day within the control group and the anticipated profit margin indicates that little or no competition is taking place in the market to drive down prices for these services.

The proposed Level II NICU project was compared to all other hospitals in the state with approved Level II NICU programs. Schedule 7, total gross revenue for the Level II NICU only is projected to be $7,094,833 for year two. With 2,831 patient days anticipated the gross revenue (gross charges) per patient day computes to $2,506. This amount is between the median and highest of $1,645 and $3,377 respectively. The project should have little positive impact on competition to promote quality assurance and cost-effectiveness.

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

The proposal is to establish a 10-bed Level II NICU through conversion of 10 existing acute care beds on the 2nd floor of the hospital. The new NICU will have nine stations in an open plan with curtained cubicles and one isolation neonatal intensive care room. The new nurse station will be quite long so that the nurses can have continuous observation of most of the entire unit. There are no hand washing stations shown, which the codes require, nor is the required flushing rim clinical service sink with bed pan flushing device shown in the soiled workroom/utility. There are some other items required for Level II NICUs, which are not indicated on the plans. However, these plans are schematic and some of the missing items will no doubt be included as the design develops.

Although the renovated area has 5,400 square feet, it appears that the Level II suite is less than the maximum of 5,000 square feet. The actual area of the suite needs to be verified to be sure that it meets this size limitation. The unit will be self-contained and will include a family sleep room as well as a breast-feeding room near the entrance from the rest of the hospital. There will be controlled access/egress and delayed panic devices on the stair door at the other end of the unit and presumably on the entrance doors too.

The application includes an existing/demolition plan of the 2nd floor as well as a proposed plan of the NICU in the same location. The existing area to be demolished has 15 semi-private rooms with toilets and showers for each room. This CON is interrelated and contingent on CON #9567 in which the 20 existing beds that will not be converted to NICU beds will become adult psychiatric beds.

The plan shows that the unit has a modified "racetrack" configuration with the nurse station making up the central core with a surrounding corridor and patient and ancillary spaces located on the outside walls. Clearances between neonatal stations meet the code requirements and the necessary exits have been provided.

The design professionals that prepared the architectural plans have extensive health care experience. There is a list of applicable codes that is mostly correct.

The costs and the schedule appear reasonable for this scope of renovation.

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 states that it provides a significant amount of charity care and Medicaid days, and proposes conditions of a minimum of 20 percent of the Level II NICU patient days will be provided to Medicaid patients and a minimum of one (1) percent of the Level II NICU patient days will be provided to charity care patients. The applicant presented a table depicting the hospital's provision from 1999 through 2001:

Historical Provision of Medicaid and Charity Care
Kendall Medical Center
1999-2001

Factor	1999	2000	2001
Medicare Patient Days	27,507	25,181	28,267
Percent of Total Patient Days	**40.89%**	**38.00%**	**39.10%**
Medicaid Patient Days	6,743	7,960	8,712
Percent of Total Patient Days	**10.02%**	**12.01%**	**12.05%**
Self Pay/Charity Patient Days	4,425	2,979	3,593
Percent of Total Patient Days	**6.58%**	**4.5%**	**4.97%**
Total Days	67,273	66,267	72,296

Source: CON Application 9566

The application also contains the projected payer distribution in the second year of operation of the proposed 10-bed Level II NICU:

Payer Distribution in the Level II NICU by Category
Second Year of Operation

Payer Category	Estimated Allocation of Cases, 10 Beds	Estimated Allocation of Patient Days, 10 Beds	% of the Allocation of Cases, 10 Beds
Charity	2.2	28	0.99%
Self Pay	6.4	83	2.93%
Medicaid	44.6	579	20.46%
Commercial	18.0	234	8.27%
Managed Care	146.0	1,906	67.35%
Other	0.0	0	0.00%
Total	**217.8**	**2,831**	**100.00%**

Source: CON Application 9566

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	FY 00 Conventional Medicaid Days	FY 00 Gross Charity Percentage of Charges
Kendall Healthcare Group, Ltd.	12.0%	1.9%
District 11 Average	14.1%	6.1%

Source: FY 2000 Actual Data/AHCA

As reflected in the table, Kendall Medical Center's provision of Medicaid and charity care is lower than the District average. Exhibit 2-1 of the application contains the hospital's Charity Care Policy. The applicant is not a designated Medicaid Disproportionate Share Provider.

F. SUMMARY

The applicant proposes to establish a 10-bed Level II NICU through the conversion of 10 acute care beds at Kendall Medical Center .

The proposed project cost is estimated to be $2,008,680 and will involve 5,400 GSF of renovated space and $83,202,720 in construction costs.

Need:
A fixed need pool of zero was published for Level II NICU services in District11. The applicant is applying outside of the fixed need pool and indicates it is applying under hospital-specific special (not normal) circumstances. Need analysis and methodologies presented by the applicant do not demonstrate need for a 10-bed Level II NICU.

Access:
The applicant does not show that there is a problem in the district accessing Level II NICU services.

Quality of Care:
The applicant is JCAHO accredited and a quality care provider.

Medicaid/Indigent Care:
According to the applicant's *Certificate of Need Predicated on Conditions* page, it will set aside a minimum of 20 percent of its Level II NICU patient days to Medicaid patients and a minimum of one (1) percent of its Level II NICU patient days to charity care patients.

Financial/ Cost:
The short-term position of the applicant is mixed and the applicant has a strong long-term position. In consideration of the applicant's cash flows along with the strength and commitment from the parent, the applicant should be able to fund all capital requirements as needed.

The project should have little positive impact on competition to promote quality assurance and cost-effectiveness.

Architectural:
Overall, the proposed project, as submitted, poses several architectural concerns. Primarily, the actual area of the new NICU needs to be verified to confirm that it meets the size limitation for a Level II NICU. Also, there are no hand washing stations shown nor is the required flushing rim clinical service sink with bedpan flushing device shown in the soiled workroom/utility. Some other required items are not indicated on the plans. The proposed project cost and schedule appear reasonable.

The project is interrelated and contingent on pending CON #9567 in which the 20 existing beds that will not be converted to NICU beds will become adult psychiatric beds.

G. RECOMMENDATION

Deny CON #9566.

CON Action Number: 9566

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: ______________________

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Karen Rivera
Health Services and Facilities Consultant Supervisor
Certificate of Need & Financial Analysis

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Jeffrey N. Gregg
Chief, Bureau of Health Facility Regulation