

STATE AGENCY ACTION REPORT
ON APPLICATION FOR CERTIFICATE OF NEED

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

Wellington Regional Medical Center, Inc./CON #9664

2623 Jetton Avenue
Tampa, Florida 33629

Authorized Representative: Thomas A. Davidson
(813) 251-5470

2. Service District/Subdistrict/County

District 9

B. PUBLIC HEARING

A public hearing was requested and held at 9:30 a.m. on April 24, 2003 at the Treasure Coast Health Council Conference Center, 4152 West Blue Heron Boulevard, Riviera Beach, Florida. There was one speaker regarding Wellington Regional Medical Center's proposed project to establish a five-bed Level III NICU. Mr. Michael Glazer, attorney representative for Tenet St. Mary's, Inc., spoke in opposition to Wellington's CON application. A tape of the hearing is enclosed in the file as well as a copy of the exhibits entered into the record at the public hearing. Mr. Glazer stated that need for a new Level III NICU has not been demonstrated nor did Wellington's application provide any documentation demonstrating serious access problems that have affected outcomes or quality of life. Mr. Glazer also pointed out that St. Mary's was approved last year to add 10 Level III NICU beds to its existing 10-bed Level III NICU program. According to Mr. Glazer, the additional beds were intended to serve current and future neonates in the service area that Wellington is proposing and therefore, urges AHCA to deny Wellington's proposed project.

Mr. Glazer offered the following analysis:

- Service Area Overlap

As indicated in Exhibit 1 of Mr. Glazer's of presentation, St. Mary's service area for Level III NICU discharges (DRG's 385-387) includes all of the zip codes proposed in the Wellington application.

- No Need for a New NICU Level III Unit

AHCA has issued a CON to St. Mary's for 10 additional beds for a total future capacity of 20 Level III NICU beds. According to Mr. Glazer, there is no reason for a further proliferation of small Level III NICU programs.

- "Not Normal Circumstance"

Mr. Glazer stated that the "not normal circumstances" identified in Wellington's application are editorial type comments, related to the utilization metrics of the existing NICU beds in the district. None of the circumstances identified by Wellington rise to the level of supporting the approval of new Level III NICU, according to Mr. Glazer.

- Recruitment and Staffing Concerns

Mr. Glazer referred to a recent Administrative Law Judge decision in which three open heart surgery applications in District 9 were denied, in part, because of the nursing shortage. He believes that the number of nurses needed to staff a new open-heart program is analogous to the staffing needs of a new Level III NICU program.

As there were no other speakers on Wellington Regional Medical Center's proposal to establish a five-bed Level III NICU, the public hearing for this project was closed.

The applicant submitted 14 letters of support from area physicians and the community for the proposed project. Letters of support were received from: Janet Wingkun, M.D. (Clinical Medical Director, NICU, Wellington Regional Medical Center); David Kanter, M.D (Corporate Medical Director for the Palm Beach practice of Pediatrix Medical Group); Lerma Te, M.D. (Associate Neonatologist, Wellington Regional Medical Center); Kishore Dass, M.D. (Medical Director of Regional Cancer Center, Wellington Regional Medical Center Board Member); Colette Brown-Graham, M.D., F.A.C.O.G. (Complete Health Care for Women); four letters were received from physicians at OB/GYN Specialist of the Palm Beaches; Jeffrey Bishop, D.O. (Chairman, Board of Directors, Wellington Regional Medical Center); three letters form Wellington Regional Medical Center Board Members; and Thomas M. Wenham, Mayor (Villages of Wellington). Most

of the letters emphasized the population growth in the area and that residents have to travel 16 miles through dense traffic to receive Level III NICU services.

C. PROJECT SUMMARY

Wellington Regional Medical Center, Inc. (CON #9644), a propriety hospital system and wholly owned subsidiary of Universal Health System, Inc., operates Wellington Regional Medical Center, a 108-bed general acute care hospital located in Palm Beach County. The applicant proposes to establish a five-bed Level III Neonatal Intensive Care Unit (NICU) program at Wellington Regional Medical Center (District 9). Wellington is licensed for 104 acute care beds and has CON approval to add 10 Level II NICU beds. The applicant modified the CON to phase-in the 10-bed project and has licensed four of the beds.

According to the applicant's *Conditions* page, it will set aside 19.7 percent of its patient days in the Level III NICU to Medicaid/Medicaid HMO and charity care patients on a combined bases.

The total project cost is estimated at \$854,041. Renovation costs are projected at \$294,000 and the project will involve 1,400 gross square feet (GSF) of renovated space.

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, Jennifer Benghuzzi, 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 29, Number 4, dated January 24, 2003 of the Florida Administrative Weekly, zero need was published for Level III NICU beds in District 9.

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 III neonatal intensive care services 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.

District 9 currently has 30 licensed Level III neonatal intensive care beds and 10 CON approved beds at St. Mary's Medical Center through the delicensure of eight Level III NICU beds at Good Samaritan Medical

Center¹, resulting in a net approval of two Level III beds. The Level III NICU beds in District 9 experienced an average occupancy rate of 72.78 percent during the period July 2001 through June 2002.

c. Other Special Circumstances:

Wellington Regional Medical Center does not have an existing Level III neonatal intensive care unit. The applicant contends that the need for the establishment of a Level III NICU unit is justified based on the following special (not normal) circumstances:

- Under-utilization of Level III NICU services in District 9
- Geographic maldistribution of Level III NICU providers
- Absence of competition in District 9 for Level III services
- Area population growth
- Increased utilization of Wellington's Level II NICU
- Growth of OB programs in the area

The applicant maintains that the continued reflection of eight inactive beds at Good Samaritan Hospital distorts the utilization data for Level III NICU services in District 9 for the specified reporting period. As noted above and in the public hearing section, St. Mary's Medical Center has a CON approved to implement beds not in use at its sister facility. The applicant states that this suppresses the projected need for additional beds and exaggerates the extent of available program resources. The first table illustrates the three-year occupancy of the existing Level III providers. The second table demonstrates what the occupancy rate would have been if the inactive beds at Good Samaritan were not configured into the calculations.

Facility	# of Beds	July 2001-June 2002	# of Beds	July 2000-June 2001	June 1999-June 2000
Good Samaritan	8	0.00%	8	0.00%	4.30%
West Boca Med. Ctr.	9	60.74%	5	76.16%	72.79%
St. Mary's Med. Ctr.	10	132.08%	10	123.64%	117.87%
Bethesda Memorial	3	95.80%	3	82.03%	-----
District Total	30	72.78%	26	71.25%	68.57%

Source: AHCA's publication, *Florida Hospital Beds and Service Utilization by District* for the periods shows.

Facility	# of Beds	July 2001-June 2002	# of Beds	July 2000-June 2001	June 1999-June 2000
West Boca Med. Ctr.	9	60.74%	5	76.16%	72.79%
St. Mary's Med. Ctr.	10	132.08%	10	123.64%	117.87%
Bethesda Memorial	3	95.80%	3	82.03%	-----
District Total	22	97.64%	18	104.8%	102.84%

Source: AHCA's publication, *Florida Hospital Beds and Service Utilization by District* for the periods shows.

¹ Good Samaritan's Level III NICU has been unoccupied for the past three calendar years.

As illustrated in the second table, the utilization rate for District 9's Level III NICUs would have been extremely high had the inactive beds for Good Samaritan been omitted from the calculations. Once St. Mary's Medical Center implements the 10 CON approved beds, however, this utilization is expected to remain below 80 percent, the occupancy standard for NICU services. In its CON Application #9516, St. Mary's showed that it might be able to achieve occupancy of 76 percent in the 10 requested Level III beds by 2004. The planning horizon for this batching cycle for Level III NICU beds is July 2005. It is unlikely that more than the 10 approved beds are needed.

The applicant presented information that indicates it believes that neonates in the district are not receiving needed services. While utilization in St. Mary's Level III NICU is very high (as noted 10 additional Level III beds have been approved for the facility), the applicant did not demonstrate that neonates needing services were denied. Letters of support from physicians do not support this contention either. Rather, letters generally indicate that travel times are difficult for residents who must travel between 16 and 40 miles to obtain services, suggesting that patients are being served, but must travel to obtain those services. For example, the letter from Dr. Janet Wingkun, Clinical Medical Director of Wellington's NICU, indicates that patients are being transferred to St. Mary's and that she believes these services are needed closer to Wellington's patient population. Dr. Wingkun does not indicate that neonates needing care cannot be admitted to St. Mary's because of high occupancy. Neonatal intensive care services are defined as tertiary care services and the travel standard, as discussed below under E. 3. e. below, is that services be available within two hours ground travel time under normal traffic conditions for 90 percent of the population in the service district. The applicant presented no information suggesting this standard was not being met.

The applicant suggests that the geographic location of the growing population in the district presents a special circumstance. The applicant states that Palm Beach County is the largest of the five counties in District 9 with respect to population and live births. In 2001, Palm Beach County accounted for 15,599 of the district's total of 18,868 live births. However, data on the Department of Health's website indicates that Palm Beach County accounted for 13,745 of District 9's total of 18,878 live births. The applicant contends that none of the other counties in the district, with the possible exception of St. Lucie County, generated enough OB volume to support a Level III program. The applicant maintains that there were more live births at Wellington in 2002 than were reported in all of Indian River County, all of Martin County, or all of Okeechobee County. Following is a chart showing data available on the Department of Health's website regarding live births in District 9.

District 9 Live Births 2001	
County	Total Live Births
Indian River	1,124
Okeechobee	562
Martin	1,219
Palm Beach	13,745
St. Lucie	2,228
Total District 9	18,878
Total State	205,800
Source: Department of Health's website	

As the table above illustrates, Palm Beach County's 2001 live births represent 72.81 percent of the live births in the district. It is again noted that St. Mary's has approval to add 10 Level III NICU beds and is located in Palm Beach County.

The applicant feels that since there is a significant and growing population in the western sector of Palm Beach County, clinical and planning reasons justify the development of a Level III NICU in the service area. The applicant provided a table in Exhibit 7 of the application to illustrate growth trends in the volume of births at western county facilities. Population projections indicate that the western sections are expected to contain an increasingly large percentage of the county's total population of women of childbearing ages. The applicant perceives that this shift in obstetrical volume to western county facilities can be expected to continue into the future. The applicant argues that that this demonstrates that there is a significant population in western Palm Beach County that does not enjoy easy access to Level III NICU services. Wellington indicates that improved access to NICU services will enhance the service area's continuum of maternal and child health services because it will reduce travel hardships on infants and parents who require NICU services. However, existing Level III NICU providers are all accessible within the time frame of 120 minutes noted in the Rule.

Neonates requiring Level III NICU services are usually transferred from the hospital of birth to a Level III facility in the area. The applicant feels that this practice results in sub-optimal outcomes and higher neonatal mortality rates. The applicant cited a study that was published in an October 2, 1996 article in *The Journal of the American Medical Association*. The purpose of the study was to examine the effect on neonatal mortality of the level of neonatal services available at the hospital of birth. Among other findings in the study, the author noted:

“Risk-adjusted mortality was lower for infants born in larger (average NICU census >15 patients per day) tertiary centers.” The results of the study also showed that “most of the mortality difference between hospitals with large Level III NICUs and other hospitals persisted when neonatal transports were considered. Thus, maternal referrals or antenatal transfers of the mother, yields lower mortality compared with subsequent neonatal transport.”² The applicant also cited findings from a study published in the May 5, 2002 edition of “*Pediatrics*” which states “Risk adjusted mortality remains significantly lower when high-risk infants are born at a hospital with large regional NICUs (an ADC > 15).

We also show that the level of care that is available at the hospital of birth is much more important to survival than is the level of care ultimately received.”³ However, the minimum unit size for Level III NICU, as discussed below in the agency rule criteria, is 15 beds. The applicant is only proposing to establish a five-bed program. Furthermore, the articles indicate that the advantages gained through the reduction of the transport of low birth weight infants appear to be outweighed by the risks associated with establishing a number of small, non-regionalized neonatal intensive care units.

The applicant maintains that the existing Level III NICU programs in District 9 are overwhelmingly owned and operated by hospitals that belong to a single multi-hospital system. The applicant specifically refers to Tenet owned hospitals, which account for 29 of the district’s 32 licensed or approved Level III NICU beds. The applicant referenced Section 408.035 (9) Florida Statutes, which indicates that applications for CON determinations will be reviewed in context with the extent to which its proposal would foster competition that promotes quality and cost-effectiveness. The applicant contends that the development of a competitive Level III NICU program will advance this criterion. The applicant proposes that its project will foster competition by offering managed care providers additional contracting options, which will impact the cost to consumers accessing care, and by offering choices to consumers and referring physicians. This criterion is addressed below under E. 4. g. The financial reviewer for this project determined that the level of managed care should have some positive impact on competition to promote quality and cost-effectiveness. However, the applicant

² Ciran Phibbs, Janet Bronstein, et.al, “The Effects of Patient Volume and Level of Care at the Hospital of Birth on Neonatal Mortality”. *JAMA*, Vol. 276, Number 13. October 2, 1996, pages 1054-1059.

³ Cifuentes, Javier, M.D., et. al., “Mortality in Low Birth Weight Infants According to the Level of Neonatal Care at Hospital of Birth”. *Pediatrics*, Vol. 109, Number 5, May 2002, pages 745-751.

proposes to establish a small five-bed unit. Therefore, while it might have some positive impact on competition, it is not clear that the unit itself will be very cost-effective even considering benefits gained with the not yet fully implemented 10-bed Level II unit, and as discussed above, there are overriding concerns about quality of care in such a small unit.

The following table illustrates the number of births by zip code for the hospital's primary service area and it also shows the population estimates of females age 15-44.

**Wellington Regional Medical Center Population Growth Trends
OB Primary Service Area**

Zip Code	Births 7/01-6/02	% of Births	Cumulative %	Age 15-44 Female Pop. 2002	Age 15-44 Female Pop. 2007	Percent Increase 2002-2007
33414 West Palm Bch.	148	10.5%	10.5%	8,552	9,193	7.5%
33463 Lake Worth	147	10.4%	20.9%	8,597	9,477	10.2%
33415 West Palm Bch.	139	9.8%	30.7%	8,822	9,296	5.4%
33411 West Palm Bch.	135	9.5%	40.2%	9,181	9,869	7.5%
33467 Lake Worth	125	8.8%	49.1%	6,507	7,216	10.9%
33461 Lake Worth	90	6.4%	55.4%	7,918	8,407	6.2%
33406 West Palm Bch.	74	5.2%	60.7%	5,138	5,253	2.2%
33470 Loxahatchee	55	3.9%	64.6%	4,998	5,873	17.5%
33460 Lake Worth	52	3.7%	68.2%	7,038	7,540	7.1%
33413 West Palm Bch.	49	3.5%	71.7%	2,177	2,389	9.7%
33462 Lake Worth	46	3.3%	75.0%	6,835	7,264	6.3%
33417 West Palm Bch.	45	3.2%	78.1%	4,911	5,195	5.8%
33436 Boynton Bch.	39	2.8%	80.9%	5,313	5,957	12.1%
33409 West Palm Bch.	31	2.2%	83.1%	5,376	5,816	8.2%
33437 Boynton Bch.	30	2.1%	85.2%	4,881	5,642	15.6%
33405 West Palm Bch.	26	2.1%	87.3%	3,966	4,074	2.7%
Subtotal-Wellington OB Primary Service Area	1,234	87.3%	87.3%	100,210	108,461	8.2%
Other Areas	180	12.7%		111,618	115,659	3.6%
Palm Beach County Total	1,414	100.00%		211,828	224,120	5.8%

Source: CON Application (Exhibits 8 and 9) Information Management Systems, Inc. and Claritas.

According to the applicant, the zip codes in Wellington's OB primary service area are expected to experience significant population growth over the next five years in females of childbearing age. Using zip code population projections for females age 15-44, the applicant shows the 2002 population for its primary service area at 100,210 and 2007 projections at 108,461, representing an 8.2 percent increase in this population. The applicant contends that the population projection indicates that the growth in OB utilization in the western sector of Palm

Beach County can be expected to grow more rapidly than in other sections in the county over the next five years. However, documentation presented at the public hearing on April 24, 2003 by Michael Glazer, reveals that St. Mary's Medical Center's service area overlaps these same zip codes. As noted earlier, St. Mary's has 10 CON approved Level III NICU beds.

The applicant claims that the birth volume at Wellington Regional increased from 999 births in the 12-month period ending June 30, 1999 to 1,434 for the 12-month period ending June 30, 2002. While the applicant has experienced growth in its birth volume over the past few years, it should be noted that it does not meet the minimum birth volume requirement of 1,500 live births to establish a Level III NICU as promulgated in the Rule.

The applicant did not demonstrate that there are any special circumstances in the district that warrant the establishment of an additional NICU program in the district. Further, because of the small size of this proposed unit, there are concerns about quality, which the applicant did not address. With the 10-bed approval for additional Level III NICU beds at St. Mary's Medical Center, need based on potential area growth should be addressed and birth volume at the hospital does not suggest hospital-specific need for a program. The applicant did not demonstrate that patients in need of care could not obtain it. Rather, the applicant has stated, through letters of support from physicians on its staff, that neonates needing care are transferred to St. Mary's Medical Center.

2. Local Health Plan Preferences

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

The October 2000 District 9 CON Allocation Factors Report lists the following preferences relevant to CON applications for neonatal intensive care beds:

- a. Priority shall be given to applicants who demonstrate a commitment to or have an historical record of serving Medicaid, charity, indigent and underserved populations.**

The applicant commits 19.7 percent of its patient days in the Level III NICU to Medicaid/Medicaid HMO and charity care patients on a combined basis.

The applicant states that approximately 22.9 percent of its OB patient cases for the 12 months ending June 30, 2002 were either Medicaid or Medicaid HMO and 2.5 percent were self-pay patients. Conversely, approximately 18.7 percent of its Level II NICU patient cases were Medicaid or Medicaid HMO and 2.0 percent were self-pay patients.

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 will set aside 19.7 percent of its patient days in the Level III NICU to Medicaid/Medicaid HMO and charity care patients on a combined basis.

The applicant projects the following payor mix for each of the first two years of operations for its proposed Level III NICU program.

Payor	Percent
Medicaid	16.0%
Medicaid HMO	2.7%
HMO/PPO	78.3%
Self Pay/Charity	2.0%
Charity	1.0%
TOTAL	100.0%

Source: CON #9664 Application.

Refer to E.4.n. 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.**

Wellington Regional Medical Center currently operates four of the 10 Level II NICU beds approved under Final Order of Case No. 00-471, CON #9253, Rendition No. AHCA 00-239-FOF-CON.

- (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 it will provide developmental follow-up through referrals to St. Mary's child development center. Staff at Wellington will assess patients prior to discharge who may require developmental follow-up and make the necessary referrals to St. Mary's program. Information concerning St. Mary's child development center appears in Appendix B of the application.

c. Ch. 59C-1.042(5), Florida Administrative Code - Minimum Unit Size. Hospitals proposing the establish of new Level III neonatal intensive care services shall propose a Level III neonatal intensive care unit of at least 15 beds, and should have 15 or more Level II neonatal intensive care unit beds. A provider shall not normally be approved for Level III neonatal intensive care services only.

The applicant is proposing to establish a five-bed Level III NICU. This proposal does not meet the minimum unit size as specified in this rule preference.

- 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.**

For the period July 2001 through June 2002, the applicant reports 1,434 births at Wellington Regional Medical Center and therefore, does not meet the minimum service volume of 1,500 live births as specified in this rule preference.

- 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 9.

- 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 fetal medical specialist on active staff of the hospital with unlimited staff privileges. Specialty children's hospital are exempt from this provisions**

The applicant states that the medical director of the Level III NICU will be Dr. Janet Wingkun, a board-certified neonatologist-perinatologist. Dr. Shawn G. Lencki will serve as the maternal-fetal specialist for the NICU program. Dr. Lencki is board-certified by the American Board of Obstetrics and Gynecology and in maternal fetal medicine. Their curricula vitas appear in Appendix C.

Schedule 6 does not reflect any physician staffing.

- (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.**

The applicant states that the head nurse for the proposed Level III NICU will be Deborah Johnson, RN. Her curricula vita is provided in Volume II, Appendix C of the application. The applicant contends that all of the proposed nursing staff for the project will be 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 indicates that all nurses assigned to the Level III NICU will be trained and certified in the skills listed above. The applicant also states that its existing Level II nursing staff is already trained in the above listed skills.

- (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 it has at least one certified respiratory care practitioner therapist trained in the care of neonates. The medical center states that it will maintain a ratio of at least one respiratory therapist for every four infants receiving assisted ventilation. Schedule doesn't state how many FTEs are designated for respiratory staff.

- (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.**

The applicant states that it currently provides blood gas determination on a 24-hour basis for its existing acute care facility, and there will be a blood gas analyzer located within the proposed NICU complex.

- (6) **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 provides on-site, on a 24-hour basis, x-ray, obstetric ultrasound, and clinical laboratory services with the ability to perform microstudies. Anesthesia is available in-house 24 hours a day via an on-call system, which ensures coverage during off hours within 30 minutes, according to the applicant.

- (7) **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.**

Wellington has a dietitian or nutritionist to provide information on patient dietary needs and to provide the patient's family instruction or counseling regarding the appropriate nutritional and dietary needs of the patient after discharge. Appendix E of the application provides a copy of the resume of Wendy Missey, dietitian for Wellington Regional.

- (8) **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 maintains a social service department that assists the patient's family in their supportive needs, including identification and referral to needed resources in the community. The applicant also indicates that it participates in the Healthy Start Visiting Program, which provides prenatal nursing visits and healthy visits to postnatal infants.

- (9) 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 will provide in-hospital intervention services for infants identified as being high risk for developmental disabilities to include developmental assessment, intervention, and parental support and education.

- (10) 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.**

The applicant states that it has an interdisciplinary discharge planning process. The personnel responsible for planning a NICU patient's discharge include: neonatologist, NICU nurses, case managers, and a representative from the hearing screening program. Patients with developmental follow-up needs are referred to the early intervention program located on the campus of St. Mary's Medical Center. A copy of the applicant's NICU discharge planning policies and procedures appear in Appendix F of the application.

- g. Ch. 59C-1.042(10) - 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.**

The applicant states that Dr. Harry Bayron, who is a board-certified pediatric cardiologist, will provide pediatric cardiology consultation services.

- (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 that it will maintain a nurse ratio in excess of 1:2 in its proposed Level III NICU at all times. All nurses assigned to the NICU will be registered nurses. However, Schedule 6A does not show the number of registered nurses.

- (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 an alarm to signal loss of vacuum;**
- c. **Twelve electrical outlets;**
- d. **Two oxygen outlets and an equal number of compressed air outlets with adequate provisions for mixing these gases;**
- e. **An incubator and 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 arterial oxygenation in the patient.**

The applicant indicates that its proposed Level III NICU will be in compliance with all of the requirements above. Refer to the architectural review below in E.4.m.

- (4) Equipment Required to be Available to Each Level III Neonatal Intensive Care Unit. Each Level III Neonatal Intensive Care Unit shall be equipped with:**

- a. **An EKG machine with print-out capacity;**
- b. **Portable Suction equipment; and**
- c. **Not less than one ventilator for every three beds.**

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 system, as defined in paragraph (11)(a), shall conform to section 64E-2.003, Florida Administrative Code.**

The applicant participates in Palm Beach County's emergency transportation system. A copy of the transfer agreement with American Medical Response was included in the application, as well as its neonatal transportation policies and procedures.

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.

Wellington Regional Medical Center currently maintains a transfer agreement with St. Mary's Medical Center; a copy of the agreement is included in Appendix H of the application. The applicant maintains that it would not unreasonable withhold consent for transfer arrangements with other area hospitals if its Level III NICU is approved.

- 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, quality of care, efficiency, 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 maintains that there is need for an additional Level III NICU program in the district, as discussed above in E. 1. However, the applicant failed to show that special circumstances exist in District 9 or at Wellington Regional Medical Center to warrant additional services. The applicant indicates that it is seeking to further its ability to serve the patients residing in its immediate area and to expand its pediatric/obstetric program. The applicant expresses concern for transferring neonates to St. Mary's indicating that it believes that the establishment of a Level III NICU program in the western section of the county will diminish the incidence of high-risk deliveries in partial service facilities. However, as discussed in E. 1. c. above, the risks of transfer are generally outweighed by the high mortality rates of neonates treated in a Level III NICU with fewer than 15 beds. According to the results of a NICU study presented in an article submitted by the applicant:

Patient volume and level of NICU care at the hospital of birth both had significant effects on mortality. Compared with hospitals without an NICU, infants born in a hospital with a level III NICU with an average NICU census of at least 15 patients per day had significantly lower risk-adjusted neonatal mortality (odds ratio, 0.62; 95 percent confidence interval, 0.47-0.82; P=.002). Risk-adjusted neonatal mortality for infants born in smaller level III NICUs, and in level II + and Level II NICUs, regardless of size, was not significantly different from hospital without an NICU, and was significantly higher than hospital with a large level III NICU.⁴

⁴ Ciran Phibbs, Janet Bronstein, et.al, "The Effects of Patient Volume and Level of Care at the Hospital of Birth on Neonatal Mortality". *JAMA*, Vol. 276, Number 13. October 2, 1996, pages 1054-1059.

The applicant has not shown that access to NICU services has been denied to area residents. The applicant's number of live births is below the standard promulgated in rule for the establishment of a Level III program. And, as discussed earlier, letters of support indicate that the hospital is transferring high-risk neonates to St. Mary's Medical Center. That hospital, according to testimony presented at the public hearing and discussed earlier, serves the same patient population as the applicant and has been approved to add 10 Level III NICU beds. Therefore, although the applicant's hope is to expand its pediatric/obstetric beds and services to better serve residents in its immediate area, it appears to be at the expense of an existing provider.

St. Mary's Medical Center is one of 11 Regional Prenatal Intensive Care Center's in the state and a high provider of care to the medically indigent. Although the applicant has committed to serve the medically indigent as a condition of award of the CON, the negative impact that this project may have on St. Mary's RPICC program and its ability to provide this tertiary service to the medically indigent outweighs the possibility of closer access to some percent of this population that approval of this application might facilitate. As noted earlier, NICU care is defined as a tertiary service and the travel standard for care is met in the planning area.

In summary: Need for the project is not evidenced by the availability, quality of care, efficiency, accessibility, and extent of utilization of existing health care facilities and health services in the applicant's service area. Further, there is concern that this project might negatively impact an existing high indigent care RPICC provider. Also, that the approval of this small program may increase mortality rates in the area rather than reduce them even though some patients would not need to be transferred.

- 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.**

Wellington Regional Medical Center is accredited by the Joint Commission on the Accreditation of Healthcare Organizations. A copy of the Medical Center Performance Report from the latest JCAHO visit was included in the application. The applicant also states that its current Performance Improvement Plan will be applied to the proposed NICU program. A review of agency records indicates the applicant had four confirmed complaints (one without deficiencies) during the past three years. Two the confirmed complaints were related to the physical plant, one was for life safety code violation, and one complaint for inappropriate discharge.

- 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's 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 applicant is not a statutory teaching hospital, nor is its primary purpose research or physician education as defined in the Florida Statutes. The applicant indicates that its project will affect the clinical needs of health professional training programs in the service area. Wellington operates an Approved Graduate Medical Education Program. It also plans to make its NICU program accessible to nursing and other allied health care training and professional programs offered by local schools and colleges. Also the applicant currently has education and training available for its employees.

- 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, 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:

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	<u>12/31/2001</u>	<u>12/31/2000</u>
Current Assets	\$ 12,758,000	\$ 12,643,000
Cash and Current Investment	\$ 1,268,000	\$ 129,000
Assets Restricted for Capital Projects	\$ 0	\$ 0
Total Assets	\$ 64,186,000	\$ 37,307,000
Current Liabilities	\$ 8,713,000	\$ 6,511,000
Total Liabilities	\$ 75,155,000	\$ 54,206,000
Total Equity	\$ -10,969,000	\$ -16,899,000
Net Operating Revenues	\$ 59,458,000	\$ 53,390,000
Interest Expense	\$ 0	\$ 0
Net Profit - Operations	\$ 3,309,000	\$ 585,000
Net Income	\$ 5,930,000	\$ 1,401,000
Cash Flow from Operations	\$ 6,252,000	\$ 2,980,000
Working Capital	\$ 4,045,000	\$ 6,132,000
Current Ratio (CA/CL)	1.5	1.9
Cash Flow to Current Liabilities (CFO/CL)	0.7	0.5
Long-Term Debt to Equity (TL-CL/TE)	-6.1	-2.8
Times Interest Earned (NPO+Int/Int)	NA	NA
Equity to Total Assets (TE/TA)	-17.1%	-45.3%
Operating Margin (NPO/NOR)	5.6%	1.1%
Total Margin (NI/NOR)	10.0%	2.6%
Return on Assets (NI/TA)	9.2%	3.8%
Operating Cash Flow to Assets (CFO/TA)	9.7%	8.0%

Short-term position:

The applicant's current ratio of 1.5 indicates current assets are one and one half that of short-term liabilities, a fair position. The working capital (current assets less current liabilities) of \$4.0 million is sufficient. The most recent year had an operating profit of \$3.3 million resulting in a margin of 5.6 percent, which is somewhat average for Florida hospitals. The ratio of cash flow to current liabilities of 0.7 is adequate. The applicant has a satisfactory short-term position.

Long-term position:

The long-term debt to equity of -6.1 reflects the negative net worth of the entity, an unsatisfactory position. The cash flow to assets of 9.7 percent is good. The total negative equity of \$(11) million with the equity to assets of -17.1 percent is weak. While the negative equity is a weakness, the fact that it is improving with positive earnings minimizes this concern. The applicant has a mediocre long-term position.

Capital requirements:

Schedule 2 indicates the applicant had \$11.2 million in capital projects planned or underway. All long-term debt is due to the parent company with no specified repayment; therefore \$11.2 million is the total funding needed.

Available capital:

Schedule 2 indicates funding for these projects will come from the parent, Universal Health Services. A letter from Universal Health Services, Inc. indicates it is committed to providing the capital required to fund all capital commitments. A copy of the parent's financial statements indicated it had net revenues of \$100 million, cash flows of \$312 million, total assets of \$2.1 billion, and stockholder's equity of \$807 million.

Conclusion:

All capital requirements should be funded 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 was derived from hospitals in peer groups that reported data in 2001; the applicant was compared to the hospitals in group 3. Per diem rates are expected to increase by an average of 3.6 percent per year. Inflation adjustments were based on the 3rd Quarter 2002 New CMS Hospital Market Basket 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.

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Net revenues per adjusted patient day (NRAPD) of \$1,385 in year one and \$1,439 in year two are similar to the control group median values of \$1,377 in year one and \$1,421 in year two. 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 \$1,226. Inflated forward to year one the NRAPD would be \$1,401.

Anticipated costs per adjusted patient day of \$1,231 in year one and \$1,263 in year two are between the group lowest and median values of \$889 and \$1,321 in year one and \$917 and \$1,363 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 \$1,148 and inflated to year one would be \$1,312.

The year two operating profit for the hospital of \$12 million computes to an operating margin per adjusted patient day of \$175 which is between the peer group median and highest of \$40 and \$378. The operating margin computes to 12.2 percent, which is very high for Florida hospitals. The 2001 financial data submitted to the agency shows the hospital with an operating margin of \$3.3 million. This project is expected to contribute \$356,303 to the operating margin.

The projected revenue and expenses fall within an acceptable range when compared to the group and are similar to its own historical amounts inflated forward. The projected profits seem overly optimistic when compared to the historical activity of the hospital. It is probable the profits may not reach the level anticipated, but either way, the projections are considered financially feasible.

COMPARATIVE TABLE

CON # 9664					
Wellington 2001 DATA Peer Group 3	2006	YEAR 2	<u>INFLATION ADJ. VALUES</u>		
	YEAR 2	ACTIVITY	Highest	Median	Lowest
	ACTIVITY	PER DAY			
ROUTINE SERVICES	184,949,663	2,691	1,632	667	356
INPATIENT AMBULATORY	0	0	237	69	7
INPATIENT ANCILLARY SERVICES	0	0	4,159	2,325	1,024
OUTPATIENT SERVICES	141,082,899	2,053	2,942	1,722	399
OTHER OPERATING REVENUE	376,747	5	42	8	0
TOTAL REVENUE	326,409,309	4,750	7,222	4,780	2,299
DEDUCTIONS FROM REVENUE	227,555,355	3,312	*	*	*
NET REVENUES	98,853,954	1,439	3,089	1,421	905
EXPENSES					
ROUTINE	16,426,265	239	336	227	137
ANCILLARY	37,030,784	539	741	413	182
AMBULATORY	4,261,823				
OVERHEAD	29,089,783	423	1,402	646	477
OTHER	0	0			
TOTAL EXPENSES	86,808,655	1,263	2,504	1,363	917
OPERATING INCOME	12,045,299	175	378	40	-458
		12.2%			
PATIENT DAYS	38,936		NOT INFLATION ADJUSTED		
ADJUSTED PATIENT DAYS	68,716				
TOTAL BED DAYS AVAILABLE	45,990				
ADJ. FACTOR	0.5666				
TOTAL NUMBER OF BEDS	126				
PERCENT OCCUPANCY	84.7%		87.5%	53.9%	27.6%
<u>PAYER TYPE</u>					
	PATIENT DAYS	% TOTAL			
MEDICARE	8,432	21.7%	64.6%	34.9%	12.8%
COMMERCIAL	0	0.0%			
MEDICAID	2,882	7.4%	29.3%	12.2%	2.8%
PRIVATE	843	2.2%			
HMO/PPO	26,710	68.6%	65.4%	39.2%	5.0%
OTHER	67	0.2%			
TOTAL	38,934	100.0%			

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

The applicant forecasts managed care to represent 68.6 percent of its patient days. This is above the control group's highest level of 65.4 percent and is above the hospital's own 2001 managed care level of 62.2 percent. The level of managed care will exert positive pressure on competition.

The proposed NICU III project was compared to all other hospitals in the state with approved NICU III programs. Schedule 7, total gross revenue for the project only is projected to be \$6,094,567 for year two. With 1,298 patient days anticipated the gross revenue (gross charges) per patient day computes to \$4,695. This amount is between the median and highest of \$3,136 and \$6,383 respectively. With the NICU III charges between the median and highest, competitive impact will be minimized.

The project should have some 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? ss. 408.035(10), Florida Statutes; Ch. 59A-3 or 59A-4, Florida Administrative Code.

The applicant proposes to add five new Level III NICU beds in space currently occupied by five LDRP rooms. These new beds are intended to augment the existing Level II beds at the facility.

The design professional that prepared the plans included in the application is not based in Florida, although the architectural firm has extensive experience with health care facilities. The application included a letter from the architect stating that their plan layout met certain specific Florida Building Code criteria. Additionally, there were copies of three pages from Chapter 419 of that code attached.

However, the design professional must not be aware that the Guidelines For Design And Construction Of Hospitals And Health Care Facilities published by the American Institute of Architects will soon be incorporated by reference in the codes governing construction of new health care facilities in Florida. The new codes are expected to be adopted by July of 2003 and this will be before this project could be submitted to the AHCA Office of Plans and Construction for review.

Section 7.3.E: Newborn Intensive Care Units of the Guidelines has many requirements for spaces that must be integrated in the unit or available nearby. In some cases, minimum square footages have been reduced, enlarged, or deleted so that some spaces must only be adequately sized for the particular use in the facility.

One of the most significant changes is the required square footage for each NICU bed. The new codes will require 120 square feet per bed and not the 80 square feet currently required by the Florida Building Code. This is the size that the proposed plan provides, and will not be acceptable under the new codes. Additionally, there will be a requirement that every NICU bed position be within 20 feet of a hands-free hand washing station. The plan does not appear to meet this requirement.

Apparently it is intended that the new Level III unit share some of the ancillary spaces in the adjacent Level II unit. These spaces may not be adequately sized to serve both units, and in some cases are on the borderline of being too remote from the Level III NICU. The proximity of spaces to each other is not always addressed in the codes, but left to good judgment of the facility and its design professional. The facility should review these size and location issues to determine that the spaces will serve their needs if this has not already been considered.

The application included an existing plan and three other plans at varying scales showing the neonatal areas. None of these plans appeared to be exactly to scale, and the largest plan seemed to be at 1/4" scale even though it was labeled as being 1/8" scale. This is a minor point but it does make verifying the room sizes and clearances difficult.

In view of the fact that the plans, as presented, are so far from being compliant with the codes under which this project would be reviewed, any further review of costs and time schedules at this stage would not be meaningful. It may not actually be possible to add the proposed five new beds to the facility if the LDRP space shown is the only space available for renovation. In short, the schematic plans need to be thoroughly revised to comply with the requirements of the new codes.

It is required that schematic drawings be submitted as part of the CON application. Although the drawings for this proposal may be more advanced than required, they have been reviewed as schematics with the expectation that they will necessarily be revised and refined during the design development (preliminary) and contract document stages. The architectural review of the application shall not be construed as an in-depth effort to determine complete compliance with all applicable codes and standards. The final responsibility for facility compliance ultimately rests with the owner.

- 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 following table provides an indication of the applicant's commitment to charity and Medicaid, with comparison to the district, based on Fiscal Year (FY) 2001 Actual Data prepared by AHCA.

**Medicaid and Charity Care Commitment
For Wellington Regional Medical Center
Compared to the District**

	FY 2001 Conventional Medicaid Days	FY 2001 Gross Charity Days Percentage
Wellington Regional	7.1%	2.2%
District 9 Average	12.9%	3.1%

Source: FY 2001 Actual Data/AHCA

Wellington's provision of both Medicaid and charity care is below the District average. The applicant is not a designated Medicaid Disproportionate Share Provider for FY 2002-2003. The applicant proposes to condition 19.7 percent of its patient days in the Level III NICU to Medicaid/Medicaid HMO and charity care patients on a combined basis.

F. SUMMARY

Wellington Regional Medical Center, Inc. proposes to establish a five-bed Level III Neonatal Intensive Care Unit to be located at Wellington Regional Medical Center (District 9).

The total project cost is estimated at \$854,041. Renovation costs are projected at \$294,000 and the project will involve 1,400 gross square feet (GSF) of renovated space.

Need:

A fixed need pool of zero was published for Level III NICU services in District 9. The applicant is applying outside of the fixed need pool and indicates it is applying under hospital-specific special (not normal) circumstances. However, no special or hospital-specific circumstances were provided that demonstrate need for an additional Level III NICU program or five additional Level III NICU beds in the district.

Access:

The applicant does not show that there is a problem in the district accessing Level III NICU services. Further, there is concern that this project might negatively impact an existing high indigent care RPICC provider and that the approval of this small program may increase mortality rates in the area rather than reduce them even though some patients would not need to be transferred.

Quality of Care:

The applicant is JCAHO accredited and a quality care provider. However, there is concern over the quality of care that might be provided in this five-bed Level III unit because of volume levels that staff need to maintain to assure a quality program.

Medicaid/Indigent Care:

According to the applicant's *Conditions* page, it will set aside 19.7 percent of its patient days in the Level III NICU to Medicaid/Medicaid HMO and charity care patients on a combined bases. Although the applicant is willing to condition award to serve the medically indigent population, there is concern that the project will negatively impact an existing RIPCC provider currently serving this same medically indigent population. This project is not likely to increase access to care to the medically indigent population in District 9.

Financial/Cost:

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

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

Architectural:

There are significant architectural concerns involved with the proposed project. The plans, as presented, are so far from being compliant with the codes under which this project would be reviewed that any further review of costs and time schedules at this stage would not be meaningful. The new codes are expected to be adopted by July 2003.

The 80 square feet per bed that the proposed plan provides will not be acceptable under the new codes. Additionally, there will be a requirement that every NICU bed position be within 20 feet of a hands-free hand-washing station. The plan does not appear to meet this requirement. Apparently it is intended that the new Level III unit share some of the ancillary spaces in the adjacent Level II unit. These spaces may not be adequately sized to serve both units, and in some cases are on the borderline of being too remote from the Level III NICU. It may not actually be possible to add the proposed five new beds to the facility if the space shown is the only space available for renovation. The schematic plans need to be thoroughly revised to comply with the requirements of the new codes.

G. RECOMMENDATION:

Deny CON #9664.

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