STATE OF FLORIDA DIVISION OF ADMINISTRATIVE HEARINGS

WELLINGTON REGIONAL MEDICAL)		
CENTER, INC., d/b/a WELLINGTON)		
REGIONAL MEDICAL CENTER,)		
)		
Petitioner,)		
)		
vs.)	Case No. 0	0-0471
)		
AGENCY FOR HEALTH CARE)		
ADMINISTRATION,)		
)		
Respondent.)		
)		

RECOMMENDED ORDER

Pursuant to notice, the Division of Administrative

Hearings, by its duly-designated Administrative Law Judge,

Eleanor M. Hunter, held a formal hearing in the above-styled

case on June 22 and 23, 2000, in Tallahassee, Florida.

APPEARANCES

For Petitioner: Robert D. Newell, Jr., Esquire Newell, Terry & Rigsby, P.A. 817 North Gadsden Street

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For Respondent: Mark S. Thomas, Esquire

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STATEMENT OF THE ISSUE

The issue is whether the Petitioner, Wellington Regional Medical Center, Inc., meets the criteria for approval of CON application number 9253 to convert 16 substance abuse beds to a seven-bed or ten-bed Level II neonatal intensive care unit.

PRELIMINARY STATEMENT

Wellington Regional Medical Center, Inc. (Wellington or WRMC) is the applicant for certificate of need (CON) Number 9253, for authorization to convert 16 substance abuse beds to a ten-bed Level II neonatal intensive care unit (NICU). The application included a partial request to convert 16 substance abuse beds to seven Level II NICU beds. The Agency for Health Care Administration (AHCA) denied the CON application in December 1999. Wellington filed a Petition for Formal Administrative Hearing in January 2000.

Although the hearing was scheduled to last from June 21-23, 2000, after a consolidated case was settled, the hearing did not start until June 22 and was concluded on June 23, 2000.

At the final hearing, Wellington presented the testimony of Kevin DiLallo, an expert in hospital administration;

Karen Wolchuck-Sher, an expert in health planning; and

Thomas Davidson, an expert in health care planning and health care financing. By filing their depositions, Wellington also presented the testimony of William Casale, M.D., an expert in

obstetrics and gynecology; Steven J. Fern, M.D., an expert in obstetrics and gynecology; Lesly Desrouleaux, M.D., an expert in obstetrics and gynecology; and Dave Owens, R.N., an expert of obstetrical nursing. At the final hearing, Wellington's Exhibits numbered 1A-H, 2A-G, 3, 4, and 6 were received into evidence. Wellington's Exhibit 5 for official recognition of SB 591 was received, with reservations, and withdrawn by Wellington after the hearing. WRMC's Notice of Filing Exhibits 8-11 was filed on July 5, 2000, and the exhibits are received in evidence without objections.

AHCA presented the testimony of Karen Rivera, an expert in CON review, and Jeffrey N. Gregg, an expert in health planning.

AHCA's Exhibits numbered 1-4 were received into evidence.

In the Pretrial Stipulation, filed on June 19, 2000, the parties agreed that Florida Administrative Code Rules 59C-1.042(3), (4), (5) - except to the extent that a seven-bed unit would not satisfy the minimum unit size of ten beds, (7), (8) - except to the extent that a medical director and respiratory therapists are not shown on Schedule 6, (9), (11), and (13) are not at issue or have been met by the applicant. The parties also stipulated that Subsections 408.035(1)(a), (c), (g), (h), (i) except to the extent that projected utilization is not achieved; and (j), (l), (m), and (n), Florida Statutes, are not applicable or have been satisfied by the applicant.

Rules 59C-1.042(6) and 59C-1.030(2), Florida Administrative Code, are at issue. Subsections 408.035(1)(b), (d), (e), (f), (i) to extent projected utilization can be achieved, (o), and (2), Florida Statutes, are also at issue in this proceeding.

FINDINGS OF FACT

- 1. The Agency for Health Care Administration (AHCA) administers the certificate of need (CON) program for health care facilities and services in the state of Florida.
- 2. Wellington Regional Medical Center, Inc. (Wellington or WRMC) is a 120-bed community-based hospital, with 104 acute care and 16 substance beds. In September 1999, Wellington applied for CON Number 9253 to convert the 16 substance abuse beds into a ten-bed Level II neonatal intensive care unit (NICU). Currently, Wellington transfers newborns requiring Level II care to St. Mary's Hospital, in West Palm Beach, approximately 45 minutes away. The St. Mary's transport team can arrive as quickly as 20 to 30 minutes, but has taken up to four hours to pick up the babies.
- 3. AHCA reviewed and denied Wellington's application, based on an absence of need in District 9 under criteria applicable to both normal and not normal circumstances, and the absence of any demonstrated problems for patients in getting access to Level II NICU care. For the January 2002 planning horizon used for applications which were, like Wellington's,

filed in September 1999, AHCA published a numerical need for zero additional Level II NICU beds in AHCA District 9. The methodology used by AHCA to calculate numeric need, factoring in the existing inventory of 70 licensed and 20 approved beds, and applying the objective for 80 percent district-wide occupancy, resulted in a numeric need for a negative 32 beds. In other words, in District 9, there is a surplus of 32 Level II NICU beds, based on the formula established in AHCA's rules. The NICU II occupancy rate for 1998 was approximately 66 percent in District 9.

4. In the absence of numerical need, Wellington applied for CON approval based on not normal circumstances, and contends it met, on balance, the requirements of the applicable criteria.

59C-1.042(6) - birth volume

5. In Rule 59C-1.042(6), Florida Administrative Code, a not normal circumstance based on minimum birth volume is set forth, in pertinent part, as follows:

Hospitals applying for Level II neonatal intensive care services shall not normally be approved unless the hospital had a minimum service volume of 1,000 live births for the most recent 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the fixed need pool.

- 6. For this application cycle, the fixed need pool was published in July 1999; therefore, calendar year 1998 is the time period for determining birth volume.
- 7. In 1998, there were 909 live births at Wellington. In 1999, live births at Wellington increased to 1,101, and, in the 12 months prior to the hearing, to 1,152. AHCA permits applicants to use the most recent data in cases involving not normal circumstances. Currently, approximately 100 live births a month occur at Wellington, which justifies the projection of 1,238 total live births for the year 2000.
- 8. The current level of live births achieved at Wellington, over 1,000, is equaled or exceeded at fewer than 70 of over 200 hospitals in Florida. For the period ending June 30, 1999, 53 of the 70 hospitals also exceeded 1,200 live births. Of the 53 hospitals with over 1,200 live births annually, 48 had Level II NICUs. Six hospitals in Florida range between 1,200 and 1,499 live births a year; five have Level II NICU.

59C-1.042(5) - minimum ten-bed unit size

9. AHCA's CON reviewer testified that she believed that AHCA had only deviated from the ten-bed minimum unit once, for CON Number 9243 to North Collier Hospital, a Medicaid disproportionate share hospital with over 2,000 live births. She also testified that, even though the applicant showed the

required occupancy level in fewer than ten beds, CON approval for a ten-bed unit was awarded to Boca Raton Community Hospital (Boca Raton), in part, based on its large number of live births. By contrast, according to the chart on page 19 in AHCA's Exhibit 2, four of the seven Level II NICU providers in District 9 operated fewer than 10 beds at the time Wellington's application was approved. Apparently, unlike in the case of the Boca Raton application, AHCA held Wellington to the requirement of showing that it could reach 80 percent occupancy in the beds, although AHCA's expert health planner testified that the standard was a "benchmark," not an absolute bar to approval.

10. In general, 1.1 Level II NICU patient days result from each live birth. The ratio of 1.1 to 1, when applied to 80 percent occupancy in a ten-bed unit, results in a mathematical necessity for 2,920 patient days a year, or a project volume of at least 2,654 live births a year. The use of the 80 percent district-wide occupancy standard for normal circumstances as a facility-specific standard for not normal circumstances is unreasonable and conflicts with the minimum volume requirement of 1,000 live births in Rule 59C-1.042(6). AHCA's application of the 80 percent occupancy requirement to Wellington is inappropriate and inconsistent with the agency's prior action. For example, in this case, arguably the failure to meet the normal standard for district occupancy might justify

requiring a higher than normal facility standard, but AHCA has not done so with any apparent consistency. Only four out of 57 Level II providers in Florida exceed 2,654, the number of live births necessary to achieve the equivalent of 80 percent occupancy in a ten-bed NICU, three of those exceed 3,000 live births a year, and the fourth is in the range between 2,500 to 2,999 live births a year. Applying the 80 percent test with a 1.1 to 1 ratio to project Level II patient days, the six most recently approved Level II NICU applicants fall short, with projected occupancies ranging from 30 to 40 percent.

59C-1.042(8) - quality of care staffing standards

11. Wellington provides obstetrical services in its

Department of Maternal Health, also called the Center for Family
Beginnings. Seven dedicated beds are used for labor, delivery,
recovery, and postpartum care in that Department, with the
frequent need to use overflow beds. Despite the screening of
mothers prior to delivery to eliminate those whose babies are
likely to need Level II or higher care, at least 25 percent of
all expected normal deliveries develop into high risk problems.
Wellington is already equipped to handle these unexpected, high
risk babies, as it must do prior to transferring them.
Wellington also provides follow-up care to high risk babies as a
result of their agreement with St. Mary's to allow "back
transferring" of stabilized babies.

- 12. Wellington has a neonatologist-perinatologist on call 24 hours a day. It has neonatal intensive care nurses with Level II and Level III experience on staff 24 hours a day.
- 13. AHCA questioned the adequacy of the staffing proposed in the CON application because a medical director and respiratory therapists are not explicitly listed on Schedule 6. The medical director will be the same neonatologist-perinatologist who is currently on staff and who will continue to receive professional fees for services, but will not be a hospital employee. That arrangement is explained in the notes to Schedule 6. Similarly, the category "Other Ancillary," Wellington explained in the assumptions to Schedule 6, includes two full-time equivalent staff positions for respiratory therapists.
- 14. Wellington has on staff two perinatologists, who are doctors specializing in high risk maternal-fetal medical care.

 One of them moved to Wellington when another NICU program in the County was closed. See Findings of Fact 26.

59C-1.030(2) - health care access criteria

15. Rule 59C-1.030(2), Florida Administrative Code, requires consideration of criteria related to the need for the services proposed and the expected accessibility of the services for residents of the district. The criteria largely overlap with those in Subsections 408.035(1)(b), (d), and (f), and (2),

Florida Statutes, which are also related to need and access. See Findings of Fact 20-25 below.

- 16. In addition to more general need and access issues, the rule requires considerations of access for low income, minorities, and other medically underserved patients, including those receiving Federal financial assistance, Medicare, Medicaid, and indigent persons. The parties stipulated that related criteria in Subsection 408.035(1)(n) - evaluating the applicant's past and proposed Medicaid service - is met or not at issue, based on Wellington's commitment to provide 30 percent Medicaid in the NICU, and historical provision of 32.4 percent Medicaid in the obstetrics unit. By stipulating that the criteria are not at issue or are met in Subsection 408.035(1)(a) - need related to district health plan - the parties necessarily agreed that the local health plan requirement for a commitment to provide at least 30 percent Medicaid/Indigent patient days was met, and so, therefore, is the income accessibility concern of the Rule.
- 17. Wellington addressed the Rule criterion for minority access to NICU services. The only Haitian doctor specializing in obstetrics and gynecology (OB/GYN) in Palm Beach County, who speaks fluent Spanish as well as Creole, delivers 99 percent of his patients' babies at Wellington. From 60 to 80 percent of

his patients come from Lake Worth, most of whom are Haitians and Hispanics, including Gualemalans and Mexicans.

- 18. Another OB/GYN group of four doctors, with privileges at four different hospitals, delivers 30 to 40 babies a month at Wellington, based on their preference for the care provided at Wellington.
- 19. The only OB/GYN group in Palm Beach County, which has two affiliated perinatologists, both of whom are on staff at Wellington, serves large numbers of patients from Clewiston, Belle Glade, Pahokee, and Okeechobee. These areas are low income, farming communities located, in driving time, from 45 minutes to 1 1/2 hours west of Wellington. Even when predicted to have high risk births, mothers from the low income areas who are told to go to St. Mary's Hospital because it has a Level II NICU are approximately 70 percent non-compliant. St. Mary's is an additional 45-minute drive east of Wellington.
 - 408.035(1)(b) availability, quality of care, efficiency, appropriateness, accessibility, extent of utilization, and adequacy of like and existing facilities and services;
 (d) availability and adequacy of alternatives, such as outpatient or home care; (e) economics of joint, cooperative, or shared resources; (f) need for services not reasonably and economically accessible in adjoining areas; and
 - 408.035(2)(a), (b) and (c) less costly, more efficient or more appropriate alternatives, such as existing inpatient facilities, sharing arrangements; and (d) serious problems for patients to obtain care without proposed service.

- 20. In addition to the absence of numeric need under normal circumstances, and the absence of the requisite birth volume which results from the imposition of the district occupancy standard to the hospital, AHCA also determined that Wellington failed to show any problems with patient access to like and existing facilities.
- 21. Currently, there are 70 licensed and 20 approved Level II NICU beds in District 9. Overall, the occupancy rate for the District is approximately 66 percent. In addition, existing Level II NICU providers are located within two hours driving time for all residents of the district, as required for NICU which is classified as a tertiary service.
- 22. Seven hospitals in District 9 provided Level II NICU care in 1998 to 1999. These included Lawnwood Regional Medical Center (Lawnwood) in St. Lucie County, Martin Memorial Medical Center (Martin Memorial) in Martin County, and Palm Beach Gardens Medical Center (Palm Beach Gardens) in Palm Beach County, West Boca Raton Hospital (West Boca), St. Mary's Hospital (St. Mary's), Good Samaritan Hospital (Good Samaritan), and Bethesda Memorial Hospital (Bethesda). In addition to the licensed beds, 20 approved beds had been allocated as follows: four for Good Samaritan, ten for Boca Raton Community Hospital, and six for West Boca.

- 23. All of the existing Level II providers are located in eastern Palm Beach County along the Interstate 95 corridor. The population of Palm Beach County is migrating west.
- 24. The Wellington community is experiencing significant growth. One indication is approval for the opening of five new schools in Wellington, three elementary, one middle, and a high school approximately 3 miles from the hospital. The number of new residential housing starts in Wellington has increased from 4,332 in 1990 to 6,012 in 1999. The housing starts in Wellington's primary service area represent over 48 percent of the total for Palm Beach County. Approximately 35,000 of the 80,000 women in Palm Beach County aged 35 to 44, who are more likely to have high risk pregnancies, live in the Wellington service area.
- 25. Births at the three obstetrics providers in western
 Palm Beach County have increased from 1,441 in 1995 to 2,580 in
 1999, including an approximately 200 percent increase at
 Wellington, from 345 in 1995 to 1,057 in 1999 (for the 12 months ending in August).
- 26. Prior to October 1, 1999, the two closest hospitals to Wellington with Level II NICU services were Good Samaritan, with seven existing and four approved beds, and St. Mary's, with 22 beds. After Good Samaritan closed its obstetrics and NICU services, the two closest Level II NICU providers to Wellington

are St. Mary's and West Boca, with nine licensed and six approved beds. For the 12-month period from July 1998 to June 1999, there were 3,832 NICU II patient days, or 149.98 percent occupancy in the seven operational beds at Good Samaritan; 5,743 patient days, or 71.52 percent in 22 beds at St. Mary's; and 3,210 patient days or 97.72 percent in the nine licensed beds at West Boca. With the closing of Good Samaritan, patients who were using its seven beds were assumed mostly likely to go to St. Mary's, which is owned by the same parent company. AHCA calculated a blended occupancy rate of 84.05 percent for St. Mary's with the addition of nine Good Samaritan beds (seven operational and two of four approved) to its existing 22 beds.

27. Despite the high occupancy in the nearest facilities, the others in the District were relatively low for the same period of time: 39.15 percent in ten Level II NICU beds at Lawnwood, 8.38 percent in five beds at Martin Memorial, 19.23 percent in five beds at Palm Beach Gardens, and 50.46 percent in 12 beds at Bethesda.

(i) - immediate or long-term financial feasibility, as related to utilization

28. AHCA rejected Wellington's projection of the volume of babies it would receive as Level II transfers from Glades

General Hospital and Palms West Hospital. For the year ending

August 1999, there were 737 live births at Glades General and

786 at Palms West. From that, Wellington projected 797 births at Glades General and 850 at Palms West in 2002. From that, Wellington expects to receive 231 transfers from Glades General and 197 from Palms West. The projections are based on historical birth to patient day ratios for the County, reasonable projections of volume, and reasonable market share assumptions.

- 29. AHCA accepted Wellington's projections of its internal birth volume, which was 1,714 live births by January 31, 2000, resulting in a range between 1,192 and 1,834 Level II days.

 Based on the reasonableness of the expected transfers and the undisputed reasonableness of internal birth projections,

 Wellington demonstrated that it will achieve 73.5 percent occupancy in a ten-bed unit, or 75.2 percent in a seven-bed unit, by January 2003.
- 30. As a result of reasonable utilization projections, as otherwise stipulated by the parties, the project is financially feasible.

Factual Summary

31. In general, Wellington demonstrated that the number of live births at Wellington, the closing of the nearest Level II provider, occupancy levels at nearby providers, the distances to other existing providers, particularly from various western areas of its service area, and the demographic and growth

patterns within the County are not normal circumstances for the approval of its proposal.

32. On balance, Wellington meets the criteria for approval for approval of CON Number 9253, to convert 16 substance abuse beds to a ten-bed Level II NICU.

CONCLUSIONS OF LAW

- 33. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of these proceedings. Sections 120.569, 120.57(1), and 120.60(5), Florida Statutes.
- 34. CON applicants have the burden of proving that their applications meet the statutory and rule criteria for approval.

 Boca Raton Artificial Kidney v. Department of Health and Rehabilitative Services, 475 So. 2d 260 (Fla. 1st DCA 1985).

 The award of a CON must be based upon a balanced consideration of the criteria. Department of Health and Rehabilitative

 Services v. Johnson Home Health Care, Inc., 447 So. 2d 361 (Fla. 1st DCA 1984); Balsam v. Department of Health and Rehabilitative

 Services, 486 So. 2d 1341 (Fla. 1st DCA 1988).
- 35. Due to the absence of numeric need under Rule 59C1.042, Florida Administrative Code, Wellington must demonstrate
 "not normal circumstances" for the approval of its CON
 application.

- 36. Wellington demonstrated not normal circumstances, as follows:
 - (a) The closing of the nearest Level II NICU which was experiencing 149 percent occupancy;
 - (b) the distance to the closest remaining provider, St. Mary's, particularly from western portions of the service area and its expected blended occupancy rate of over 80 percent occupancy;
 - (c) the poverty levels and rate of noncompliance for patients referred to St.
 Mary's from the western area communities;
 - (d) the substantial growth in population, the demographics, and the increase in births in western Palm Beach County hospitals, especially at Wellington; and
 - (e) the movement of specialists in obstetrics, neonatology and perinatology into the Wellington service area as result of the closing of Good Samaritan's program and the migration of the population.
- 37. In addition to establishing not normal circumstances, Wellington met the criteria for quality of care by proposing appropriate adequate staffing, as required by Rule 59C-1.042(8), Florida Administrative Code.
- 38. Existing providers which are geographically accessible from the community around Wellington are over-utilized. They are geographically inaccessible to the medically indigent and traditionally underserved, low income, minorities in the western areas of the Wellington service area. Section 408.035(1)(b) and

- 408.035(2)(a), (b), and (d), Florida Statutes; and Rule 59C-1.030(2), Florida Administrative Code.
- 39. There is no evidence that alternatives to inpatient Level II NICU care are available. Section 408.035(1)(d), Florida Statutes.
- 40. There is no evidence of possible improvements in service, from any available operation or modernization of joint or shared health care resources. AHCA alluded to St. Mary's and Good Samaritan as a consolidated alternative, but their high blended occupancy rate does not indicate much available capacity. Section 408.035(1)(e) and (2)(c), Florida Statutes.
- 41. There is no evidence of any special equipment or services that are economically accessible in adjoining districts that meet the Level II NICU services proposed. Section 408.035(1)(f), Florida Statutes.
- 42. Wellington's proposal is financially feasible, based on the reasonableness of its projected utilization in a ten-bed unit. Subsection 408.035(1)(i), Florida Statutes; and Rule 59C-1.042(5), Florida Administrative Code. The evidence did not indicate that the project enhances the continuum of care in a multilevel health care system. Subsection 408.035(1)(o), Florida Statutes. Having demonstrated not normal circumstances, by either stipulation or based on the evidence, Wellington met all of the criteria for issuance of the CON for a ten-bed Level

II NICU, except for not enhancing care within multilevel health care system. Therefore, on balance, Wellington demonstrated entitlement to CON Number 9253.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is

RECOMMENDED that the Agency for Health Care Administration enter a final order issuing Certificate of Need Number 9253 to Wellington Regional Medical Center, Inc., to convert 16 substance abuse beds to 10 Level II neonatal intensive care beds.

DONE AND ENTERED this <u>25th</u> day of August, 2000, in Tallahassee, Leon County, Florida.

ELEANOR M. HUNTER
Administrative Law Judge
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Filed with the Clerk of the Division of Administrative Hearings this <u>25th</u> day of August, 2000.

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.