

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

BETHESDA MEMORIAL HOSPITAL, INC.,)
)
 Petitioner,)
)
 vs.) Case No. 96-1029
)
 AGENCY FOR HEALTH CARE)
 ADMINISTRATION,)
)
 Respondent.)
 _____)

RECOMMENDED ORDER

Pursuant to notice, a formal hearing was held in this case on November 19 through 21, 1997, in Tallahassee, Florida, before J. D. Parrish, a designated Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Kenneth F. Hoffman, Esquire
M. Christopher Bryant, Esquire
Oertel, Hoffman, Fernandez & Cole, P.A.
Post Office Box 6507
Tallahassee, Florida 32314-6507

For Respondent: Richard A. Patterson, Esquire
Agency for Health Care Administration
Fort Knox Building 3
2727 Mahan Drive, Suite 3407B
Tallahassee, Florida 32308-5403

STATEMENT OF THE ISSUES

Whether the Petitioner, Bethesda Memorial Hospital, Inc., (Bethesda) is entitled to a certificate of need (CON) in order to convert three general acute care beds for use as Level III neonatal intensive care unit (NICU) beds.

PRELIMINARY STATEMENT

This case began when Bethesda filed an application with the Agency for Health Care Administration (AHCA or Agency) for a CON to develop a three-bed Level III NICU. This CON was assigned number 8235. The proposed NICU was to be located at Bethesda's existing facility in Palm Beach County, Florida, the Agency's District 9. In its preliminary review of the request, the Agency denied the application, and the instant proceeding ensued as Bethesda timely filed a Petition for Formal Administrative Hearing.

Prior to hearing, the parties filed a Prehearing Stipulation which outlined statutory and rule criteria which the applicant has met, or which are not at issue in this proceeding. More specifically, as stipulated, the following criteria are met, or are not at issue: Section 408.035(1)(a), (c), (e), (f), (g), (h), (i), (j), (k), (m), (n), and (o), Florida Statutes; Section 408.035(2)(c) and (e), Florida Statutes; Rule 59C-1.042(3)(e), (f), (g), (h), and (k), Florida Administrative Code; Rules 59C-1.042(4), (6), (8), (9), (10), (11), (12), and (13), Florida Administrative Code. Accordingly, the findings of fact herein address only those provisions which remain at issue.

At the hearing, the parties offered witnesses and exhibits which are more particularly chronicled in the transcript of these proceedings. Such transcript was filed with the Division of Administrative Hearings on December 15, 1997. By stipulation,

the parties agreed to file their Proposed Recommended Orders by January 14, 1998. Such proposals have been considered in the preparation of this order.

Additionally, Petitioner filed as supplemental authority, a copy of a recent pleading from the appeal of DOAH Case No. 97-1161. Such document was filed on February 13, 1998, and, as it related to the issue of whether the Agency may deviate from its rule-mandated unit size, has been considered in the preparation of this order.

On February 17, 1998, the Florida Statutory Teaching Hospital Council, Public Health Trust of Dade County, Florida, as Jackson Memorial Hospital, Miami Children's Hospital, and All Children's Hospital filed an Amicus Argument in response to the Proposed Recommended Order submitted by Bethesda. Such argument has not been considered. None of the hospitals named therein filed for, nor received, leave to file such Amicus Argument in the instant proceeding.

FINDINGS OF FACT

1. The Agency for Health Care Administration is the state agency charged with the responsibility of reviewing applications such as the one at issue in this proceeding.

2. The parties have stipulated that whether or not the subject application should be approved must be decided upon a weighing and balancing of all pertinent statutory and rule criteria.

3. Bethesda's letter of intent and application for CON were timely filed in an appropriate batching cycle.

4. Bethesda is a 362-bed acute care hospital located in Boynton Beach, Palm Beach County, Florida. As such, it is located within the Agency's District 9.

5. The approval of the CON at issue would allow Bethesda to convert three of its existing acute care beds to Level III NICU beds.

6. This approval would expand Bethesda's existing NICU from 12 beds, which are designated Level II NICU beds, to a total of 15 beds for the combined NICU.

7. Bethesda received a CON for its existing NICU in 1985. From its inception, the unit has been staffed and equipped for the highest level of NICU care and, in fact, performed Level III care until 1995 when the Agency ordered it to stop admitting babies of less than 1000 grams in weight.

8. At the time of the original approval of the Bethesda NICU, the Agency did not distinguish between Level II and Level III NICU beds. Nevertheless, Bethesda staffed and equipped its unit based upon the highest level of care because of the population it has historically served.

9. Later, as the Agency developed more distinct guidelines between Level II and Level III NICU beds (as well as a statewide bed-need methodology), Bethesda found it could not technically

continue to do what it had historically done, i.e., serve a Level III newborn.

10. Bethesda has historically served these Level III newborns because it is under contract with the Palm Beach County Public Health Unit (PHU) to care for indigent mothers and at-risk babies.

11. This agreement to serve indigent mothers and at-risk babies has resulted in a significant number of babies being delivered at Bethesda requiring neonatal intensive care at all levels.

12. Until 1989, Bethesda was the only hospital to provide obstetrical care in the southern portion of Palm Beach County, much less make exceptional provision for indigent birth mothers.

13. As it developed, Bethesda provided quality obstetrical, pediatric, and neonatology services in an area of Palm Beach County where other providers were less than enthusiastic about the market.

14. Except for St. Mary's Hospital in the northern portion of the county, no other provider has extended services to the indigent as demonstrated by Bethesda.

15. Moreover, Bethesda has offered to condition its CON approval on the provision that it render a minimum of 35 percent of the facility's entire NICU patient days, including Level II and Level III, to Medicaid/charity patients. Thus, a major emphasis of this application is care for the indigent.

16. Of all patients cared for in the south Palm Beach County neonatal programs, ninety-nine percent are indigent. While a provider may receive reimbursement for certain services (from Medicaid or local health district funds), the patients themselves (birth mothers and babies) are indigent.

17. Additionally, one-third of the pregnancies processed through the PHU are high-risk due to diabetes, infectious diseases, or other complications.

18. As a logical consequence of the complications with the birth mother, the babies born through the PHU program tend to be sicker than average.

19. While Palm Beach County has demonstrated a remarkable improvement in providing pre-natal care to birth mothers and thereby improving at-risk results, Bethesda continues to play a critical role in extending care to this needy population.

20. Bethesda is the exclusive hospital used by the PHU in south Palm Beach County. It is utilized because it is geographically located near the patient population. Further, Bethesda's reputation in this community makes it attractive to those in need.

21. Bethesda is engaged in a three-way partnership with St. Mary's Hospital and the PHU to lower infant mortality in the county. They have created an integrated care plan for south Palm Beach County maternity patients. Bethesda, physicians in the community (including obstetricians, gynecologists, neonatologists

and pediatricians), and the PHU have worked together for 11 years to make sure that protocols are available so that pre-natal care is available to all who need it. These parties work closely with Healthy Mothers/Healthy Babies and other voluntary organizations to bring patients to the PHU or to Bethesda.

22. The PHU physicians and midwives deliver between 800 and 1,000 babies a year. About 25 percent of these babies from the southern portion of the county will require some kind of Level II or Level III NICU care during their stay in the hospital. Thus, 200 to 250 babies needing NICU care come through the PHU each year.

23. It would also be expected that non-indigent mothers from the southern portion of the county would deliver babies requiring NICU care.

24. Bethesda plans to open outlying health clinics to enhance services offered to local communities within the Bethesda zip codes. These programs or clinics are expected to result in an estimated 20 percent increase in the volume of indigent pregnant women served by Bethesda.

25. The availability of services to the local communities may also assist patients to keep their scheduled appointments. There is a difference between the number of patients scheduled to see PHU physicians and those who actually show up, due to the inconvenience and financial burden of getting to the health unit.

Having the clinic locations readily available may alleviate the inconveniences to the indigent mother.

26. Under the present circumstances, when a Level III baby is delivered at Bethesda it must be transferred to another facility.

27. These transfers create a major burden for the birth mother. Remembering that the mother would not typically be transferred with the child (and would not require the extended stay some neonates demand), the issue of transportation for the parent may be insurmountable.

28. For example, in order to leave a convenient location to visit once or twice a day, an indigent mother must arrange transportation to and from the Level III facility where the baby has been sent. This may entail additional expenses for the parent such as lost wages or extending times for babysitters watching other children in the home. These additional expenses may be more than the indigent family can bear.

29. The nearest Level III NICU provider to whom Bethesda now transfers patients is St. Mary's Hospital. This facility is, by automobile, approximately 30-40 minutes from Bethesda depending on traffic conditions. Bus transportation directly connecting one site to the other, if it were available (which it is not), would presumably take longer.

30. Currently, even when it is determined that a maternity patient should be sent to St. Mary's Hospital for pre-natal care,

the mothers are presenting for delivery at Bethesda. This occurs because Bethesda is geographically located in the area where they live. The baby is born at Bethesda and a decision must be made how best to deal with the health issues of the child.

31. Of the patients referred from Bethesda to St. Mary's Hospital for pre-natal care, only 5 percent deliver at St. Mary's. Ninety-five percent return to Bethesda for delivery even though they were told to go to St. Mary's.

32. The main reason for this failure of patients to follow up at St. Mary's Hospital is the lack of affordable transportation. Many indigent women do not have cars or access to them. The existing facilities in Palm Beach County for Level III care are not reasonably available, appropriate, or accessible alternatives for these patients.

33. AHCA District 9 has only three Level III NICU providers. They are all in Palm Beach County, with St. Mary's Hospital and Good Samaritan Hospital (now owned by the same company) in the northern part of the county (West Palm Beach) and West Boca in the southern part (Boca Raton).

34. West Boca is not a reasonable alternative for the NICU patient population served by Bethesda. West Boca does not serve the lower income patients. In fact, West Boca transfers patients without financial resources to Bethesda. West Boca transfers indigent women in labor early enough so that COBRA regulations are met. Pertinent to this case, historically, West Boca

transferred indigent Level III NICU patients to Bethesda until 1994.

35. During the last three years, Level III NICU utilization at Good Samaritan and St. Mary's Hospital has averaged better than 90 percent. To average 90 percent means that the beds are often full or there are more patients than there are beds. Accordingly, these providers are operating at what is essentially capacity.

36. It is, therefore, not surprising that St. Mary's Hospital supports Bethesda's CON application in this proceeding. No existing provider within District 9, including West Boca, formally opposed the instant application.

37. A primary service area is the area from which a hospital draws the overwhelming majority of its patients for a given service and is defined by zip code level information. The primary service area of Bethesda for providing newborn and neonatal services is wholly within what has been described in this record as the southern portion of Palm Beach County.

38. The primary service areas of West Boca and Bethesda for newborn and neonatal services do not significantly overlap. In fact, 40 percent to 45 percent of these services provided by West Boca have been to residents of Broward County. In this regard, West Boca's neonatal services compete more directly with those of Broward General Hospital than Bethesda.

39. Bethesda's NICU is currently staffed and equipped for

Level III services. From a medical standpoint, the CON proposal will result in a quality 15-bed dual unit, which is very efficient from the neonatologist's standpoint.

40. The neonatologists staffing the Bethesda NICU are associated with the same group serving St. Mary's Hospital and Broward General Hospital, both Regional Perinatal Intensive Care Centers (RPICC). This helps assure proficiency with large volumes at more than one program.

41. The nursing staff at Bethesda all have at least two years of Level III experience, and no nurse is currently hired for the NICU without that level of experience.

42. From a neonatal nursing care standpoint, the addition of the three Level III beds would result in quality, cost-efficient care. The proposed combined unit would allow for flexibility of making daily staff assignments and would enhance care for the babies.

43. The combined 15-bed NICU is large enough to provide quality, cost-effective Level II and III care. Bethesda has the physician staffing, nurse and therapist staffing, equipment, facilities, and hospital services to provide proper quality tertiary care for these newborns.

44. Since 1993, Mease Hospital in Dunedin, Florida, has operated a five-bed Level III NICU combined with a five-bed Level II NICU in one room. It has proven to be a quality program with a low mortality rate. The five-bed Level III NICU provides cost-

efficient care. There is no reason Bethesda cannot duplicate the record Mease has demonstrated.

45. High quality, neonatal intensive care may be easier to achieve with Level II and III beds in the same room than with any other configuration of beds.

46. Bethesda will not be able to treat every sick baby. It cannot care for babies requiring open heart surgery (Bethesda does not have an open heart surgery program), for those needing extra-corporeal membrane oxygenation (ECMO), nor those seeking pediatric cardiac catheterization.

47. None of the three existing Level III facilities in District 9, however, has open heart surgery or ECMO available. Like Bethesda they, too, must transfer out for these services.

48. Fortunately, the Agency rule allows a provider to make written arrangements with other Level III providers to provide those services in the same or nearest service area. AHCA has stipulated that Bethesda has the appropriate written transfer agreements pursuant to Rule 59C-1.042(12), Florida Administrative Code.

49. For the number of babies to be served by Bethesda, the ability to serve Level III babies will improve the quality of care. There are medical risks in transferring babies from one facility to another. When adequate staffing and facilities are available at the hospital of birth, transferring the infant to another provider may pose an unnecessary risk.

50. The risks inherent in transfers do not always outweigh the benefit. For example, transferring the child may delay certain treatments such as use of "surfactants" which protect a baby's lungs. Other risks such as those associated with maintaining the infant's blood pressure or body temperature make transfers difficult and, in some instances, medically questionable.

51. Bethesda's application for the instant CON meets the applicable local and state health plans.

52. Bethesda has an established record of providing quality care and will be well able to provide quality of care for the services allowed by the proposed addition of three Level III NICU beds.

53. It is unrealistic for Bethesda to refuse admission to patients requiring Level III NICU services given the historical and current patterns of births for this District.

54. Bethesda's proposed addition of three Level III beds to its NICU is financially feasible both in the short- and long-term.

55. Bethesda's Level III NICU beds will be programmatically accessible to its patient population.

56. Although 90 percent of the District 9 population is within two hours ground travel time of an existing Level III NICU bed, such accessibility does not consider the unique characteristics of the indigent population the proposed beds at

Bethesda will serve. Moreover, the provider who would otherwise serve the Level III patient under such scenario supports this application.

57. The existing facilities providing care to the indigent population operate at capacity and are fully utilized. The only facility not fully utilized (West Boca) has no significant history of providing care to the Medicaid/indigent population.

58. The proposed construction or renovation of the Bethesda unit to accommodate fifteen NICU stations is reasonable. While Bethesda will have to meet certain minimum licensing standards in the configuration of the NICU, it is anticipated that such standards will be met with little difficulty or significant expense to Bethesda.

59. The unchallenged fixed-need pool for the batching cycle applicable to this case was one Level III bed.

60. Bethesda has met all Agency requirements regarding "Emergency Transportation," "Transfer Agreements," and "Data Reporting Requirements."

61. The Agency's rule regarding minimum unit size for a Level III NICU has not been met. However, this requirement has not been adhered to by the Agency in several instances.

62. In AHCA District 9, there are three hospitals with NICU Level III programs. Not one of these programs has 15 beds. St. Mary's Hospital (a RPICC) has ten beds, Good Samaritan has eight beds, and West Boca has five beds. The quality of care at these

providers is presumably adequate despite the fact that they were approved and licensed by the Agency with less than fifteen beds.

63. Moreover, the Agency has never considered the 15-bed minimum an absolute bar to the application for, or the review of, lesser-numbered beds.

64. In fact, the Agency approved new Level III NICU beds at Mease Hospital (a five-bed unit), West Boca Hospital (a five-bed unit), and Miami Baptist Hospital (a seven-bed unit) after the rule was promulgated. Additionally, the total number of all NICU beds at Mease and West Boca is less than fifteen.

65. Thus, as stipulated in South Miami Hospital, Inc. v. Agency for Health Care Administration, Case No. 97-04875, currently pending before the First District Court of Appeal, the Agency has "consistently interpreted those unit size rule provisions as permissive."

66. Bethesda has presented not normal circumstances supporting this CON application which are hereby accepted. Such circumstances include: accessibility issues for indigent or Medicaid mothers and babies; the lack of Level III beds in the southern portion of the county where 60 percent of all resident live births are delivered; the fact that approximately one-third of the low birth weight mothers reside in the service area for Bethesda yet the majority of the Level III beds are in the northern portion of the county; and the fact that 30 percent of Bethesda's patients are clients from the PHU.

67. The average occupancy rate for Level III NICU beds for the year applicable to this application was 80.9 percent. As a result, the rule mandated minimum average occupancy rate has been met.

CONCLUSIONS OF LAW

68. The Division of Administrative Hearings has jurisdiction over the parties to, and the subject matter of, these proceedings.

69. As the applicant, Bethesda has the burden of proof to establish its entitlement to the CON sought. Boca Raton Artificial Kidney Center, Inc. v. Department of HRS, 475 So. 2d 260 (Fla. 1st DCA 1985).

70. More specifically, as stipulated by the parties, Bethesda must establish, upon a weighing of all applicable and statutory rule criteria, whether its application for a CON to convert three general acute care beds for use as Level III NICU beds should be approved.

71. Having weighed such criteria, it is concluded Bethesda has met its burden.

72. Utilizing the methodology contained in Rule 59C-1.042(3)(e), Florida Administrative Code, there is insufficient numeric need for the proposed beds sought by Bethesda. Under the need methodology, only one Level III bed could be approved.

73. Nevertheless, this applicant has demonstrated not normal circumstances justifying the addition of three Level III NICU beds.

74. The applicant has demonstrated that, when reviewed in the context of availability, quality of care, efficiency, accessibility, past utilization, projected utilization, and the adequacy of other providers to meet the needs for the service district, this proposal will meet the not normal circumstances of this district.

75. Except as to the minimum size of the proposed Level III NICU, this applicant has demonstrated compliance with the applicable statutory or rule criteria. The rule criteria setting forth a minimum size of 15 beds for a new Level III NICU cannot be met.

76. Rule 59C-1.042(5), Florida Administrative Code, provides:

Minimum Unit Size. Hospitals proposing the establishment 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. Hospitals proposing the establishment of new Level II neonatal intensive care services only shall propose a Level II neonatal intensive care unit with a minimum of 10 beds. Hospitals under contract with the Department of HRS' Children's Medical Services Program for the provision of regional perinatal intensive care center or step-down neonatal special care unit care are exempt from these requirements.

77. Notwithstanding the clear language of this rule, the Agency has allowed and granted applications for new Level III NICU beds below the 15-bed minimum size. The instant application must be reviewed in the same context given the Agency's decisions wherein it has granted Level III NICU beds below the minimum size. As such, it must be concluded the Agency has the authority to grant approval of the instant application.

78. Neither Mease Hospital nor West Boca will offer the level of indigent care to which this applicant proposes to be bound. Neither unit had more expertise nor quality of care than that as demonstrated by Bethesda. Neither facility was contractually obligated to provide services through a county-wide network seeking to assure adequate medical accessibility for its residents. Bethesda's application seeks to serve the population needing its services most.

79. NICU services are defined as a tertiary health service. Section 408.032(20), Florida Statutes, provides:

(20) "Tertiary health service" means a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, organ transplantation, specialty burn units, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet

contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health services.

80. In this case, Bethesda has demonstrated there will be sufficient volume and proper expertise to ensure quality of care for the proposed Level III NICU beds. Moreover, the unit size should be sufficient to promote quality care. The combined fifteen-bed unit will perform with enhanced efficiency and scheduling. All NICU babies should benefit from this approach. In this instance, limiting these services to other providers will serve no purpose.

81. Having considered the evidence presented and the argument of counsel, it is concluded Bethesda has demonstrated by a preponderance of the competent, substantial evidence, that the Agency should grant CON application Number 8235 and allow this applicant to convert three general acute care beds to three Level III NICU beds, so that its combined NICU will total 15 beds.

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 approving CON application Number 8235 with the condition that Bethesda provide indigent/Medicaid care as proposed in the application.

DONE AND ENTERED this 24th day of February, 1998, in
Tallahassee, Leon County, Florida.

J. D. PARRISH
Administrative Law Judge
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-3060
(850) 488-9675 SUNCOM 278-9675
Fax Filing (850) 921-6847

Filed with the Clerk of the
Division of Administrative Hearings
this 24th day of February, 1998.

COPIES FURNISHED:

Sam Power, Agency Clerk
Agency for Health Care Administration
Fort Knox Building 3
2727 Mahan Drive, Suite 3431
Tallahassee, Florida 32308-5403

Paul J. Martin, General Counsel
Agency for Health Care Administration
Fort Knox Building 3
2727 Mahan Drive, Suite 3431
Tallahassee, Florida 32308-5403

Richard A. Patterson, Esquire
Agency for Health Care Administration
Fort Knox Building 3
2727 Mahan Drive, Suite 3407B
Tallahassee, Florida 32308-5403

Kenneth F. Hoffman, Esquire
M. Christopher Bryant, Esquire
Oertel, Hoffman, Fernandez & Cole, P.A.
Post Office Box 6507
Tallahassee, Florida 32314-6507

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.