A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

The Nemours Foundation/CON #9939
4600 Touchton Road East
Building 200, Suite 2500
Jacksonville, Florida 32246

Authorized Representative: David J. Bailey, M.D.
(904) 232-4236

2. Service District/Subdistrict/County

District 7

B. PUBLIC HEARING

A public hearing was not held or requested regarding the establishment of a five-bed Level II NICU within a proposed 82-bed Class II children’s hospital in District 7.

The applicant submitted three binders\(^1\) containing approximately 1,000 letters of support for the proposed hospital. These are the same letters submitted for CON numbers 9953 and 9952. Letters were submitted by relatives of former patients, area health care providers, children’s health community organizations, community leaders and Nemours staff. The content of the letters ranged from one sentence expressing general support for the hospital project to detailed stories of a patient’s involvement with the Nemours Foundation in Florida and/or Delaware. A small percentage of letters indicated having to travel to Gainesville, Jacksonville or Miami for specialized care and/or waiting for a hospital bed at existing facilities. It is noted that the applicant expects to provide services from its proposed Orlando area location to children in Escambia County and other areas with further driving distances than those described in these letters of support.

\(^1\) Volumes III, IV and V were each three inches wide, with volumes IV and V containing approximately half of their volume in blank form letter requests.
Fourteen letters of opposition were received regarding the establishment of the three proposed projects: class II children’s hospital, Level II NICU and Level III NICU. Nine of the 14 letters were provided by administrative and clinical staff with Orlando Regional Healthcare, including the women’s and children’s component of Orlando Regional Healthcare, Arnold Palmer Hospital and Winnie Palmer Hospital. The remaining five letters were submitted by the President of Health Central, the Executive Vice President of Health First, the President of Halifax Community Health System and two area physicians. These letters were similar in content and provided the following objections to the projects: impact on Arnold Palmer Hospital; increased health care costs; decrease in health care quality due to reduced volumes; strain on limited staffing resources; duplication of services; pediatric subspecialty care is largely outpatient and Nemours needs no CON approval to expand its outpatient center; the proposed hospital would not provide obstetric or perinatology services, necessitating a separation of mothers from babies; a “stand alone NICU” would require that all patients be transferred in from outlying hospitals, hospitals that already operate NICU units; the target population of the Nemours project is limited; Nemours’ physicians have privileges at area hospitals, already preserving the continuity of care for those patients. Included in this count of fourteen letters is the letter submitted by Karl W. Hodges, VP of Business Development for Orlando Regional Healthcare, who included an update to a study that was provided in opposition to Nemours’ previous submission of these three projects, as well as a memorandum regarding the potential impact of a new pediatric hospital in central Florida. The update quotes from the State Agency Action Report issued for the prior Nemours submission and re-states the conclusions from the initial study, which included the following: negative impact on existing providers; insufficient volume exists to support a high quality program; strain on limited staffing resources.

An additional letter was provided by the Regional Vice President of Florida Hospital, indicating that Florida Hospital did not have the opportunity to review the most recent submission by Nemours before the omissions deadline of October 18, 2006, but that Florida Hospital hopes Nemours has addressed the deficiencies identified during the review of their previous application. The letter specifically indicates that the latest application should establish need for the proposed clinical services, a commitment to providing services that are not already available, a comparison of the services available in Central Florida to those available

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2 The study, “Examination of the Competitiveness and the Levels and Changes in Patient Health Care Revenues and Expenditures Across Florida’s Regional Acute Care Health Markets” by Tim Lynch, PhD, President of Econometrics Consultants, Inc., was commissioned by Arnold Palmer and Orlando Regional Health Care.
in Boston, Cincinnati and Chicago, and further distinction of the proposed care. The letter is referencing “top tier” children’s hospitals that are located in those cities: For 2006, Children’s Hospital Boston is the second ranked children’s hospital in the nation; Children’s Hospital Medical Center – Ohio in Cincinnati is the eighth ranked children’s hospital in the nation; Children’s Memorial Hospital – Chicago is the tenth ranked children’s hospital in the nation. It is noted that none of the hospitals run by the Orlando Regional Healthcare System, Adventist doing business as Florida Hospital, Health Central nor the Nemours-operated Alfred I duPont Hospital in Wilmington, Delaware are among hospitals considered “top tier” in the nation\(^3\). It is further noted that, while some of the top tier hospitals admit expectant mothers, like third ranked Johns Hopkins Hospital in Baltimore, fourth ranked Rainbow Babies and Children’s Hospital Cleveland and sixth ranked New York Presbyterian, the three mentioned by the Regional President of Florida Hospital do not. In each facility’s 2004 fiscal year, all showed zero births according to *U.S. News and World Report*’s website and *U.S. News & World Report*’s listing of services offered by each does not include obstetrical care.

C. **PROJECT SUMMARY**

The Nemours Foundation (CON #9939) is applying to establish a five-bed Level II neonatal intensive care unit (NICU) in District 7. The unit would be located in Orange County within the proposed 82-bed Class II children’s hospital being concurrently reviewed in this batching cycle under CON #9953. The applicant currently operates a children’s hospital in Wilmington, Delaware and four major children’s specialty outpatient centers. One of the outpatient centers is located in Wilmington, Delaware, and the other three are in the Florida cities of Jacksonville, Orlando and Pensacola. The applicant has submitted two additional applications for this batch to establish a class II children’s hospital (CON #9953) and an eight-bed Level III NICU (CON #9952) all at the same proposed Orlando area location.

The applicant agreed to condition an approval of the project to the following 21 provisions:

1. At least 50 percent of total patient days will be Medicaid/Medicaid HMO or patients qualifying for charity care.
2. It will limit the annual amounts it collects from the Medicaid program for hospital-based inpatient services in each fiscal year to the lesser of either the inpatient per diem rate that would be assigned to its hospital by the Florida Medicaid program, or the

average of the Medicaid assigned rates to All Children’s Hospital and Miami Children’s Hospital. It will limit the annual amounts it collects from the Medicaid program for hospital-based outpatient services in each fiscal year to the lesser of either the outpatient per visit rate that would be assigned to its hospital by the Florida Medicaid program, or the average of the Medicaid assigned rates to All Children’s Hospital and Miami Children’s Hospital.

3. Two special programs would be established:
   a. An advisory board with child advocacy organizations; and,
   b. A special relationship with Medicaid to improve access to subspecialty care.

4. At least 50 full-time equivalent sub-specialist physicians will be added on the campus of Nemours’ Orlando Children’s Hospital (NOCH) within five years of opening.

5. The hospital will use computerized physician order entry.

6. There will be one seamless electronic medical record with coordination of care between the inpatient and outpatient environments.

7. Patient centered rooms with video/audio screens will be available for patients and providers, including:
   a. Electronic health records; and
   b. Connection to the internet for patient and family’s use.

8. Surgeons and surgical teams will be trained and certified in minimally invasive techniques.

9. A data warehouse for risk adjustment, long-term analysis and best practice determinations will be created.

10. The hospital will include a simulation laboratory to assist providers with cognitive and procedural skills.

11. An evidence-based clinical practice infrastructure would be created.

12. The internet would be used (kidshealth.org) to provide health education to children.

13. The hospital will use the PEDI-QS, the National Pediatric Quality Assurance System adopted by JCAHO to improve care and cooperate with national organizations.

14. The hospital will be completely wired and set up for monitored rooms to allow for surveillance and assistance in coordination of care.

15. Necessary resources and funding will be provided for:
   a. A community outreach program;
   b. Building strategic alliances in the five-county region;
   c. Developing an educational program for child health promotion among minorities; and
   d. Involving youth in advocacy and peer to peer health promotion.

16. The applicant proposes to secure funding for seven sub-speciality programs.

17. A minimum of $3 million annually will be provided to clinical outcomes/clinical research.
18. Space dedicated to clinical research will be created.
19. A program to transport patients in need of specialized services from other hospitals to NOCH will be provided.
20. A pediatric subspecialty physician group would be employed in the Orlando market.
21. The applicant will subsidize any shortfalls in revenues over expenses.

The total project cost is estimated at $4,951,773 and involves $3,550,400 in construction costs and 7,925 gross square feet (GSF) of new construction.

D. REVIEW PROCEDURE

The evaluation process is structured by the certificate of need review criteria found in Section 408.035, Florida Statutes. These criteria form the basis for the goals of the review process. The goals represent desirable outcomes to be attained by successful applicants who demonstrate an overall compliance with the criteria. Analysis of an applicant’s capability to undertake the proposed project successfully is conducted by assessing the responses provided in the application and independent information gathered by the reviewer.

Applications are analyzed to identify strengths and weaknesses in each proposal. If more than one application is submitted for the same type of project in the same district (subdistrict), applications are comparatively reviewed to determine which applicant best meets the review criteria.

Section 59C-1.010(3)(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 Karen Weaver Webb analyzed the application in its entirety with consultation from the financial analyst John Williamson and the architect Scott Waltz, who evaluated the architectural and the schematic drawings.
E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

The following indicate the level of conformity of the proposed project with the criteria and application content requirements found in Florida Statutes, sections 408.035, and 408.037, and applicable rules of the State of Florida, Chapters 59C-1 and 59C-2, Florida Administrative Code.

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 32, Number 30 of the Florida Administrative Weekly dated July 28, 2006, zero need was published for Level II NICU beds in District 7.

   Section 408.036(3)(l), Florida Statutes allows a hospital that experienced a minimum of 1,500 births during the previous 12-month period to establish a Level II NICU with at least 10 beds outside of comparative review, if the applicant demonstrates that it meets certain requirements for quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation and data reporting found in Agency certificate of need rules for Level II and Level III neonatal intensive care units, as well as if the applicant commits to the provision of services to Medicaid and charity patients at a level equal to or greater than the district average.

   The applicant does not own or operate a hospital in Florida and therefore does not qualify for this CON exemption. The applicant is applying during a batching cycle under special (not normal) circumstances. The applicant contends the primary special circumstance is the need for the Level II NICU services in a comprehensive specialty (Class II) children’s hospital in District 7 in order to offer continuity of services. The applicant contends that the Level II and III NICUs are necessary for the proposed Class II hospital in order to provide care focused on the overall health of the patients, instead of having the proposed hospital provide what the applicant terms ‘episodic’ care.

   The applicant maintains that Level II NICU services in a children’s hospital are different than those provided in a general acute care hospital because the children’s hospital serves as a regional referral center with the capacity to treat complex cases. However, this model of care, the regional referral center, has been used in Florida for a number of years and is still used by the Department of Health, Children’s Medical Services. It has been only recently (July 2004) that the Florida
legislature determined that, although NICU services are still determined
to be tertiary, the number of births at any hospital determines need and
therefore CON review is not required, other than to ensure evidence is
provided by the hospital seeking the CON exemption that it can meet
quality of care standards for NICU services and that it will provide care to
the medically indigent. The applicant has applied to establish a lesser
number (by one-half) of Level II NICU beds than is generally understood
to be needed to accommodate the volume required to ensure quality of
care.

Several recent studies have looked at mortality rates for neonates and at
what constitutes the disparities in care across hospitals. Referral of
neonates to a referral center by hospitals with poor outcomes is
considered one solution. Nemours proposes to become a referral center.
These same studies also indicate certain volumes are needed to be
maintained at these referral centers in order to assure quality care and
improved mortality. For example in 2004, a RAND healthcare
researcher, Jeannette Rogowski, addressed the question of how
accurately patient volume predicts quality of care for very low birth
weight infants and determined that the “Leapfrog Standard” that
recommends infants with an expected birth weight of less than 1,500
grams, a gestational age of less than 32 weeks, or correctable major birth
defects be delivered at a regional NICU that serves an average of 15 or
more patients a day. The study determined that higher volume does
predict a fairly large decrease in mortality and references a chart
published in the Journal of the American Medical Association
illustrating the reduction. The Agency’s minimum unit standard for a Level III NICU
is 15 beds and the standard for a Level II NICU is 10 beds. The applicant
is proposing to establish units of approximately one-half those sizes:
Level III is proposed at eight beds rather than 15, and Level II is
proposed at five beds rather than 10. The applicant states that the

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4. 408.032(17), Florida Statutes “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 services include, but are not limited to, pediatric
cardiac catheterization, pediatric open-heart surgery, organ transplantation, 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.
5. A number of recent studies continue to confirm that volume plays an important role in mortality
rates of neonates.
6. RAND Research “Highlight” summarizing: Rogowski, Jeannette A. Jeffrey D. Horbar, Douglas O.
Staiger, Michael Kenny, Joseph Carpenter, and Jeffrey Geppert, “Indirect Versus Direct Hospital
Quality Indicators for Very Low Birthweight Infants” Journal of the American Medical Association,
7. The “Leapfrog Standard” is published by The Leapfrog Group at www.leapfroggroup.org. The group
was founded by The Business Roundtable with support from The Robert Wood Johnson Foundation.
lesser numbers are proposed because the proposed children’s hospital
would not offer an obstetrical program that would generate larger
volumes of patients, and would not require larger units at the outset.
This statement is problematic in two ways and demonstrates that the
applicant does not intend to provide care that is focused on the overall
health of the patients, as opposed to having the proposed hospital
provide what the applicant terms ‘episodic’ care. The applicant states
that its model of care is integrated and efficient and will eliminate patient
transfers, and so it not only offers something unique to the area, but also
offers a seamless system providing a continuum of care that will replace
what it describes as the current ‘patchwork’ system, providing ‘episodic’
care. The applicant contends that this system is needed from Florida’s
panhandle to the Orlando area; however, as a specialty children’s
hospital, the applicant would not be able to admit expectant mothers,
and therefore, any neonate the proposed facility would admit to its Level
II or III unit would be discharged and transferred from the admitting
hospital, and mother and child would be separated at birth. It is likely
that the applicant does not realistically anticipate transferring a large
number of neonates from Escambia County, for example, to the Orlando
area, and this may be one reason the applicant has not proposed to
establish what health care studies have shown to be an adequate
number of beds to ensure quality of care. The applicant states its
expectation that additional beds would be required in future years.

In addition, a quality of care fact sheet published by the Agency for
Healthcare Research and Quality (AHRQ) states that for low birth weight
neonates, birth in a regional NICU and level of care at the birth hospital
increased survival rate. As noted above, the applicant will not offer
obstetric services, so the patients admitted to this Level II NICU would
have been transferred and would not be able to take advantage of this
increased survival rate. The applicant states that quality of care would
not suffer at the proposed NICU because full-time neonatologists would
be available 24 hours per day, seven days per week, and that the
Nemours Foundation would subsidize the proposed facility and NICU
units to whatever degree necessary to maintain operations. The
applicant appears to contend that its NICU and hospital will employ the
best, and therefore, standards and studies that are applied to other
hospitals should not be applied to this proposal. Specifically, the
applicant appears to contend that volume studies for doctors and
nursing staff would not apply here because the Nemours Foundation will
subsidize the facility. Whether that apparent contention is reasonable
cannot be determined in this review, as the applicant has generally
indicated that its reputation is all that is needed to demonstrate its
ability to provide quality care. While The Nemours Foundation is
recognized as one of the nation’s largest pediatric health care systems

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9 Cifuentes, Bronstein, Phibbs, et al, Pediatrics 109(5):745-751
and has been recognized in Florida for its technological advances in an outpatient setting\textsuperscript{10}, volume studies have not indicated that large national pediatric health care systems should be excluded. It is noted that the applicant also contents this facility will become a “top tier” hospital and bases that contention on its reputation and its electronic medical records system\textsuperscript{11}. The Nemours-operated Alfred I. duPont children’s hospital in Wilmington, Delaware was not named among the top 26 pediatric hospitals in the nation in \textit{U.S. News and World Report’s} 2006 listing of “top tier” hospitals\textsuperscript{12}.

The applicant states that the Regional Perinatal Intensive Care Centers (RPICC) in the service area would not be impacted by the proposed project, since the proposed project would “augment the capabilities” of the RPICCs, by treating a small number of complex cases and then returning the patients to the referring hospital as soon as is medically appropriate. This would mean two transfers of children, the initial discharge and transfer from the birth hospital to Nemours, then a transfer back to the admitting hospital. As noted earlier, the applicant has stated one of the reasons this proposal is needed in the area is that it offers continuous seamless care to pediatric patients within a single system at one hospital.

There are 131 licensed Level II NICU beds in District 7 as of the writing of this report. Arnold Palmer Hospital for Women & Children was approved via notification N0600006 on August 18, 2006 to delicense eight of its existing Level II NICU beds to be re-licensed as Level III NICU beds. No other notifications or exemptions were received by the Agency regarding District 7 NICU beds as of this writing.


\textsuperscript{11}\url{http://www.nemoursmansion.org/internet?url=no/news/releases/2006/061009_comprehensive_pe ds_locations.html}

\textsuperscript{12}\url{http://www.usnews.com/usnews/health/best-hospitals/rankings/specreppedi.htm}
The table above indicates Level II NICU occupancy increasing slightly between 2004 and 2005. Since these percentages were calculated, Arnold Palmer Hospital has added 34 Level II NICU beds and Osceola Regional Medical Center licensed an additional four. Because CON need formulas consider approved beds, zero need was published for additional Level II beds in District 7.

The projected number of gross beds needed in District 7 has increased from 119 in 2004 to 125 in 2005, leaving the district’s newly enlarged Level II NICU bed count with six more beds than indicated by the need formula. This calculation includes the previously mentioned 34 Level II NICU beds licensed for Arnold Palmer and four new beds at Osceola Regional Medical Center, increasing its capacity to 10 Level II NICU beds.

Because a greater number of Level II NICU beds are now licensed in the district than are required by the need formula, the applicant must demonstrate need for its proposed NICU outside of data considered in the calculation of the published fixed need pool. The applicant states that existing NICU providers in the service area are associated with larger adult systems and do not offer the “highly specialized and focused NICU care” proposed by the applicant. It should be noted that of the top 10 ranked children’s hospitals in the nation, as ranked by US News and World Report in 2005, at least three operated within larger systems providing care for adult patients. It should be further noted that the applicant’s existing facility in Wilmington, Delaware was not included in these rankings. The applicant states that its proposed NICU programs would bring greater availability of pediatric subspecialty resources to District 7; however, as stated in the accompanying State Agency Action Report for CON #9953, the applicant states an existing District 7 provider strategically began hiring away Nemours’ physicians when the applicant first announced its application intentions, in an effort to weaken the applicant’s proposal. The applicant states that its physician staff was reduced to 27.6 FTE, but that it is actively recruiting physicians to those practice positions that were lost. The applicant
indicates that this recruitment from the Nemours staff began after June 30, 2005, and indicates that replacements had not yet been recruited by its most recent application (omissions deadline of October 18, 2006). This revelation from the applicant suggests that availability of pediatric subspecialty resources may already be strained in the area. In other words, if the applicant is unable to maintain necessary physician staff at its existing clinic, it is not clear that the applicant could recruit and retain the necessary physician staff that the applicant indicates would distinguish its hospital and NICU programs from the existing providers.

The majority of CON application #9939 is a duplication of the accompanying CON application #9953, for a class II children’s hospital, with little information provided in CON application #9939 regarding need for the applicant’s proposed NICU program. The applicant makes numerous broad statements indicating that its hospital would be superior to existing services, and therefore its NICU programs would be superior. The applicant offers as evidence of its quality its use of the Electronic Medical Record (EMR) and other technologies, as well as a “child friendly” and “culturally competent” environment. The applicant states that NICU patients who would be transferred from existing facilities to the proposed facility’s NICU would benefit from the subspecialists and specialized resources it plans to implement, but as previously noted, the applicant conversely divulges difficulties with staffing its existing outpatient clinic in Orlando with these subspecialists. While considerable information is provided regarding the applicant’s reputation for quality, insufficient information is provided to indicate need for the proposed NICUs. As discussed earlier, the applicant does not expect to have the volume generally considered as an indicator of quality services.

Because the proposed facility would not provide obstetrical services, newborns that would utilize the applicant’s Level II NICU services would need to be transported to the proposed facility. Immediate transfer of a newborn may not be possible due to the baby’s condition or external factors interfering with transportation.

The applicant presents additional special circumstances in E.1.d. below which are addressed in that section.

b. Regardless of whether bed need is shown under the need formula, the establishment of new Level II neonatal intensive care services within a district shall not normally be approved unless the average occupancy rate for Level II beds in the district equals or exceeds 80 percent for the most recent 12-month period ending six months prior to the beginning date of the quarter of the publication of the fixed need pool.
Level II NICU utilization rates during the last two reporting periods have exceeded 80 percent, as seen in the following table repeated from earlier discussion:

<table>
<thead>
<tr>
<th>Level II NICU Bed Utilization - District 7</th>
<th># Beds</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holmes Regional Medical Center</td>
<td>10</td>
<td>18.80%</td>
<td>27.45%</td>
</tr>
<tr>
<td>Florida Hospital-Orlando</td>
<td>28</td>
<td>73.63%</td>
<td>82.14%</td>
</tr>
<tr>
<td>Arnold Palmer Hospital for Women &amp; Children</td>
<td>34*</td>
<td>164.06%*</td>
<td>166.83%*</td>
</tr>
<tr>
<td>Winter Park Memorial Hospital</td>
<td>5</td>
<td>74.26%</td>
<td>59.34%</td>
</tr>
<tr>
<td>Osceola Regional Medical Center</td>
<td>6*</td>
<td>70.95%</td>
<td>61.24%*</td>
</tr>
<tr>
<td>Wuesthoff Medical Center - Rockledge</td>
<td>10</td>
<td>47.92%</td>
<td>45.29%</td>
</tr>
<tr>
<td>District 7</td>
<td>93*</td>
<td>97.89%*</td>
<td>100.26%*</td>
</tr>
</tbody>
</table>

Source: Florida Hospital Bed Need Projections and Service Utilizations by District, published July 2005 and 2006

* Arnold Palmer licensed an additional 34 NICU Level II beds since 2005, for a total of 68, and was subsequently approved to delicense 8 of the 68 to be relicensed as NICU Level III beds. Osceola licensed an additional four NICU Level II beds since 2005, for a total of 10 Level II NICU beds.

As seen above, occupancy in District 7 exceeded 80 percent occupancy for the time period specified in rule. Since the end of year 2005, Arnold Palmer Hospital licensed an additional 34 Level II NICU beds, for a total of 68 licensed as of this writing\[13]. Osceola Regional Medical Center licensed an additional four Level II NICU beds, for a total of 10. These bed additions likely have already addressed the over utilization of the bed counts indicated in the table above. It should also be noted that existing hospitals may add NICU beds by notifying the Agency of such intentions.

c. Conversion of Underutilized Acute Care Beds. New Level II or Level III neonatal intensive care unit beds shall normally be approved only if the applicant converts a number of acute care beds as defined in Rule 59C-1.038, excluding specialty beds, which is equal to the number of Level II or Level III beds proposed, unless the applicant can reasonably project an occupancy rate of 75 percent for the applicable planning horizon, based on historical utilization patterns, for all acute care beds, excluding specialty beds. If the conversion of the number of acute care beds which equals the number of proposed Level II or Level III beds would result in an acute care occupancy exceeding 75 percent for the applicable planning horizon, the applicant shall only be required to convert the number of beds necessary to achieve a projected 75 percent acute care occupancy for the applicable planning horizon, excluding specialty beds.

The applicant proposes to establish the Level II NICU project in a new hospital (CON #9953). Therefore, this provision does not apply to this proposal. Additionally, with recent changes in CON regulation, existing

\[13\] Arnold Palmer Hospital was approved on 8/18/2006 to delicense eight Level II NICU beds and relicense as Level III NICU beds. This delicensing and relicensing had not occurred as of this writing.
hospitals may add acute care beds by notifying the Agency of their intention to add if the hospital is located in an area not defined in statute as “low-growth.” At this time, no county in District 7 meets the statutory definition of “low-growth”.

d. **Other Special Circumstances:**

The applicant contends the primary special circumstance is the need for the Level II NICU services in a comprehensive specialty (Class II) children’s hospital in District 7 in order to offer continuity of services. The applicant contends that the Level II and III NICUs are necessary for the proposed Class II hospital in order to provide care focused on the overall health of the patients, instead of having the proposed hospital provide what the applicant terms ‘episodic’ care. The applicant maintains that Level II NICU services in a children’s hospital are different than those provided in a general acute care hospital because the children’s hospital serves as a regional referral center with the capacity to treat complex cases. However, this model of care, the regional referral center, has been used in Florida for a number of years and is still used by the Department of Health, Children’s Medical Services. It has been only recently (July 2004) that the Florida legislature determined that, although NICU services are still determined to be tertiary\(^{14}\), the number of births at any hospital determines need, and therefore, CON review is not required, other than to ensure evidence is provided by the hospital seeking the CON exemption that it can meet quality of care standards for NICU services and that it will provide care to the medically indigent. The applicant has applied to establish a lesser number (by one-half) of Level II NICU beds than is generally understood to be needed to accommodate the volume required to ensure quality of care.

The applicant states that existing NICU providers in the service area are associated with larger adult systems and do not offer the “highly specialized and focused NICU care” proposed by the applicant. It should be noted that of the top 10 ranked children’s hospitals in the nation, as ranked by US News and World Report in 2005, at least three operated within larger systems providing care for adult patients. It should be further noted that the applicant’s existing facility in Wilmington, Delaware was not included in these rankings. The applicant states that

\(^{14}\) s. 408.032(17), Florida Statutes "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, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, 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.
its proposed NICU programs would bring greater availability of pediatric subspecialty resources to District 7; however, as discussed in the accompanying State Agency Action Report for CON #9953, the applicant states an existing District 7 provider strategically began hiring away Nemours’ physicians when the applicant first announced its application intentions, in an attempt (as described by the applicant) to weaken the applicant’s proposal. The applicant states that its physician staff was reduced to 27.6 FTE, but that it is actively recruiting physicians to those practice positions that were lost. This revelation from the applicant suggests that availability of pediatric subspecialty resources may already be strained in the area. In other words, if the applicant is unable to maintain necessary physician staff at its existing clinic, it is not clear that the applicant could recruit and retain the necessary physician staff that the applicant indicates would distinguish its hospital and NICU programs from the existing providers. The applicant states that NICU patients who would be transferred from existing facilities to the proposed facility’s NICU would benefit from the subspecialists and specialized resources it plans to implement, but as previously noted, the applicant conversely divulges difficulties with staffing its existing outpatient clinic in Orlando with these subspecialists, wherein the Nemours physician staff decreased by approximately half and remained as such for the fifteen months prior to the submission of this most recent application. No indication is given that any replacement had occurred by the omissions deadline of this current batching cycle (October 18, 2006).

The applicant additionally offers the following as evidence of need for the three proposed projects: the applicant’s long-standing commitment to children’s health care in Florida; a significant population of children with medically complex conditions that needs the benefits offered by the proposal; the applicant’s experience in Delaware; the proposed projects would result in a fully integrated freestanding pediatric hospital; the Nemours Foundation has the financial resources and organizational commitment to fund and sustain the proposed ‘top tier’ projects; growing pediatric population.

The applicant’s commitment to children’s health care in Florida would enhance an application for a certificate of need for a project with demonstrable need; however, need is not demonstrated for the proposed projects, as existing providers in the service area have the ability to add beds outside of CON review to accommodate population growth, and the applicant indicates difficulties maintaining a physician staff at its existing Orlando clinic for greater than 15 months prior to submission of its current application. It is not clear that the applicant could maintain the necessary physician staff at the proposed facility with the proposed NICU programs. This contention does not represent a special circumstance.
The applicant states there is a “significant population of children with medically complex conditions”\(^{15}\) that needs the benefits offered by the proposal. The applicant does not quantify its estimate of “significant,” but instead states that defining “medically complex” is no simple task. Conversely, the applicant states that the proposed facility would “serve only a relatively small number of complex cases”\(^{16}\) and that with regards to pediatric subspecialist physicians, “the volume of patients they may treat is relatively low”\(^{17}\). The applicant states on page 53 of the CON application that children ‘clearly are’ currently receiving hospital services, but that the proposed projects would offer an alternative of enhanced quality and comprehensiveness. The applicant’s evidence of enhanced quality and comprehensiveness includes the proposed staff of subspecialist physicians and the proposed EMR. The applicant has indicated difficulties with maintaining a physician staff at its existing Orlando clinic, which it attributes to competition with an existing provider, and therefore it is not clear that the applicant could maintain the referenced staff of subspecialist physicians. The applicant provides no indication that physician replacement occurred from the time that physician staff reductions began through the time of submission for this latest application, greater than 15 months. The applicant contends that the proposed EMR would be superior to the EMR systems proposed by most other applicants for new hospitals, but this contention cannot be adequately evaluated. This contention does not represent a special circumstance.

The applicant’s experience in Delaware would enhance an application for a certificate of need for a project with demonstrable need; however, need is not demonstrated for the proposed projects, as existing providers in the service area have the ability to add beds outside of CON review to accommodate population growth, and the applicant indicates difficulties maintaining a physician staff at its existing Orlando clinic. It is not clear that the applicant could maintain the necessary physician staff at the proposed facility with the proposed NICU programs. This contention does not represent a special circumstance.

The applicant states that the proposed projects would result in a fully integrated freestanding pediatric hospital that is unlike the existing freestanding pediatric hospitals in the state. From the applicant’s discussion in CON application #9953, ‘fully integrated’ is interpreted to mean the implementation of the EMR system as well as the concentration of services at one site. As discussed previously, the superiority of the EMR system proposed by the applicant over those proposed by most other applicants for new hospitals cannot be

\(^{15}\) Page 53 of CON application 9939.  
\(^{16}\) Page 31 of CON application 9939.  
\(^{17}\) Page 54 of CON application 9939.
adequately evaluated. As discussed in the State Agency Action Report for CON application #9953, it is not clear that the benefits of consolidating services at one site would outweigh the likely results of the proposed projects, results such as aggravated staffing shortages, compromised ability to maintain innovative programs and/or quality standards, operational inefficiencies and duplication of services. As discussed previously, the applicant indicates it is already experiencing physician staffing difficulties due to competition with an existing provider. Additionally, the applicant cannot admit expectant mothers, and neonates would be transferred from area hospitals to Nemours, and then according to the applicant, back again, so it is less clear that the hospital would provide a full continuum of care. This contention does not represent a special circumstance.

The applicant states the Nemours Foundation has the financial resources and organizational commitment to fund and sustain the proposed ‘top tier’ projects. The applicant’s financial resources and organizational commitment would enhance an application for a certificate of need for a project with demonstrable need; however, need is not demonstrated for the proposed projects, as existing providers in the service area have the ability to add beds outside of CON review to accommodate population growth, and the applicant indicates difficulties maintaining a physician staff at its existing Orlando clinic. It is not clear that the applicant could maintain the necessary physician staff at the proposed facility with the proposed NICU programs. Further, the applicant’s existing facility in Delaware is not itself ranked as a top tier children’s hospital, so it is not clear that financial resources and organizational commitment equate to top tier services. This contention does not represent a special circumstance.

The applicant states that Florida’s pediatric population is growing rapidly and will have increasing needs for specialized care. Discussion of the 17 and under population is relevant to the applicant’s proposal to establish a class II hospital, and therefore growth of that population is discussed in the State Agency Action Report for that application, CON #9953. More applicable to this application for NICU services is the growth of the female population of child bearing age. The following table illustrates the service area population growth for females ages 15-44:

<table>
<thead>
<tr>
<th>Service Area Population Growth (Females 15-44)</th>
<th>2007</th>
<th>2008</th>
<th>2010</th>
<th>2012</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>District 1</td>
<td>141,253</td>
<td>142,673</td>
<td>145,998</td>
<td>148,902</td>
<td>5.42%</td>
</tr>
<tr>
<td>District 2</td>
<td>158,565</td>
<td>159,364</td>
<td>160,113</td>
<td>162,124</td>
<td>2.24%</td>
</tr>
<tr>
<td>District 3</td>
<td>267,832</td>
<td>271,334</td>
<td>276,344</td>
<td>282,796</td>
<td>5.59%</td>
</tr>
<tr>
<td>District 4</td>
<td>384,148</td>
<td>388,496</td>
<td>394,579</td>
<td>402,864</td>
<td>4.87%</td>
</tr>
<tr>
<td>District 7</td>
<td>492,398</td>
<td>501,848</td>
<td>520,253</td>
<td>537,757</td>
<td>9.21%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,444,196</strong></td>
<td><strong>1,463,715</strong></td>
<td><strong>1,497,287</strong></td>
<td><strong>1,534,443</strong></td>
<td><strong>6.25%</strong></td>
</tr>
<tr>
<td><strong>State</strong></td>
<td><strong>3,571,463</strong></td>
<td><strong>3,613,674</strong></td>
<td><strong>3,686,144</strong></td>
<td><strong>3,767,622</strong></td>
<td><strong>5.49%</strong></td>
</tr>
</tbody>
</table>

As seen above, the service area proposed by the applicant is projected to average a growth of its female population ages 15-44 that is 0.76 percent greater than the growth projected for the state. District 7 is projected to average a growth of its female population ages 15-44 that is 3.72 percent greater than the growth projected for the state. It is not clear that 0.76 percent or 3.72 percent represent unusual growth. Nevertheless, 38 Level II NICU beds have been added to the District 7 count since the CY 2005 utilization was computed (with eight to be delicensed and relicensed as Level III beds). This recent expansion combined with the ability of District 7 facilities to further add beds outside of CON review do not indicate forecasted growth will exceed the ability of existing providers to accommodate the growth.

The applicant’s contentions of special circumstance are not supported.

2. 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.

The applicant is the sole District 7 Level II NICU applicant in this batch and does not currently operate a NICU unit in Florida. The applicant’s estimates of utilization by payer class are contained in Schedule 7B and addressed in response to this provision. The applicant projects the following payer mix for its Level II NICU program:
Pediatric (17 and under) patient days by payer category for hospitals with NICU units in District 7 are shown in the table below for CY 2005:

<table>
<thead>
<tr>
<th>Payer</th>
<th>Patient Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHAMPUS</td>
<td>1.5%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>42.2%</td>
</tr>
<tr>
<td>Medicaid HMO</td>
<td>8.2%</td>
</tr>
<tr>
<td>Private</td>
<td>4.1%</td>
</tr>
<tr>
<td>All Commercial Insurance</td>
<td>43.1%</td>
</tr>
<tr>
<td>Charity</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

Source: CON Application 9939, Page 36.

The applicant’s estimated payer mix is approximately equal to recent provisions by existing providers in District 7 for Medicaid, Medicaid HMO and charity care during calendar year 2005.

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

The applicant is the sole District 7 Level II NICU applicant in this batch. The applicant has submitted simultaneous applications to develop a five-bed Level II NICU and an eight-bed Level III NICU (CON #9952). The application complies with this provision.
(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 it will ensure post-discharge services for all Level II NICU patients including progress monitoring and appropriate community referrals. The applicant emphasizes its commitment to investing financial resources and human capital to ensure appropriate follow up occurs, including investing in technology such as the following:

- Seamless electronic health records for coordination of care between inpatient and outpatient settings;
- Allowing the patients’ primary care provider access to the electronic records;
- Remote home monitoring for transmittal of cognitive and physiologic patient information;
- Utilization of data to design decision support and feedback systems;
- Provider simulation laboratory to assist providers in learning and refreshing procedural and cognitive skills;
- A website, Kidshealth.org, for patients and family teaching.

In the accompanying CON application #9953, the applicant states that a “true EMR” is not in use by any of the current providers, and cites a study wherein approximately 10 percent of EMR systems were described to be fully operational and are “capable of multiple functions such as order- and prescription-entry and decision support.” While proposing EMR systems for new hospitals is effectively standard and EMRs are no longer considered an innovation in a new hospital facility, the applicant contends its system would be superior to the systems currently employed in the service area. Without specific itemized analysis comparing the applicant’s proposed system to those of all existing providers in the area, this contention cannot be adequately evaluated.

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19 CON application 9953, page 90.
c. **Ch. 59C-1.042(5), Florida Administrative Code - Minimum Unit Size.** Hospitals proposing the establishment of new Level III neonatal intensive care services shall propose a Level III neonatal intensive care unit with a minimum of 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 Health and Rehabilitative Services’ Children’s Medical Services Program for the provision of regional perinatal intensive care center or step-down neonatal special unit care are exempt from these requirements.

This application is for a five-bed Level II NICU submitted in conjunction with an application for an eight-bed Level III NICU (CON #9952), neither of which complies with this provision.

The applicant states that AHCA has approved smaller units under special circumstances, which the applicant contends consists of the need for NICU services in a comprehensive specialty (Class II) children’s hospital in order to offer continuity of services. It is noted that none of the referenced applicants proposed to establish top-tier specialty hospitals and all were existing facilities with a large number of births. The applicant states that because the proposed facility would not have an obstetrical program to generate larger volumes of patients, a lesser number of NICU beds is expected to be sufficient to meet demand for at least the first three years of the project. The applicant contends these size requirements stem from concerns about quality of care and financial feasibility, and concludes that these requirements are not applicable to its proposal because it will employ neonatologists to staff the NICUs 24 hours per day, seven days per week, and that the Nemours Foundation will subsidize the operations of the NICU programs as long as necessary. It should be noted that in the accompanying CON application #9953, the applicant divulges complications with physician retention at its existing Orlando clinic, which it attributes to competition with an existing provider. Because the applicant has experienced staffing difficulties without the proposed additional facility, it is not clear that the applicant would not experience similar staffing difficulties should the proposed project be approved.

The applicant is not a regional perinatal intensive center or step-down neonatal special care unit.

The proposed project does not comply with this provision and insufficient information is provided to exempt the proposed project from the provision requirements.
d. **Ch. 59C-1.042(6) - Minimum Birth Volume Requirement.** Hospitals applying for Level II neonatal intensive care services shall not normally be approved unless the hospital has a minimum service volume of 1,000 live births for the most recent 12-month period ending six months prior to the beginning date of the quarter of the publication of the fixed bed need pool. Specialty children’s hospitals are exempt from these requirements.

The application is for the establishment of a Level II NICU in a specialty children’s hospital, for which the applicant is applying with the accompanying CON application #9953. As discussed in the State Agency Action Report for CON application #9953, need for a children’s specialty hospital for this area is not demonstrated.

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.

As demonstrated in the driving distances chart below, Level II NICU services are currently available and accessible within the two hours ground time to all District 7 residents:

**Map Mileage to Existing NICU Providers in District 7**

<table>
<thead>
<tr>
<th></th>
<th>Holmes Regional Medical Center</th>
<th>Wuestoff Med. Ctr. - Rockledge</th>
<th>Osceola Regional Medical Center</th>
<th>Florida Hospital- Orlando</th>
<th>Arnold Palmer Hospital</th>
<th>Winter Park Memorial Hospital</th>
<th>Nemours Proposed Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holmes Regional Medical Center</td>
<td>17</td>
<td>41</td>
<td>57</td>
<td>55</td>
<td>56</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>Wuestoff Med. Ctr. - Rockledge</td>
<td>50</td>
<td>42</td>
<td>43</td>
<td>42</td>
<td>41</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Osceola Regional Medical Center</td>
<td>56</td>
<td>42</td>
<td>19</td>
<td>15</td>
<td>21</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Florida Hospital- Orlando</td>
<td>55</td>
<td>42</td>
<td>19</td>
<td>3.4</td>
<td>3.2</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Arnold Palmer Hospital</td>
<td>55</td>
<td>42</td>
<td>15</td>
<td>3.8</td>
<td>6.25</td>
<td>3.8</td>
<td></td>
</tr>
<tr>
<td>Winter Park Memorial Hospital</td>
<td>55</td>
<td>41.2</td>
<td>15</td>
<td>3.7</td>
<td>6.25</td>
<td>3.8</td>
<td>9.1</td>
</tr>
<tr>
<td>Nemours Proposed Site</td>
<td>55</td>
<td>44</td>
<td>14</td>
<td>6</td>
<td>3.77</td>
<td>9.1</td>
<td></td>
</tr>
</tbody>
</table>

*Source: Microsoft MapPoint*
As seen in the table above, the proposed site is within 10 miles of three existing providers of NICU services. It is not clear that the proposed project would improve accessibility for residents of District 7. The applicant states that its program would be available to 90 percent of residents of District 7 within a two-hour ground travel time.

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

(1) **Physician Staffing:** Level II neonatal intensive care services shall be directed by a neonatologist or a group of neonatologists who are on active staff of the hospital with unlimited privileges and provide 24-hour coverage, and who are either board-certified or board-eligible in neonatal-perinatal medicine. 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 provision.

The applicant has submitted simultaneous applications to develop a five-bed Level II NICU, an eight-bed Level III NICU (CON #9952) and a Class II specialty children’s hospital (CON #9953). As a specialty children’s hospital, the applicant would be exempt from this provision, but as noted earlier, need for a children’s specialty hospital for this area is not demonstrated.

The applicant states its Level II NICU program would be directed by a board certified neonatologist employed by Nemours Clinic - Orlando and supported by additional physicians, also employed by Nemours, to provide 24-hour coverage. Schedule 6A, the applicant’s proposed staffing pattern, indicates 0.3 FTEs allotted for the medical director and no allotments are indicated for additional physician staffing.

The Level III NICU requirements do not apply to this project for Level II beds.

(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 it will employ a head nurse who will be a registered professional nurse with experience and training in
neonatal intensive care nursing. Staffing would reportedly be maintained at ratios to exceed the requirement that at least one-half of the nursing personnel assigned to each work shift in Level II and Level III neonatal intensive care units be registered nurses. The applicant states its nursing staff would include neonatal nurse practitioners and advanced practice nurses.

Schedule 6A, the applicant’s staffing pattern, indicates 8.4 and 11.2 FTEs of registered nurses for the project’s first and second operational years, respectively.

(3) **Special Skills of Nursing Staff:** Nurses in Level II and Level III neonatal intensive care units shall be trained to administer cardio-respiratory monitoring, assist in ventilation, administer I.V. fluids, provide pre-operative and post-operative care of newborns requiring surgery, manage neonates being transported, and provide emergency treatment of conditions such as apnea, seizures, and respiratory distress.

The applicant states it will comply with this requirement and will include on its nursing staff neonatal nurse practitioners and advanced practice nurses. The applicant does not address its credentialing program or staff training protocols.

(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 will comply with this requirement. The applicant revised the proposed staffing pattern since its previous submission of this proposal to expand the allotments for respiratory therapists.

(5) **Blood Gases Determination:** 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 it will comply with this requirement. The applicant does not allot for laboratory staffing in its Schedule 6A for the first two operational years.
Ancillary Service Requirements: Hospitals providing Level II or Level III neonatal intensive care services shall provide on-site, on a 24-hour basis, x-ray, obstetric ultrasound, and clinical laboratory services. Anesthesia shall be available on an on-call basis within 30 minutes. Clinical laboratory services shall have the capability to perform microstudies.

The applicant states it will comply with these requirements, including obstetric ultrasound. It should be noted that the proposed NICU program would be part of the applicant’s proposed specialty children’s hospital, where obstetrical services would not be provided.

Nutritional Services: Each hospital with Level II or Level III neonatal intensive care services shall have a dietician or nutritionist to provide information on patient dietary needs while in the hospital and to provide the patient’s family instruction or counseling regarding the appropriate nutritional and dietary needs of the patient after discharge.

The applicant states it will comply with this requirement. The applicant’s proposed staffing pattern in the Schedule 6A does not indicate any staffing allotment for the dietary department for the first two operational years.

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 states its social work department will coordinate the appropriate social services for patients, including family counseling, discharge planning, and referral to community agencies. For children potentially eligible for the Medicaid, Children’s Medical Services or Developmental Services programs, referrals would reportedly be made to the appropriate eligibility worker for eligibility determination.
CON Action Number: 9939

(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 states it will provide these services as required and describes the role of social workers to include assisting the patient’s families with counseling, crisis intervention, identification of community resources, discharge plans, financial/insurance matters and advocacy.

The applicant indicates that its proposed EMR would assist in the care of developmentally disabled newborns.

The applicant’s Schedule 6A staffing pattern indicates 0.5 FTEs for social workers for the first and second years of operation. It should be noted that a social worker working half-time may experience difficulties accomplishing all of the above indicated tasks.

(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 its Class II hospital would handle discharge planning using an interdisciplinary team approach, and that social workers would coordinate with the interdisciplinary care team in developing a needs assessment to be incorporated in the discharge plan.

g. **Ch. 59C-1.042(9), Florida Administrative Code - Level II Neonatal Intensive Care Unit Standards:** The following standards shall apply to Level II neonatal intensive care services:

(1) **Nurse to Neonate Staffing Ratio.** Hospitals shall have a nurse to neonate ratio of at least 1:4 in Level II neonatal intensive care units at all times. At least 50 percent of the nurses shall be registered nurses.

Schedule 6A indicates 8.4 RNs FTEs staffing during the first year of operation (2010), increasing to 11.2 during the second year (2011). The applicant’s projected occupancy for 2010 is 42 percent.
increasing to 56 percent during 2011. The staffing schedule shows 2.8 to 4.2 FTEs per each eight-hour shift. This ratio complies with the requirement.

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

- a. Fifty square feet per infant;
- b. Two wall-mounted suction outlets preferably equipped with a unit alarm to signal loss of vacuum;
- c. Eight electrical outlets;
- d. Two oxygen outlets and an equal number of compressed air outlets and adequate provisions for mixing these gases;
- e. An incubator or radiant warmer;
- f. One heated humidifier and oxyhood;
- g. One respiration or heart rate monitor;
- h. One resuscitation bag and mask;
- i. One infusion pump;
- j. At least one oxygen analyzer for every three beds;
- k. At least one non-invasive blood pressure monitoring device for every three beds;
- l. At least one portable suction device; and
- m. Not less than one ventilator for every three beds.

The applicant states it will comply with these requirements. The architectural review presented in section E.3.f. below contains further discussion.

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

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

The applicant states it will comply with this requirement.

h. **Level III Neonatal Intensive Care Unit Standards.**

The proposed program is a Level II NICU unit. This requirement for Level III units does not apply.
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.

The applicant states it will provide 24-hour transport for the high-risk NICU population using a transport team trained and credentialed to handle advanced neonatal life support, equipment use and newborn assessment. Ground ambulance, helicopters, and fixed wing aircraft will be available for transport.

(2) **Requirements for Emergency Transportation System.** Emergency transportation system, as defined in paragraph (11)(a), shall conform to section 64E-2.006, Florida Administrative Code.

The applicant states it will comply with all requirements of Section 10D-66.52, Florida Administrative Code.

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.

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20 The applicant likely intended to refer to Chapter 10D-66.052, Florida Administrative Code, the rule indicated in 59C-1.042(11)(b) dealing with Interfacility Transfers. Chapter 10D-66.052, Florida Administrative Code has been repealed. Chapter 10D-66.0525, Florida Administrative Code, dealing with Neonatal Interfacility Transfers has been transferred to 64E-2.006.
The applicant has submitted applications for a five-bed Level II NICU and an eight-bed Level III NICU (CON #9952). If both programs are approved, this provision will not apply.

**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.

1. **Utilization Data.**
2. **Patient Origin Data.**

The applicant states it will comply with reporting requirements within 45 days after the end of each calendar quarter.

**3. 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.

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 District 7. Population projections are not demonstrated to be sufficient to exceed available capacity at existing facilities, particularly considering the ability of the existing facilities to add NICU beds outside of CON review.

The applicant primarily focuses its application on the establishment of the Class II hospital and not on the establishment of a Level II NICU. The applicant primarily focuses its discussion on District 7 and not on the surrounding districts of the proposed service area, which includes Districts 1, 2, 3, 4 and 7. The applicant contends its proposal would be superior to existing resources, primarily due to its proposal to employ subspecialist physicians, but because the applicant has indicated it is already experiencing difficulties staffing its existing Orlando clinic with physicians (due to competition with an existing inpatient provider), this contention is not supported. An existing provider, Arnold Palmer Hospital for Women and Children, has expressed an expectation of negative impact. Because the proposed facility (and proposed NICU programs) would be within 10 roadway miles of three existing providers of similar services, it is not demonstrated that geographic access would be improved with the proposed project. Of the five districts proposed in the applicant’s service area, it appears that the applicant has chosen to
locate its proposed project in the district that is most likely to result in a duplication of services. Although the applicant contends that the services it is proposing are unique and unavailable to its proposed service area, the applicant did not provide comparative information to support that claim, and so it cannot be determined in this review whether the proposed services are unique and unavailable, other than the fact that there is no Class II children’s hospital in the top portion of the state. Additionally, the applicant contends that it will build a top tier hospital, based partly on its reputation. However, as noted earlier, the applicant’s existing children’s hospital was not included in a ranking of the top 26 children’s hospitals in the nation released in 2006. As discussed in section E.3.g. below, the applicant is proposing to provide a percentage of care to Medicaid and charity patients that is approximately equal to the provisions by existing area providers, and so it is not clear that financial access would be increased with the proposed projects.

Arnold Palmer Hospital recently increased its Level II NICU by 34 beds and Osceola Regional Medical Center recently increased its Level II NICU by four beds, both of which will likely decrease NICU utilization in District 7. It is again noted that these facilities may license additional NICU beds with notification to the Agency, and are not required to submit applications for CON review.

Volume standards are widely accepted as indicators of quality care in medical industry literature. The applicant has proposed to operate fewer beds than the minimum stated in rule to ensure quality care. The applicant projects occupancies in these beds of 42 percent and 56 percent respectively for years one and two.

The application does not demonstrate need based on availability, quality of care, efficiency, accessibility and extent of utilization of existing health care facilities. Quality of care issues are discussed below in Section 3.b.

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

The applicant does not own or operate any hospitals in Florida.

The applicant discusses its conformity with JCAHO standards and states that it was a key developer of the National Pediatric Quality System adopted by JCAHO to identify standardized performance measures for pediatric acute care settings, as other widely accepted performance measures are focused on adults and are stated to be not applicable to health care for children. The applicant addresses its quality model, and states that “Nemours is not hesitant to invest in technology to foster communication and care as long as that care is excellent.” Quality
points itemized by the applicant include an integrated electronic health record, remote home monitoring, which allows access to and from a provider from outside the facility, a “Simulation Laboratory” to assist providers with procedural and cognitive skills, as well as the utilization of kidshealth.org as a teaching tool for patients and parents. The applicant provides much discussion throughout the application on the importance of ‘best practices’ and evidence based medicine, as well as its plans to establish the proposed facility as a ‘top tier’ children’s hospital. The applicant states that it collects and monitors patient satisfaction data for quantifying and implementing improvement strategies, and that in 2004, 97 percent of returned surveys indicated the care received at Alfred I. duPont Hospital was ‘very good’ or ‘the very best’. As noted above, the applicant claims that this new hospital will be a top tier hospital, exceeding that of Alfred I. duPont Hospital for children, but yet has provided information in these applications that raises questions about the quality of care it will provide. Quality and safety initiatives described by the applicant include: the Pedi-QS national pediatric quality system adopted by JCAHO as a care improvement measurement; the Nemours Clinical Management Program, which is described as a data management system; Nemours Biomedical Research; and the implementation of the EMR.

Available evidence indicates the applicant has the ability to provide quality care; however, the ability to provide quality care is not equivalent to need for an additional hospital in an area with stagnant utilization and the ability to add beds outside of CON review.

c. **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 of The Nemours Foundation for the periods ending December 31, 2004 and 2005 were analyzed for the purpose of evaluating the applicant’s ability to provide the operational funding and the development and start-up costs necessary to implement the project as proposed. (See table).
The Nemours Foundation was formed in 1936 pursuant to the last will and testament of Alfred I. duPont for the primary purpose of providing for the care and treatment of crippled children, but not of the incurables, and for the care of the elderly, particularly couples. Nemours operates a children’s hospital and specialty clinic in Delaware, and three specialty children’s clinics in Florida.

**Short-Term Position:**
The applicant’s current ratio of 2.2 indicates current assets are 220 percent of current liabilities, an average position. The ratio of cash flows to current liabilities of .06 is also an average position. The working capital (current assets less current liabilities) of $132.1 million is a measure of excess liquidity that could be used to fund capital projects. Overall, the applicant has an average short-term position.

**Long-Term Position:**
The ratio of long-term debt to net equity of 0.2 indicates long-term debt is only 20 percent of equity. Long-term debt consists of reserves for professional and patient care liabilities and $91.5 million in bond funds for construction projects. Nemours uses a self insurance trust fund to insure for possible professional and patient care losses. The ratio of cash flow to assets of 6.2 percent is below average, but an acceptable position. The most recent year had net income of $23.0 million, which results in an operating margin of 4.2 percent.
The applicant is not typical of Florida hospitals in that they receive a significant level of funding from the Alfred I. duPont Testamentary Trust fund, $111.6 million in 2005. As a result they have a good long-term position.

**Capital Requirements:**
Schedule 2 indicates the applicant has capital projects totaling $439.8 million, including maturities of long term debt through 2007 of $1.9 million.

**Available Capital:**
Funding for this project will be come from a $128.0 million equity contribution and $130.0 million from the proceeds of long-term tax-exempt bonds. A letter provided by the applicant from Bank of America Securities which stated they believed Nemours is likely to obtain financing for these projects.

The applicant had $119.3 million in cash and $68.9 million in operating cash flows.

**Staffing:**
Proposed staffing patterns for years one and two of the level II NICU are shown in the table below:

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADMINISTRATION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administrator</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Nurse Manager</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Secretary</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td><strong>PHYSICIANS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Director</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>NURSING</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RN</td>
<td>8.4</td>
<td>11.2</td>
</tr>
<tr>
<td>Ward Clerks</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>10.4</td>
<td>13.2</td>
</tr>
<tr>
<td><strong>ANCILLARY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Therapist</td>
<td>4.2</td>
<td>4.2</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>4.2</td>
<td>4.2</td>
</tr>
<tr>
<td><strong>SOCIAL SERVICES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Worker</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>GRAND TOTAL</strong></td>
<td>16.5</td>
<td>19.3</td>
</tr>
</tbody>
</table>

Source: CON Application 9939, Schedule 6A

The 4.2 FTEs for respiratory therapists are apportioned as 1.4 FTEs for each of the morning, evening and night shifts, reflecting a correction from the applicant’s previous submission wherein a respiratory therapist was not scheduled for all shifts as required by Chapter 59C-1.042(8), Florida Administrative Code. The applicant did not, however, provide a
CON Action Number: 9939

correction for the medical director allotment, and in fact reduced the FTE from 0.4 in the previous submission to 0.3 in this CON #9939. Chapter 59C-1.042(8) requires level II NICUs to maintain 24-hour coverage of at least one neonatologist. No additional staffs are indicated to meet this physician requirement. The staffing pattern does not indicate any staff for the dietary, housekeeping or laundry departments. The proposed nursing patterns comply with the minimum staffing requirements.

The applicant states that at the time of submission for the previous CON application #9917, the Nemours Children’s Clinic Orlando employed 55.85 FTE physicians, but that an existing provider in the area strategically began hiring away Nemours’ physicians in an effort to weaken the applicant’s proposal. The applicant states that its physician staff was reduced to 27.6 FTE, but that it is actively recruiting physicians to those practice positions that were lost. The applicant indicates that this reduction persisted for greater than 15 months prior to this most recent application, with the only suggestion of physician replacement being that the applicant intends to have a full physician staff before implementing the proposed project. This revelation from the applicant suggests that staffing recruitment may already be an issue in this service area, and the introduction of an additional facility may strain staffing resources further. In other words, if the applicant is unable to maintain necessary physician staff at its existing clinic, it is not clear that the applicant could recruit and retain the necessary physician staff at the proposed hospital.

The applicant states that it offers a generous benefits program, fully paid malpractice insurance, 10 days per year of continuing education, annual funding of $3,500 per physician per year for professional dues and memberships, with travel expenses paid to continuing educational programs and/or research presentations. The applicant states that its recruitment campaign will rest on its existing clinical networks and affiliations with medical schools and other associations. The applicant contends need for pediatric subspecialties in the service area, and states that subspecialists are attracted to environments that provide them with a hospital for admission of patients with complex conditions, subspecialty clinics for ambulatory care and opportunities for research and teaching. The applicant contends that by establishing this type of hospital, the desired subspecialists would be attracted to District 7. The applicant lists pediatric rheumatology, allergy/immunology and dermatology as priority areas for recruitment, but as discussed in the State Agency Action Report for CON application #9953, these specialties are not absent from the service area.

Retention efforts are described to include the following: sign on bonus program; employee referral bonus program; relocation assistance for those relocating to the greater Orlando area; premium pay for hard to fill
subspecialty positions; compensation for certification attained by nurses and nursing managers; educational financial assistance to pursue higher level nursing degrees; and, internships for nursing subspecialty practice and research.

**Conclusion:**
Funding for CON numbers 9939, 9952 and 9953 is likely to be available as needed.

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

The applicant is applying to establish a five-bed level II NICU under CON #9939. This project is expected to increase net revenues by $2.3 million in year one and $3.2 million in year two, while costs increase by $2.3 million and $2.8 million in year one and two respectively. This project would increase the loss from operations in year one by $59,303 and decrease the loss by $390,688 in year two.

The proposed NICU II cost per patient day from Schedule 8 was compared to all other hospitals in the state with approved NICU II programs in 2005. Values were adjusted to year 2 (2011). Costs for year 2 of $2,733 are between the median and highest value in the state of $2,104 and $4,296. With projected cost in year two between the median and highest values compared to other hospitals, costs appear feasible.

Fifty percent of patient days are expected to come from Medicaid and Medicaid HMOs. This is consistent with other programs in the state.

The opportunity exists for price-based competition among approximately 50 percent of the applicants’ projected patient days. If realized, price-based competition will likely have a positive impact on quality and cost-effectiveness.

Assuming the applicant will be able to meet its projected occupancy and payer mix assumptions, financial feasibility of CON numbers 9939, 9952 and 9953 appears likely.

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

Competition to promote quality and cost-effectiveness is generally driven by the best combination of high quality and fair price.

The impact of the price of services on consumer choice is limited to the payer type. Most consumers do not pay directly for hospital services rather they are covered by a third-party payer. The impact of price
competition would be limited to third-party payers that negotiate price for services, namely managed care organizations. The applicant is projecting that approximately 54 percent of its patient days are expected to come from managed care organizations. The highest level of managed care in the comparative group was 47.1 percent.

The opportunity exists for price-based competition among approximately 54 percent of the applicants’ projected patient days for the hospital project. If realized, price-based competition could have a positive impact on quality and cost-effectiveness, if extenuating circumstances in the proposed service area are excluded from consideration. Staffing shortages, low utilization, the ability to add beds outside of CON review for facilities in this service area and the likelihood of duplication of services (and the resulting effects of duplication on quality, costs and efficiency) with this proposal together indicate that the isolated economic model typically applied to evaluate likely effects of a proposal on competition cannot be applied in this instance. It is likely that the proposed projects would aggravate existing staffing shortages and could further dilute utilization of existing services, as well as duplicating those services, among other issues.

**f. 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 application is for a new 82-bed acute care hospital dedicated to children’s health care. This will be a new facility located in Orlando on Vineland Road in Orange County. The site is a 28-acre planned development site that will include, in addition to the hospital building, an outpatient building, medical office building, parking structure, and central energy plant for the hospital. The applicant proposes to construct a new 82-bed acute care hospital consisting of 381,232 GSF. The central energy plant is planned to be detached from the hospital and located adjacent to the medical office building.

The room complement will be made up of all private rooms and have a bed configuration of 72 medical/surgical beds, 10 PICU beds, five Level II NICU beds and eight Level III NICU beds. The NICU and PICU rooms are located on the fifth floor, vertically above the surgical suite, which is located on the third floor. The requirement to provide at least 10 percent of the bedrooms to be handicapped accessible has not been clearly indicated on the plans, but will not be a problem because all of the rooms are much larger than required.

This is an eight-story building with a basement. The patient tower comprises the top four floors of the facility.
The functions of the proposed hospital are to be located in this eight-story facility of non-combustible construction that will be fully sprinklered and are defined as follows:

- **Basement Level** – The basement level contains some clinical support spaces such as the laboratory, pathology and pharmacy. Materials management and bulk storage are also located here but the loading dock is located remotely from the building and is connected by a service tunnel. This tunnel also connects the central energy plant to the hospital and it is assumed that the major utilities serving this building will be brought through this tunnel too. The IT function of the facility and the food preparation area are also located in this basement. The food preparation area including kitchen, receiving, storage and dietary offices serves the dining area located on the second floor. It is unclear how this food will be supplied to the dining area on the second floor because the three service elevators also serving the surgical suite are remotely located from the dining area.

- There are four elevators that are shown to serve the kitchen directly below the dining area and food court, but these elevators are the public elevators. It is unclear why these elevators terminate directly in the kitchen and food preparation area of the building.

- **First floor** – The first floor contains a multi-story main entrance lobby, with four public elevators and covered drop-off area. Located on the opposite side of the facility is the ambulance and pedestrian entry to the emergency department so these functions are clearly separated. There is a waiting area for the emergency department and several trauma rooms. The emergency department is also located adjacent to the radiological department for fast and convenient access. There is also a gift shop and a Kids’ Health Exploratorium adjacent to the main lobby. Adjacent to outpatient radiology is a waiting area with an outside garden.

- The central energy plant is attached to this schematic plan near the loading dock.

- **Second Floor** – The second floor opens in part to the lower lobby and waiting spaces and contains the dining area, food court and a large tiered auditorium. The egress from this assembly space may pose some life safety problems and there is an extended dead-end corridor at the dining area and elevator lobby. However, this can be redesigned at the schematic review stage. This floor also contains the administrative functions of the facility with teaching and class rooms.
• Third Floor – The third floor is dedicated to surgical services and contains six operating rooms, central sterile, recovery, offices and family waiting areas. Some of this area has not yet been well defined so there are some circulation problems on part of the floor that can be resolved at the schematic stage review.

• Fourth Floor – The fourth floor is reduced in size from the lower floors and contains services for speech and physical therapies. There is also a roof top garden on this level for meditation therapy.

• Fifth Floor – The fifth floor begins the patient rooms and contains the NICU and PICU beds. It is vertically connected to the surgical suite below with the patient/staff elevators. The NICU is composed of all private rooms and appears to be well designed. Each room has direct visual control by the nurse who is taking care of the infants in those rooms. The PICU is also well designed to be functional and pleasing for both family and staff. There is a large family waiting area with family sleep room and family kitchen so that the families feel welcomed into the space. The public and staff areas are clearly separated and the circulation well thought out on this floor.

• Sixth Floor– Eighth Floor- These floors contain the medical/surgical beds of 24 beds each and are each designed in a typical race track design with 12 beds in each half of the floor. The rooms are sized large enough to have family areas within the rooms to encourage families to become involved in the healing process. There is a large family lounge with play and activity areas, as well as a school class room. These floors seem to work well and to encourage family centered care and a healing environment.

The applicant states the construction will conform to all current applicable building codes, including the National Fire Protection Association codes and the requirements of the Florida Building Code. There are some problems associated with the vertical egress from the building and some circulation code problems in the building but these will be able to be resolved within the program of the building as designed. The application asserts the site is not within the 100-year flood plain or the category 3 surge inundation areas and has taken into consideration the hurricane requirements.

The construction cost per square foot and per patient bed is much higher than other applicants recently reviewed and may have to do with the construction of a parking structure and the remote central energy plant. Another factor may be the facilities plan for LEED (Leadership in Energy and Environmental Design) certification, which often results in higher initial costs. These higher costs are offset by reduced lifecycle costs, which usually lead to an overall savings over the life of the building.
The plans submitted with this application were very schematic in detail 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.

**g. 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.**

Nemours is the sole District 7 applicant for a Level II NICU in this batching cycle and does not currently operate any hospitals in Florida.

The applicant’s estimates of utilization by payer class are contained in Schedule 7B for the Level II NICU, excluding the associated class II hospital projections:

<p>| Payer Mix Projections for Year 2 of Proposed Hospital |</p>
<table>
<thead>
<tr>
<th>Payer</th>
<th>Percent of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid</td>
<td>42%</td>
</tr>
<tr>
<td>Medicaid HMO</td>
<td>8%</td>
</tr>
<tr>
<td>Self Pay</td>
<td>5%</td>
</tr>
<tr>
<td>All Commercial Insurance</td>
<td>2%</td>
</tr>
<tr>
<td>Other Managed Care</td>
<td>41%</td>
</tr>
<tr>
<td>Other Payers</td>
<td>2%</td>
</tr>
</tbody>
</table>

Source: CON Application 9939, Schedule 7B.

Pediatric (17 and under) patient days by payer category for hospitals with NICU units in District 7 are shown in the table below for CY 2005:

<p>| Percent Pediatric Patient Days by Payer Category for Calendar Year 2005 |</p>
<table>
<thead>
<tr>
<th>Facility</th>
<th>Medicaid/ Medicaid HMO</th>
<th>Charity</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arnold Palmer Hospital</td>
<td>53.87%</td>
<td>1.57%</td>
<td>55.44%</td>
</tr>
<tr>
<td>Florida Hospital</td>
<td>47.69%</td>
<td>3.01%</td>
<td>50.70%</td>
</tr>
<tr>
<td>Holmes Regional Medical</td>
<td>41.97%</td>
<td>1.86%</td>
<td>43.83%</td>
</tr>
<tr>
<td>Osceola Regional Medical</td>
<td>48.38%</td>
<td>1.59%</td>
<td>49.97%</td>
</tr>
<tr>
<td>Winter Park Memorial Hospital</td>
<td>38.94%</td>
<td>5.64%</td>
<td>44.58%</td>
</tr>
<tr>
<td>Wuesthoff Medical-Rockledge</td>
<td>51.98%</td>
<td>0.00%</td>
<td>51.98%</td>
</tr>
</tbody>
</table>

Source: Florida Center for Health Information and Policy Analysis (FCHIPA), formerly the State Center for Health Statistics.

The applicant’s proposed payer mix for Medicaid, Medicaid HMO and charity care is approximately equal to the provision by facilities in District 7 that currently operate a NICU unit. The applicant’s proposed condition of 50 percent combined Medicaid and charity care would place the proposed facility just under Arnold Palmer Hospital in terms of total
Medicaid and charity provisions. Therefore, it does not appear that approval of the proposed project would increase access for Medicaid and charity patients in this area, since the existing providers with like services are providing similar levels of Medicaid and charity care as are being proposed by the applicant.

The applicant has additionally conditioned approval of the project to limiting the annual amounts it collects from the Medicaid program for hospital-based inpatient services in each fiscal year to the lesser of either the inpatient per diem rate that would be assigned to its hospital by the Florida Medicaid program, or the average of the Medicaid assigned rates to All Children’s Hospital and Miami Children’s Hospital. The applicant proposes a similar condition with regards to hospital-based outpatient services. Medicaid assigns individual inpatient per diem rates to each hospital, and as such, the proposed facility, if approved, would have a Medicaid assigned per diem rate independent of the rates for All Children’s Hospital and Miami Children’s Hospital. Payment for outpatient hospital visits is based on billable revenue codes and not on per visit rates. The applicant’s proposed conditions regarding Medicaid reimbursement are therefore unclear, and despite a similar finding in the State Agency Action Report for CON numbers 9915-9917, the applicant has not provided additional explanation.

The applicant includes a copy of its financial assistance program in appendix M of volume II of the CON application, and states that it provides access to pediatric patients regardless of their financial status. The applicant states that it has historically subsidized shortfalls in operations of its clinics to ensure the physicians and services would remain available, and that since 1980 these subsidies have totaled $561 million, with $147 million of this dedicated to the Orlando clinic.

F. SUMMARY

The Nemours Foundation (CON #9939) is applying to establish a five-bed Level II neonatal intensive care unit (NICU) in District 7. The unit would be located in Orange County within the proposed 82-bed Class II children’s hospital being concurrently reviewed in this batching cycle under CON #9953. The applicant currently operates a children’s hospital in Wilmington, Delaware and four major children’s specialty outpatient centers. One of the outpatient centers is located in Wilmington, Delaware, and the other three are in the Florida cities of Jacksonville, Orlando and Pensacola. The applicant has submitted two additional applications for this batch to establish a class II children’s hospital (CON #9953) and an eight-bed Level III NICU (CON #9952) all at the same proposed location.
The total project cost is estimated at $4,951,773 and involves $3,550,400 in construction costs and 7,925 gross square feet (GSF) of new construction.

**Need:**

The proposed project is not in response to published need.

The applicant contends special circumstances warrant approval of a new Level II NICU in District 7 to serve as a regional referral center for central and north Florida (its proposed service area) to serve the sickest neonates. However, despite claims that it will serve as a regional center, it has proposed a small Level II NICU one-half the size of a unit that is considered necessary to ensure quality care. The applicant contends special circumstances exist in the area, including population growth, the proposal of providing subspecialty services not otherwise available in the proposed service area and the proposal of providing innovative integrated care for medically complex children.

Population projections for females ages 15-44 in the service area are approximately equal to the projections statewide, and therefore do not appear unusual. Existing Class I and Class II facilities have the ability to add beds outside of CON review if not located in a low-growth county. The applicant indicates difficulties with maintaining a physician staff at its existing Orlando clinic, while conversely stating that its proposal to recruit subspecialty physicians will distinguish its facility from existing providers. The applicant is proposing to locate within 10 miles of three existing Level II NICU providers, one of which submitted written opposition that the proposed project would result in negative impact.

Need is not demonstrated for a Level II NICU under special circumstances.

**Quality of Care:**

The applicant does not own or operate any hospitals in Florida.

Quality points itemized by the applicant include an integrated electronic health record, remote home monitoring, a simulation laboratory for providers and the utilization of a teaching website. Available evidence indicates the applicant has the ability to provide quality care. Whether the applicant would operate a top-tier hospital is in question. The applicant’s existing children’s hospital was not featured in a national ranking of 26 top-tier pediatric hospitals.
Medicaid/Indigent Care:

The applicant’s proposed payer mix for Medicaid, Medicaid HMO and charity care is approximately equal to the provision by facilities in District 7 that currently operate a NICU unit, as well as the provisions of existing Class II hospitals in the state. The applicant’s proposal would not likely offer increased financial access for Medicaid or charity patients.

Financial/Cost:

The applicant has an average short-term position and a good long-term position. Funding is likely to be available as needed. Financial feasibility is possible should the applicant’s assumptions regarding utilization be realized.

Architectural:

The food preparation area in the basement is located near three service elevators which open to the second floor at an area remotely located from the dining area. These elevators also serve the surgical suite. Public elevators terminate directly in the kitchen and food preparation area of the building. The egress from the assembly space on the second floor may pose life safety problems. There is an extended dead-end corridor on the second floor.

The applicant states the construction will conform to all current applicable building codes. There are some problems associated with the vertical egress from the building and some circulation code problems in the building, but these could be resolved within the building as designed. The applicant states the site is not within the 100-year flood plain or the category 3 surge inundation areas and has taken into consideration the hurricane requirements.

The construction cost per square foot and per patient bed is much higher than other applicants recently reviewed and may have to do with the construction of a parking structure and the remote central energy plant. Another factor may be the facilities plan for LEED certification, which often results in higher initial costs.

G. RECOMMENDATION:

Deny CON #9939.
AUTHORIZED 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