STATE AGENCY ACTION REPORT
ON APPLICATION FOR CERTIFICATE OF NEED

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

University of Miami/CON #10041
University of Miami Hospital & Clinics
1475 North West 12th Avenue, Suite 4037
Miami, Florida 33136

Authorized Representatives: Mr. Michael Gittelman, Administrator
(305) 243-4382

2. Service District/Subdistrict

There are presently two operational adult bone marrow transplantation programs in Organ Transplant Service Area 4, which includes the following service areas: Districts 10 and 11; Collier County only (in District 8) and Palm Beach County only (in District 9).

B. PUBLIC HEARING

A public hearing was not held or requested. However, letters of support were received by the Agency for Health Care Administration (the Agency) and were submitted by the applicant proposing to establish a new adult bone marrow transplantation program, as discussed below.

Letters of Support

A total of 26 unduplicated letters of support were received to promote the project. Of the 36 letters, all were signed with 24 having a December 2008 date. The support letters are briefly described below in the following sequence: University of Miami president and board of governors (four letters); University of Miami/Miller School of Medicine staff physicians (10 letters); non-University of Miami/Miller School of
Medicine staff physicians (four letters); a University of Miami/Miller School of Medicine registered nurse (RN) [one letter]; community support (three letters) and current/former patients or family members (four letters).

University of Miami President Donna Shalala, PhD, offered her support, stating that University of Miami/Miller School of Medicine’s Sylvester Comprehensive Cancer Center is South Florida’s only university-based cancer center. Joan Scheiner, Chair, Board of Governors and Jayne Malfitano, President and Vice-Chair, Board of Governors, Sylvester Comprehensive Cancer Center, along with Board Member Richard Morgan, Managing Partner-South Florida Offices, Buchanan Ingersoll & Rooney, P.C., all offered their support. These board members generally state the advantage to patients of being able to seek treatment locally. In addition to being a board member, Mr. Morgan advised he is also chair of Friends for Sylvester1.

The following 10 physicians and one registered nurse (RN) identified themselves as University of Miami/Miller School of Medicine staff and support the project: Marc Lippman, MD, Chair, Department of Medicine (and medical oncologist); Pascal Goldschmidt, MD, Senior Vice President for Medical Affairs and Dean; W. Jarrad Goodwin, MD, FACS, Director, Sylvester Comprehensive Cancer Center; Joseph Rosenblatt, MD, Director of Clinical and Translational Research, Sylvester Comprehensive Cancer Center and Chief, Hematology/Oncology; Gerald Byrne, Jr., MD, Professor of Pathology and Director of Hematopathology; Alan Pollack, MD, PhD, Chair, Radiation Oncology and Associate Director, Community Professional Relationships; John Byrnes, MD, MBA, FACP, Professor of Medicine and Chief of Hematology and Medical Oncology, Miami VA Medical Center; Mark Goodman, MD and Interim Director, Sylvester Comprehensive Cancer Center (two years ending May 2008); M. Escalon, MD, MS (Sylvester Comprehensive Cancer Center resident and attending physician); Denise Pereira, Assistant Professor of Clinical Medicine and Anne Smith, RN, OCN, MBA, Associate Administrator of Clinical Services & Chief Nursing Officer.

The common themes described by these practitioners are as follows: challenges to expand the existing adult bone marrow transplantation program at Jackson Memorial Hospital; exceptional transplantation services between the combined efforts of University of Miami and Jackson Memorial, the challenges to patients that must seek care

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1 Friends for Sylvester is a foundation that raises unrestricted funds directed to one of Sylvester’s priority research areas - breast cancer, prostate cancer, immunotherapy, therapeutics, and psychosocial oncology.
elsewhere (outside the area) due to existing limitations at Jackson Memorial, and a large elderly population in the South Florida area likely to be in need of adult bone marrow transplantation due to cancers that are more responsive to bone marrow transplant treatment. There is also comment that the current University of Miami/Jackson Memorial Hospital transplant team has more innovative, state-of-the art and cutting-edge research transplantation options that will improve care and survival rates. Many of the physician letters highly honor and respect Krishna Komanduri, MD, (formerly of University of Texas/MD Andersen Cancer Center) but now Director, Adult Stem Cell Transplant Program and Professor of Medicine, Microbiology and Immunology, University of Miami/Miller School of Medicine as a world leader in innovative bone marrow transplantation research, practice and treatment. While many of these physicians advise that many or a large number of patients must seek bone marrow transplantation services elsewhere due to local challenges that they believe would be resolved if the project is approved, none provide a probable or likely estimate of the number of patients that are negatively impacted by the existing Transplant Service Area 4 adult bone marrow transplantation service arrangement.

Four non-University of Miami/Miller School of Medicine physicians support the project and they are as follows: Roger Brito, DO, President, Hematology and Medical Oncology of Southern Palm Beach County; Humberto Caldera, MD, Hematologist/Oncologist, Hematology/Oncology Associates (a seven physician group in Palm Beach County); Harry Aldrich, MD. and Lawrence Negret, MD. Dr. Brito indicates he is the senior partner of four board-certified oncology physicians, trained at the University of Miami Miller School of Medicine as an internal medicine resident and treated bone marrow patients as a Fellow at the University of Texas MD Andersen Cancer Center. Dr. Brito states that project approval would provide sufficient capacity so that patients could have access to needed services in less than an hour drive away (Dr. Brito did not state an estimate of the number of patients in his group that currently are negatively impacted by the existing bone marrow transplantation arrangement in Transplant Service Area 4). Dr. Caldera advised he received his hematology/oncology training at University of Miami and has a sub-specialty in blood and marrow transplantation from the University of Texas, MD Andersen Cancer Center. He (Dr. Caldera) states he knows about the “severe space limitations” for the bone marrow program at Jackson Memorial; he also states his group has had to send “many” applicable patients to other locations, both in Florida and elsewhere (Dr. Caldera did not state the number of patients referred to other locations or that are unable to receive needed services locally).
Dr. Aldrich advises that particularly in South Florida, Hispanic and/or African American patients are traditionally underrepresented in applicable donor registries and that umbilical cord blood (consistent with the project) should help alleviate this challenge for ethnic minorities. Dr. Negret states that he is in private practice but is a former trainee at Sylvester Comprehensive Cancer Center. Dr. Negret states that he has a large number of patients with hematological disorders and tries to refer them locally but is aware that space is limited at Jackson Memorial.

Greater Miami Chamber of Commerce President/CEO Barry Johnson offered his support, stated project approval would open additional space and allow for quicker response to patients in the earlier stages of their diseases and offer more options for older patients, in what Mr. Johnson stated to be the seventh largest metropolitan statistical area in the United States. Julie Kornfeld, MPH, Cancer Information Service Program Director, National Cancer Institute, CIS-Coastal Region and Tutsie Lipkin, President, Papanicolaou Corps for Cancer Research, Inc. also gave their support.

To summarize comments by four current/former patients/family members who have received bone marrow transplantation services in the area, it is stressed there is value in having treatment available locally rather than the challenges and pitfalls of obtaining it distantly.

**Letters of Opposition**

The Agency received one timely letter of opposition to this project, from Marvin O’Quinn, Emeritus President and CEO, Jackson Health System, Public Health Trust. Mr. O’Quinn states that Jackson Health System is home to the Miami Transplant Institute (the Institute) and is affiliated with the University of Miami Leonard M. Miller School of Medicine (University of Miami/Miller School of Medicine) and already operates a bone marrow program. He contends that approval would negatively impact quality at the existing program. Mr. O’Quinn asserted that project approval would dilute limited patient volume, cannibalize or otherwise strain staffing resources and potentially undermine a healthy payer mix at Jackson Memorial Hospital. He states that Jackson Health System’s transplant team performed 971 transplants with 40 being bone marrow transplants last year and during calendar years 2005-2007 performed 159 adult bone marrow transplants\(^2\). Jackson Health System plans to upgrade and expand its six-bed bone marrow transplant unit to 25 beds and has already undertaken joint recruiting efforts with the

\(^2\) Agency utilization data for the 12 months ending June 2008, confirm 40 adult bone marrow transplants at Jackson Memorial and during CY 2005-2007, Jackson had 149 total bone marrow transplants.
Miller School to recruit a nationally known transplant surgeon to lead the program, according to Mr. O'Quinn. He also states that Jackson seeks to maintain current quality levels while building thereon through facility and staffing development which it has made financial investments in, with plans for future investment in the near future. Mr. O'Quinn states that Jackson Health System spends approximately half a billion dollars annually for Miami-Dade residents who cannot afford health care and that approval to add a duplicative transplantation program would immediately decrease patient volume and revenues and negatively impact the Public Health Trust. There is concern that the project could “cherry pick” cases of interest, especially if there are no requirements that the project support charity care. Mr. O'Quinn concludes that there is not enough volume to warrant an additional program.

C. PROJECT SUMMARY

The applicant seeks approval for an adult autologous and allogeneic bone marrow transplantation program at the University of Miami Hospital & Clinics in Miami, Florida, Transplant Service Area 4. The hospital’s licensed bed compliment is to rise from 40 to 58 (18 additional beds), with 12 of the beds dedicated to the project. Because of the existing interrelationship between Jackson Memorial and the applicant, the project is stated to be an expansion of the existing program and physically proximate to Jackson Memorial. The applicant states the following five reasons justify the project: limitations within the physical plant at Jackson Memorial that inhibit the numbers and types of adults receiving bone marrow transplants; expansion of the hematology and oncology programs at the University of Miami; dedication of resources to hematology and oncology programs at the University of Miami with emphasis on bone marrow transplantation; reduced access and availability for patients to bone marrow transplants within Transplant Service Area 4 and as a consequence out-migration for care and a reduction in the numbers of bone marrow transplants performed and enhancements and that improvements in bone marrow transplants directly impact survival rates. The project includes 12 private inpatient rooms at the University of Miami Hospital & Clinics site.

The adult bone marrow transplantation program, if approved, is to be operational by January 1, 2011, with a project cost total of $10,678,362. The project involves 1,875 gross square feet (GSF) of new construction and 11,691 GSF of renovation at a construction cost of $3,617,060.
The applicant proposes to condition the project to the specific location being the University of Miami Hospital & Clinics, to provide adult bone marrow transplantation to at least one charity care patient per year and to 9.5 percent of the program’s total patient days being provided to Medicaid patients.

The applicant understands that conformance with any and all conditions require demonstration by submitting an annual report to the Agency for each calendar year. The applicant agrees to provide the required annual report.

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 meet the review criteria.

Section 59C-1.010(2) (b), Florida Administrative Code, allows no application amendment information subsequent to the application being deemed complete. The burden of proof to entitlement of a certificate rests with the applicant. As such, the applicant is responsible for the representations in the application. This is attested to as part of the application in the Certification of the Applicant.

As part of the fact-finding, the consultant, Steve Love analyzed the application in its entirety with consultation from the financial analyst Felton Bradley, who evaluated the financial data and consultation from 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; applicable rules of the State of Florida, Chapter 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?  Or does the project proposed seek beds or services in excess of the fixed need pool?  Rule 59C-1.008(2), Florida Administrative Code.

   There is no fixed need pool publication for adult bone marrow transplant programs. Therefore, it is the applicant’s responsibility to demonstrate the need for the project, including a projection of the expected number of adult bone marrow transplants that will be performed in the first years of operation.

   There are presently two operational adult bone marrow transplant programs in Transplant Service Area 4. As noted at the beginning of this review, Transplant Service Area 4 includes Districts 10 and 11 and also Collier County only (in District 8) and Palm Beach County only (in District 9).

   Data reported to the Agency for the most recent reporting period, July 1, 2007 through June 30, 2008 show the following adult bone marrow transplant utilization data:

<table>
<thead>
<tr>
<th>Hospital</th>
<th>OTSA*</th>
<th>District</th>
<th>Total Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shands at Univ. of FL</td>
<td>1</td>
<td>3</td>
<td>150</td>
</tr>
<tr>
<td>St. Luke’s Hospital/Mayo Clinic*</td>
<td>1</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>H. Lee Moffitt Cancer Center</td>
<td>2</td>
<td>6</td>
<td>270</td>
</tr>
<tr>
<td>Florida Hospital-Orlando</td>
<td>3</td>
<td>7</td>
<td>38</td>
</tr>
<tr>
<td>Good Samaritan Medical Center</td>
<td>4</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>Jackson Memorial Hospital</td>
<td>4</td>
<td>11</td>
<td>40</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>538</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs published October 3, 2008.


Note: *OTSA is Organ Transplant Service Area as defined in Rule 59C-1.044(2)(f) F.A.C.

   It is noted that for the period only two procedures were performed at Good Samaritan Medical Center, while 40 were performed at Jackson Memorial.
Adult Bone Marrow Transplantation Facilities
Mileage Chart Including Applicant

<table>
<thead>
<tr>
<th>Facility/Transplant Service Area (TSA)</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shands Hospital at UF (TSA 1)</td>
<td>110</td>
<td>119</td>
<td>119</td>
<td>110</td>
<td>150</td>
<td>608</td>
</tr>
<tr>
<td>Mayo Clinic/St. Luke’s Hosp. (TSA 1)</td>
<td>28</td>
<td>34</td>
<td>27</td>
<td>43</td>
<td>38</td>
<td>170</td>
</tr>
<tr>
<td>H. Lee Moffitt Cancer Center (TSA 2)</td>
<td>163</td>
<td>204</td>
<td>235</td>
<td>270</td>
<td>270</td>
<td>1,142</td>
</tr>
<tr>
<td>Florida Hospital-Orlando (TSA 3)</td>
<td>32</td>
<td>45</td>
<td>39</td>
<td>29</td>
<td>38</td>
<td>183</td>
</tr>
<tr>
<td>Good Samaritan Medical Center (TSA 4)</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Jackson Memorial Hospital (TSA 4)</td>
<td>49</td>
<td>47</td>
<td>53</td>
<td>48</td>
<td>40</td>
<td>237</td>
</tr>
<tr>
<td><strong>State Total</strong></td>
<td>386</td>
<td>449</td>
<td>478</td>
<td>502</td>
<td>538</td>
<td>2,353</td>
</tr>
</tbody>
</table>


The above chart shows that there is distance of less than a mile between the applicant and Jackson Memorial Hospital. The applicant and Jackson Memorial presently have a working relationship to provide bone marrow transplantation. The greatest single population concentration in Transplant Service Area 4 is Miami-Dade County. After Good Samaritan Medical Center, a low volume provider with limited services, the next nearest adult bone marrow transplantation facility is Florida Hospital-Orlando, at approximately 236.65 miles. The third nearest facility is H. Lee Moffitt Cancer Center & Research Institute (otherwise referenced as H. Lee Moffitt Cancer Center), at approximately 284.61 miles. The fourth nearest facility is Shands Hospital at the University of Florida, at approximately 336.54 miles and the most distant from Jackson Memorial is Mayo Clinic-Jacksonville, at approximately 344.46 miles.

Below is a five-year chart to account for adult bone marrow transplants over the time period.
Historic data also show for the five years ending June 30, 2008, H. Lee Moffitt Cancer Center & Research Institute maintained the highest volume of adult bone marrow transplantations of the seven facilities, followed by Shands at the University of Florida as next highest volume, then Jackson Memorial Hospital, then Florida Hospital-Orlando, then St. Luke’s Hospital/Mayo Clinic and the least volume was Good Samaritan Medical Center, which is the only provider that limits its services to autologous (the patient’s own cells) peripheral blood stem cell bone marrow transplant. National Marrow Donor Program data indicates that seven out of 10 bone marrow transplant patients have to look outside their family and use an unrelated donor. So, Good Samaritan’s program is expected to remain small. Again for the same period statewide, adult bone marrow transplantations trended upward each year, with H. Lee Moffitt Cancer Center being the only authorized provider that consistently provided more or the same number of these procedures each year.

The applicant notes that umbilical cord blood is a factor in improved survival rates among this patient population and that the applicant has staff and technology more conducive to successfully utilizing umbilical cord blood.

The chart below shows the improved life expectancy (one year survival) of unrelated transplant recipients at United States’ transplant centers, which has improved nearly 10 percent in just four years.

<table>
<thead>
<tr>
<th>Improved Survival with Unrelated Transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Year</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>2003</td>
</tr>
<tr>
<td>2006</td>
</tr>
<tr>
<td>2007</td>
</tr>
</tbody>
</table>


The National Marrow Donation Program also indicates that recent studies have demonstrated that unrelated donor transplant outcomes are now comparable to related donor transplant outcomes in several patient populations.

The applicant also comments on particular donor challenges associated with African-American and Hispanic patients who seek adult bone marrow transplantation. The National Marrow Donor Program has 90,000 cord blood units on its registry and notes that about 350 patients

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3 Source: [http://www.marrow.org](http://www.marrow.org) for the National Marrow Donor Program website.
are matched monthly and receive transplants but the search can be more challenging for patients from diverse racial and ethnic backgrounds. The applicant proposes a 76-page need argument (CON #10041, E.1 Need Analysis). The applicant presents itself as expanding and augmenting the bone marrow program at Jackson Memorial (due to the ongoing relationship and physical proximity between the two providers). The applicant advises its proposal expands space and resources, affords greater treatment flexibility, promotes greater research and physician training and also avoids the complications of travel and aftercare. However, Jackson Memorial indicates it plans to expand its existing six bed unit to 25 beds and that it is investing in upgrading the existing program.

It is stated that patient care will be improved and out-migration will be reduced (such as relatively appreciable out-migration to H. Lee Moffitt Cancer Center). The applicant states that of the 98 cases transplanted in CY 2007, 52 left the service area for the procedure. Agency data indicates that for the 12-month period ending June 30, 2008, 45 of 88 Transplant Service Area 4 residents, or approximately 51.14 percent, received bone marrow procedures in Service Area 4 facilities while the remaining 43 residents (approximately 48.86) received the procedures in other organ transplant service areas, primarily Transplant Service Area 3 (H. Lee Moffitt Cancer Center).

The applicant describes space limitations at Jackson Memorial (E.1. Need Analysis, page #4) and states that there is currently no outpatient management of transplant patients there. However, outpatient bone marrow transplant management does not require a CON and it is noted that the applicant has indicated to the Agency’s Hospital & Outpatient Services section that it will be providing outpatient bone marrow transplant services. There is an emphasis the project would enhance and promote expansion of the hematology and oncology programs at the University of Miami. According to the applicant the project would enhance nine shared research resources.

The applicant describes reduced access and availability for patients to bone marrow transplantation within Transplant Service Area 4 (E.1. Need Analysis, page #14). In the applicant’s Table 1-2, it is stated that for calendar year 2007, of the 98 Service Area 4 residents transplanted in Florida facilities, 52 left the service area for the procedure, 47 of these were performed at H. Lee Moffitt Cancer Center, with the Jackson Memorial program serving only 42. As stated above, Agency data indicates approximately 49 percent out-migration during the 12 months

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4 Ibid.
ended June 30, 2008. The applicant advises that advances in bone marrow research and practice are cutting edge, that such is the practice at the University of Miami and that Jackson Memorial lags in keeping up-to-date with research in this area. A support letter by the lead researcher in this area of study at the University of Miami, Krishna Komanduri, MD, supports this claim. Dr. Komanduri also noted that he treated “many” South Florida residents during his time at MD Anderson (Houston,Texas).

In its analysis of need, the applicant addresses three areas: cancer and the role of bone marrow transplantation in treatment and cure; population demographics with increased numbers of transplants for patients 50 years and older and quantification of need. This project would enhance and improve survival rates based on leading trend data (E.1. Need Analysis, page #24). The applicant advises that by 2014, Transplant Service Area 4 will have 6.4 million residents and that of these 5.0 million will be adults. The applicant finds that applicable cancers that are more responsive to successful bone marrow treatment warrant the project (E.1. Need Analysis, page #33).

Cancer and bone marrow transplantation in treatment and cure

The applicant states that autologous transplantation is most commonly used to treat relapsed hematological malignancies, including non-Hodgkin's lymphoma, Hodgkin's disease and multiple myeloma. Allogeneic transplantation is most commonly applied to treat high-risk and/or relapsed acute lymphoid and myeloid leukemia, chronic myeloid leukemia, and relapsed chronic lymphocytic leukemia and low grade lymphoma. Other diseases often treated with bone marrow transplantation include bone marrow failure states (including aplastic anemia), and marrow diseases likely to progress to acute leukemia and/or marrow failure (including myelofibrosis and myelodysplasia). While these hematological diseases constitute the indication for most autologous and allogeneic stem cell transplants, earlier studies have demonstrated feasibility and efficacy of bone marrow transplantation in the therapy of many primary solid tumors: neuroblastoma, demoplastics small round cell tumor, Ewing's sarcoma, and germ cell neoplasms and benign but life-threatening hematologic conditions like sickle cell anemia and thalassemia. In addition, there are congenital diseases which may or may not appear in the adult patient. Congenital diseases include lysosomal storage disorders, mucopolosaccharidoses, mucopolysaccharidoses, glycoproteinoses, Wolman's disease (acid lipase deficiency) and others.
The applicant cites the improving outcomes for acute myelogeneous or lymphoblastic leukemia, chronic myelogenous leukemia and aplastic anemia in patients who receive allogeneic bone marrow transplant. A study comparing long-term survival and late deaths after allogeneic transplantation found that for patients in the study who were free from the disease two years after transplantation had the probability of 89 percent for living for five more years with the disease probably cured. For those with aplastic anemia who underwent the procedure, the risk of death in the sixth year after transplantation was similar to that for the general population. Mortality was higher for those with acute lymphoblastic leukemia or chronic myelogenous leukemia and through the ninth year it was higher for those with acute myelogenous leukemia. However, mortality for this group of patients with these diseases many years after transplantation is still higher than it is for the normal population. The applicant also cites a National Marrow Donor Program study reporting 3,600 patients transplanted in 2007 averaging 300 per month in unrelated donor transplants, up from 3,200 in 2006. The growth is fueled by advances in matching and the numbers of registered individuals with the registry, which now has 6.9 million adult marrow and peripheral blood stem cell (PBSC) volunteers and more than 73,000 cord blood units (February 2008). Finding donor and matching are now faster and more efficient, with increased likelihood of finding a match. DNA-based tissue typing enables typing at a higher resolution, improvements in understanding of matching criteria and which HLA loci are most significant to outcomes improve survival.

The reviewer checked this website and found that there were 2,640 adult transplants in CY 2007 and approximately 3,400 in CY 2008. As previously stated, the site indicates that there are approximately 90,000 cord blood units on the registry as of February 5, 2009. Since 2004, the number of cord blood transplants facilitated by the National Donor Program has nearly doubled each year. It is indicated that it can take as little as a few weeks to as long as two months to find a donor or cord blood unit.

**Population Demographics**

The applicant states that the service area’s July 2007 adult population of 4,568,635 is projected to increase to 4,796,361 (year one of the project), and comprises approximately 31 percent of the state’s adult population. The following table shows the projected population growth from July CY 2007 to July 2011 (year one of the project).
The applicant provided a year by year projection through July 2014. The applicant next prepares an incidence rate per disease types based on CY 2007 data for each county in the service area. This data indicates that only 16 of the 98 (16.3 percent) bone marrow transplant cases were provided to patients over 65 years while 86 of the 490 (17.5 percent) state totals were provided to age 65 and over patients. The applicant indicates that with greater use of peripheral stem cells and cord blood; greater availability to this age group will occur. This is consistent with the National Donor Program trend citing use for patients 50 and older increasing.

Quantification of Need

The applicant applies the CY 2007 incidence rate to forecast adult cases by cancer type for CY 2011 for the service area and the state.

**Forecasted Adult Cases by Cancer in CY 2011 for Service Area 4 and State**

<table>
<thead>
<tr>
<th>Patient County in Service Area 4</th>
<th>Total 2011 Population</th>
<th>All Cancer</th>
<th>Leukemia</th>
<th>Non-Hodgkins</th>
<th>Hodgkins</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collier</td>
<td>366,458</td>
<td>2,347</td>
<td>36</td>
<td>89</td>
<td>11</td>
<td>2,212</td>
</tr>
<tr>
<td>Palm Beach</td>
<td>1,365,720</td>
<td>8,915</td>
<td>147</td>
<td>389</td>
<td>38</td>
<td>8,341</td>
</tr>
<tr>
<td>Broward</td>
<td>1,836,485</td>
<td>9,343</td>
<td>150</td>
<td>386</td>
<td>43</td>
<td>8,764</td>
</tr>
<tr>
<td>Miami-Dade</td>
<td>2,547,610</td>
<td>11,455</td>
<td>169</td>
<td>485</td>
<td>74</td>
<td>10,728</td>
</tr>
<tr>
<td>Monroe</td>
<td>78,962</td>
<td>423</td>
<td>8</td>
<td>16</td>
<td>2</td>
<td>397</td>
</tr>
<tr>
<td><strong>TSA 4 Total</strong></td>
<td><strong>6,195,235</strong></td>
<td><strong>32,483</strong></td>
<td><strong>510</strong></td>
<td><strong>1,365</strong></td>
<td><strong>168</strong></td>
<td><strong>30,442</strong></td>
</tr>
<tr>
<td>State Total</td>
<td>19,717,454</td>
<td>110,607</td>
<td>1,783</td>
<td>4,240</td>
<td>522</td>
<td>104,063</td>
</tr>
</tbody>
</table>

Source: CON Application #10041 page 39.

Note: The applicant’s table has Leukemia at 509, Non-Hodgkins at 1,364 and Hodgkins at 167 and others at 30,443 probably due to rounding.

The next step is to apply the state’s transplant rate by type of cancer to develop the rates for each category of cancer that may likely receive a transplant. The following table summarizes:
These rates are then applied to subsequent years. Incidence rates were held constant and the numbers of cases by cancer type inflated only by annual population growth rates from 2007 to the appropriate year. See the table on page 14 for the CY 2011 growth rates. For 2014 these were 3.03 percent for Collier, 1.70 percent for Palm Beach, 1.34 percent for Broward, 1.18 percent for Miami-Dade and -0.33 for Monroe Counties. Transplant Service Area 4 population for 2014 is projected to have a growth rate of 1.44 percent for the service area compared to 1.81 for the state.

The applicant estimates 35, 44, 52 and 60 bone marrow transplants for the first four years of operation, respectively (first year ending December 31, 2011). Approximately 50 percent are anticipated to be autologous transplants, using the patients own stem cells while approximately 40 percent are anticipated to be allogeneic, with about half using matched-related donor cells and about half matched-unrelated donor cells. The remaining 10 percent would account for other alternatives, such as cord blood transplants.

The applicant quantifies need by forecasting that in each of the first four years of operations (2011-2014), the applicant and Jackson Memorial will jointly range from 77 procedures (in 2011) to 120 (in 2014) [E.1. Need Analysis, page #40). These estimates would seem to be likely reasonable, especially if more applicable patients seek care within Transplant Service Area 4 as opposed to seeking it in other areas (such as H. Lee Moffitt Cancer Center, Transplant Service Area 2).

With Jackson Memorial expanding its existing bone marrow transplant program, with all of Transplant Service Area 4 having 50 bone marrow procedures in the 12-month period ending June 30, 2008, it is likely that the applicant’s estimates would compromise the likely payer mix and patient count at Jackson Memorial, in the near future, if it was not for the out-migration rate (43 such procedures being provided to Transplant Service Area 4 residents at non-Transplant Service Area 4 facilities for the year ending June 30, 2008). It appears that if the applicant’s estimates are realized and if demand trends continue upward statewide as they have for the past five consecutive years, the payer mix and
patient count at Jackson Memorial should not be markedly compromised. This is provided that applicable patients seek care at Transplant Service Area 4 bone marrow facilities.

The applicant shows that the payer can be a factor in bone marrow procedures (E.1 Need Analysis, page #35), concluding that Medicaid reimbursed for Service Area 4 residents at 11.2 percent compared to statewide at 8.4 percent. Agency data for CY 2007 shows 72 Service Area 4 bone marrow transplant discharges and 491 statewide for CY 2007 and that Medicaid and Medicaid HMO patient days accounted for 16.9 percent of Service Area 4’s total and 11.6 percent of Florida’s total. There were 1,594 patient days for the 72 service area patients (or an average daily census (ADC) of 4.36 patients) and 10,368 patient days (28.4 ADC) for the state. The applicant proposes to condition CON approval to Medicaid at 9.5 percent of its total bone marrow transplant patient days, which is below the service area and the state average.

The applicant summarizes its justification as follows. Growth will continue within the transplant service area, with almost one-third of the state’s adult population residing within the five counties. The incidence of cancers treated with bone and peripheral stem cell transplantation will continue to produce a need for treatment and cure. The service area residents’ profile of which cancers and other diseases are treated with transplantation differs somewhat from that of the state resident, with treatment for Hodgkin’s Disease more pronounced than for some of the other cancers. Older adults within the transplant service area experience reduced access to the procedure. The numbers of transplants performed within the transplant service area is low and as a result residents go outside the transplant service area for treatment. Broad cultural diversity within Transplant Service Area 4 means that a greater proportion of patients who lack matched related donors will be more likely to require alternative donor sources (including cord blood transplants) due to the known difficulty with obtaining matched unrelated registry donors for populations under-represented in national registries. The applicant states that currently, no alternative donor program (e.g., cord blood transplantation program) exists for adult transplant recipients in Transplant Service Area 4. There is no reason given as to why cord blood transplantation is not offered or cannot be offered within the current working relationship between Jackson Memorial and the applicant.
2. **Applications for the establishment of new adult allogeneic and adult autologous bone marrow transplantation program shall not normally be approved in a service planning area unless the following additional criteria are met (Note: the applicant’s response to allogeneic bone marrow transplantation also addresses autologous bone marrow transplantation when required, so we are not repeating those standards):**

   (a) **Adult Allogeneic Bone Marrow Transplantation Programs:**
   
   Adult allogeneic bone marrow transplantation programs shall be limited to teaching and research hospitals. Applicants shall meet the following requirements. (Rule 59C-1.044(9)(b) Florida Administrative Code).

   The applicant reports that University of Miami Hospital and Clinics is a teaching and research hospital, specializing in the care of cancer patients. The facility, while part of the University of Miami Hospital group is not a statutory teaching hospital. The applicant presents a detailed discussion of the University of Miami’s shared research resources that facilitate cancer research on pages 7-14 of the application.

   (1) **Applicants shall be able to project that at least 10 adult allogeneic transplants will be performed each year. New units shall be able to project the minimum volume for the third year of operation.**

   The applicant estimates 35, 44, 52 and 60 bone marrow transplants for the first four years of operation, respectively (first year ending June 30, 2011). Approximately 50 percent are anticipated to be autologous transplants, using the patient’s own stem cells while approximately 40 percent are anticipated to be allogeneic, with about half using matched-related donor cells and about half matched-unrelated donor cells. The remaining 10 percent would account for other alternatives, such as cord blood transplants. Therefore, the applicant anticipates exceeding the required 10 allogeneic and autologous transplants by the first year.

   (2) **A program director who is a board-certified hematologist or oncologist with experience in the treatment and management of adult acute oncological cases involving high dose chemotherapy or high dose radiation therapy. The program director must have formal training in bone marrow transplantation.**
The applicant advises the bone marrow program director will be Krishna Komanduri, MD. This physician is stated to have extensive experience in bone marrow transplantation and cases involving high dose chemotherapy and high dose radiation therapy, as Director of the Clinical Fellowship Program, Associate Director of Hematology/Oncology Fellowship Program, and Associate Professor of the Department of Stem Cell Transplantation, Division of Cancer Medicine at MD Anderson Cancer Center at the University of Texas. Per the applicant, Dr. Komanduri became certified by the American Board of Internal Medicine (ABIM) in 1994 and became certified by the ABIM in Medical Oncology and in Hematology in 1997. Dr. Komanduri’s extensive resume dated September 26, 2008 was included in the application’s Volume 3, Attachment 10.

(3) Clinical nurses with experience in the care of critically ill immuno-suppressed patients. Nursing staff shall be dedicated full time to the program.

The applicant reports that many of the current nursing staff at the University of Miami Hospital and Clinics are highly qualified in treating critically ill immune-suppressed patients. The applicant advises its planned adult bone marrow program manager/coordinator to be Peggy McNiece, RN, CHTC and that she has held this position since July 2008. Ms. McNiece is reported to be a licensed RN in Florida and Colorado, a National Marrow Donor Program Certified Hematopoietic Transplant Coordinator, American Health Association Basic Life Support Healthcare Provider, and is CITI Certified in clinical research at the University of Miami. Per the applicant, Ms. McNiece’s prior experience includes Adult and Pediatric Bone Marrow Transplant Case Manager at Johns Hopkins Hospital, Baltimore, MD; Allogeneic Blood and Marrow Transplant Coordinator, Rocky Mountain Blood and Marrow Transplant Program, Denver, CO and Blood and Marrow Transplant Coordinator, University of Colorado Hospital, Denver, CO. The application’s Volume 3, Attachment 10 includes Ms. McNiece’s resume.
(4) An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders. The team shall direct permanent follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications.

The applicant provides a summary table of 15 physicians as part of the interdisciplinary team. An additional member of the staff is listed as a Ph.D. Of these doctors, the applicant reports the following: 10 have hematology expertise; 11 have oncology and immunologic diseases expertise; 15 have neoplastic disease expertise (including with hematopoietic and lymphopoietic malignancies) and 13 have non-neoplastic disorders expertise. The application’s Volume 3, Attachment 10 includes resumes of these physicians.

(5) Inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant unit shall have a minimum of two beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders.

The project is stated to expand the existing 40-bed University of Miami Hospital and Clinics/Sylvester Comprehensive Cancer Center and thereby create the new bone marrow program. Eighteen total beds are proposed for addition, including 12 inpatient beds to serve the bone marrow program and a six-bed intensive care unit. Three of the six ICU beds will be dedicated to bone marrow patients and three dedicated to any cancer patients (whether bone marrow patients or other). All 12 inpatient rooms for the bone marrow program will be private rooms with private toilet rooms. Two of the 12 rooms are to be isolation rooms with separate anterooms containing a counter and scrub sink. The applicant advises these rooms will also have positive pressure, reverse isolation procedures and terminal high efficiency particulate aerosol filtration on air blowers.
All rooms will have full height partitions, sealed to the structure above, to prevent infections, as well as scrubbable floors, walls, ceilings, doors, windows, and curtains, per the applicant. Additional scrub sinks will be located outside the bone marrow patient rooms.

(6) **A radiation therapy division on-site which is capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. The division shall be under the direction of a board certified radiation oncologist.**

The applicant reports that Arnold Markoe, MD, Sc.D. Professor and Chairman Emeritus, Department of Radiation Oncology, University of Miami/Miller School of Medicine will direct the program. The applicant advises this physician is certified by the American Board of Radiology and has held his current position since 1996. In addition to the listed chairmanship, Dr. Markoe is stated to be Attending Physician at the University of Miami Hospital and Clinics, Jackson Memorial Hospital, Anne Bates Leach Eye Hospital/Bascom Palmer Eye Institute, University of Miami Medical Group/University of Miami School of Medicine, and the Veterans Affairs Medical Center in Miami, Florida. The application’s Volume 3, Attachment 10 includes Dr. Markoe’s resume. The applicant advises its existing radiation therapy division on-site includes practitioners that provide sub-lethal x-radiation, bone marrow ablation, and total lymphoid irradiation. Further, the applicant reports that the most common forms of radiation include the following: external radiation; intensity modulated radiation therapy; three dimensional conformal radiation and high dose rate brachytherapy.

(7) **A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion, separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements.**

Per the applicant, this criterion will initially be accomplished by contractual arrangements but the applicant states plans for an on-site cell processing laboratory and by the fourth year of operation, construction of a new tissue-typing
laboratory. The laboratory will perform all processing of bone marrow, peripheral blood progenitor cell products and cord blood products that will be required and per the applicant, these procedures will include T cell depletion, separation of lymphocyte or hematopoietic subsets and removal to prevent graft-versus-host disease.

Dr. Ian McNiece, Professor of Medicine and Director of the Experimental and Clinical Cell Based Therapies Program, Interdisciplinary Stem Cell Institute, University of Miami, has agreed to be director and will assist in the design of the laboratory, per the applicant. The applicant includes a current and signed letter of intent from Dr. McNiece (Exhibit 2-12/Letter of Intent from Dr. Ian McNiece). Per the applicant, Dr. McNiece’s experience in cell therapy and hematopoietic progenitor cell processing for bone marrow transplantation includes five years as Director of the Cell Processing Laboratory at the bone marrow transplant program at Johns Hopkins University and five years at the bone marrow transplant program at the University of Colorado. This physician is also reported to have been a laboratory inspector for the Foundation for the Accreditation of Cellular Therapy for the past 10 years. The application’s Volume 3, Attachment 10 includes Dr. McNiece’s resume.

(8) **An on-site laboratory equipped for the evaluation and cryopreservation of bone marrow.**

The applicant addresses this criterion in item number (7) immediately above and in addition, states that the proposed laboratory will be equipped to provide cryopreservation and characterization of products. Until the new laboratory is constructed and in operation, the applicant advises the existing on-site laboratory will provide applicable services.

(9) **An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up.**

Per the applicant, the University of Miami Hospital and Clinics/Sylvester Comprehensive Cancer Center (also referenced as the Sylvester Comprehensive Cancer Center and Research Institute) is stated to be the research
The applicant offers a Protocol Review Committee Manual (Exhibit 2-13/Protocol Review Committee Polices and Procedures) and a list of ongoing research (Exhibit 2-14/Open Research Studies) to describe its commitment to this criterion. This commitment includes outcome monitoring and long-term patient follow-up.

(10) **An established research-oriented oncology program.**

The applicant indicates the 240 physicians and scientists at the University of Miami Hospital and Clinics/Sylvester Comprehensive Cancer Center are involved in cancer care and research, grouped into four multidisciplinary research programs, as follows: biobehavioral oncology and cancer epidemiology; molecular targets and developmental therapeutics; tumor immunobiology and immunotherapy and viral oncology. The applicant previously described related ongoing research (Exhibit 2-14/Open Research Studies).

(11) **A patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence.**

The applicant reports a support services division, responsible for monitoring and improving patient and guest satisfaction. Support services departments include environmental services, food and nutrition services, the information center, parking and valet services, and patient relations, among others, per the applicant. A visitor information center is reported, providing patients and guests with information on local hotels, restaurants, public transportation, directions and maps.

According to the application, the hospital has arrangements for extended stays and has negotiated rates for patients along with negotiated rates with area car rental companies. Exhibit 2-15 includes the pamphlet entitled ‘Patient & Guest Accommodations 2008’ which describes these arrangements.

(12) **An outpatient unit for close supervision of discharged patients.**

According to the applicant, the existing outpatient unit of the hospital is being expanded to accommodate the bone marrow
program. The outpatient unit is stated to be used for infusion, extraction analysis and research, as well as follow-up examinations. A planned first floor expansion will provide the outpatient exam rooms for the bone marrow transplant program, with family and general waiting areas and a central registration area for follow-up visits. On the second floor, renovations are stated to include an 11-station infusion unit that will include the following: a central nursing station; toilet room; nourishment station; clean supply room; soiled holding room and equipment storage room. It will be located adjacent to the existing Cancer Treatment Unit (CTU), which has 13 treatment rooms. The two CTU rooms adjacent to the Infusion Unit will be converted to dual use as cell extraction rooms, per the applicant, and a cell therapy process room, blood bank, T.B. lab and clinical research lab will also be provided.

2. Agency Rule Criteria

Chapter 59C-1.044, Florida Administrative Code, contains criteria and standards by which the department is to review the establishment of organ transplantation programs under the certificate of need program. Appropriate areas addressed by the rule and the applicant’s responses to these criteria are as follows:

a. Coordination of Services. Chapter 59C-1.044(3), Florida Administrative Code. Applicants for transplantation programs, regardless of the type of transplantation program, shall have:

1. Staff and other resources necessary to care for the patient’s chronic illness prior to transplantation, during transplantation, and in the post-operative period. Services and facilities for inpatient and outpatient care shall be available on a 24-hour basis.

The applicant has staff and other resources to provide both inpatient and outpatient services on a 24-hour basis at its existing 40-bed facility, including: pharmacy; respiratory; nursing; infusion; cardiology; ambulatory; radiation oncology; evaluation and treatment; laboratory; food; clinical nutrition; Courtelis Center (addressing psychosocial oncology) and imaging. The applicant indicates that the existing hospital provides inpatient and outpatient care, research facilities and support services for 15
multidisciplinary site disease groups, including a group for leukemia, lymphoma and myeloma. The applicant states intentions of serving as an extension of the program at Jackson Memorial Hospital.

2. **If cadaveric transplantation will be part of the transplantation program, a written agreement with an organ acquisition center for organ procurement is required.** A system by which 24-hour call can be maintained for assessment, management and retrieval of all referred donors, cadaver donors or organs shared by other transplant or organ procurement agencies is mandatory.

This is not applicable to bone marrow transplantation programs.

3. **An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required.**

The applicant advises that the facility will undergo renovation and expansion for the 18-bed adult transplant project to include a new six-bed ICU on the second floor, with three of the six beds dedicated to adult bone marrow transplantation patients and three for any cancer patients at the hospital. It is stated the ICU will include prolonged reverse isolation. The applicant anticipates that most bone marrow patients will remain in reverse isolation-equipped private rooms on the fourth floor but can be moved to the ICU, if necessary.

4. **A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate.**

The applicant states a bone marrow transplant clinical review committee will meet weekly and review candidates for adult bone marrow transplant, indicating that the committee will be comprised as follows: a chairman (Krishna Komanduri, MD); a four-physician bone marrow transplant physician staff; a three-physician and one advanced registered nurse practitioner [ARNP] staff and a six-member support staff (some licensed medical staff and some non-licensed). A determination of candidate selection is based on
a consensus by the medical team. A pre-bone marrow transplant work-up is also conducted for anticipated candidates set within the following 14 days. Potential candidates are initially presented by the bone marrow transplant coordinator and the bone marrow transplant attending physician.

5. **Written protocols for patient care for each type of organ transplantation program including, at a minimum, patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and immediate post-discharge phases of the program.**

The applicant provides a detailed discussion of the applicable protocols and states it will follow the guidelines developed by the National Marrow Donor Program (NMDP) and the American Society for Blood and Marrow Transplantation (ASBMT).

6. **Detailed therapeutic and evaluative procedures for the acute and long-term management of each transplant program patient, including the management of commonly encountered complications.**

The applicant describes acute and long-term management of patients, with typical and atypical complication and regimens. Both acute and chronic graft-versus-host disease is discussed, with effects on the patient, likely time of on-set, signs and symptoms, nursing management, diagnostic tools and medical treatment. The applicant’s description of the applicable therapeutic and evaluative procedures demonstrates that it is prepared to manage any complications.

7. **Equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is necessary. This requirement may be met through an agreement with an organ procurement agency.**

This is not applicable to bone marrow transplantation programs.
8. **An on-site tissue-typing laboratory or a contractual arrangement with an outside laboratory within the State of Florida, which meets the requirements of the American Society of Histocompatibility.**

The applicant states its Department of Pathology will contract with a licensed and fully qualified laboratory during start-up and early years until volumes reach a level where the HLA-matching can be done within the University of Miami laboratory. However, the applicant does not provide a letter of commitment from an applicable laboratory to provide tissue-typing.

9. **Pathology services with the capability of studying and promptly reporting the patient’s response to the organ transplantation surgery, and analyzing appropriate biopsy material.**

The applicant states that it will use the University of Miami’s existing histopathology laboratory to process biopsy materials. Exhibit 2-6 includes a letter from Mehrdad Nadji, MD, Interim Chairman of Pathology and Merce Jorda, MD, PhD, Chief of Laboratory Services which states their commitment to provide an on-site tissue-typing laboratory or to have a contractual agreement with an outside laboratory within Florida.

10. **Blood banking facilities.**

The applicant advises it is in the process of creating a blood bank, which will be directed by Sherry Shariatmadar, MD, who is currently the consultant for the blood bank at the University of Miami. According to the applicant, Dr. Shariatmadar is board-certified in blood banking transfusion medicine and an Associate Professor at the University of Miami/Miller School of Medicine. Dr. Shariatmadar is stated to have over 10 years of experience in blood banking, transfusion medicine, stem cell collection, processing and cryopreservation. Dr. Shariatmadar’s resume is included in Volume 3 of the application.

The applicant states it has contracts with Community Blood Centers of South Florida to provide blood and blood products to the bone marrow program.
11. **A program for the education and training of staff regarding the special care of transplantation patients.**

The applicant advises that the educational coordinator for the existing hospital is to assist the bone marrow team in developing applicable education materials and curriculum for patients and their families. Major program components are stated as follows: nursing orientation; oncology education (including, among others, a bone marrow series component and a nine part end-of-life series component) and a preceptorship program. There is also a description of a four part lecture series by Dr. Krishna Komanduri, Director, Bone Marrow Transplant Program and Peggy McNiece, Adult Bone Marrow Transplant Program Manager/Coordinator. The applicant provides applicable in-service training materials in Exhibit 2-8.

12. **Education programs for patients, their families and the patient's primary care physician regarding after-care for transplantation patients.**

The applicant provides a 2006 blood and bone marrow transplant patient information manual by the National Marrow Donor Program-Office of Patient Advocacy in Exhibit 2-9. The applicant also advises patients are directed to the Cancer Information Service, Leukemia and Lymphoma Society and the International Myeloma Foundation. Other materials listed include a bone marrow newsletter, books, videos and audios.

The applicant states an applicable education curriculum will be developed for the hospital and educational topics prepared for the medical, clinical and nursing staff will be reviewed and presented, as appropriate, to patients and their families. The stated focus will be on the entire disease process, with attention to aftercare and outpatient guidelines.
b. **Staffing Requirements.** Applicants for transplantation programs, regardless of the type of transplantation program, shall meet the following staffing requirements. Chapter 59C-1.044(4), Florida Administrative Code.

1. A staff of physicians with expertise in caring for patients with end-stage disease requiring transplantation. The staff shall have medical specialties or sub-specialties appropriate for the type of transplantation program to be established. The program shall employ a transplant physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing (UNOS) June 1994. A physician with one-year experience in the management of infectious diseases in the transplant patient shall be a member of the transplant team.

The applicant identifies 21 physicians, most of whom are University of Miami/Miller School of Medicine staff, that are listed as part of the project. Some of the listed physicians are University of Miami/Miller School of Medicine staff and are as follows: Krishna Komanduri, MD, Bone Marrow Transplant Program Director; John Byrnes, MD, Chief, Hematology/Medical Oncology; Julio Baredo, MD, Director, Children’s Cancer Program and M. Beatriz Currier, MD, Medical Director, Courtelis Center for Psychosocial Oncology; Michele Ilene Morris, MD, Director, Immunocompromised Host Section, Division of Infectious Diseases; Phillip Ruiz, MD, PhD, Director, Immunopathology and Alan Pollack, MD, PhD, Professor and Chairman, Radiation Oncology. Seven of the 21 physicians listed are stated to have direct Jackson Memorial Hospital affiliation, these include the following: Peter Cassileth, MD; Merce Jorda, MD, PhD, Medical Director of Laboratory Services; Martha Kato, MD, FAPM, Director, Psychiatric Consultation Services; Gary Kleiner, MD, PhD; Marc Lippman, MD; Izidore Lossos, MD and Sherry Shariatmadar, MD. With seven physicians already affiliated with the transplant program at Jackson Memorial Hospital, this is reflective of the already interwoven coordination between the two facilities (the applicant and Jackson Memorial).

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2. **A program director who shall have a minimum one year formal training and one year of experience at a transplantation program for the same type of organ transplantation program proposed.**

The applicant provides an extensive description of its project director - Krishna Komanduri, MD., who also serves as the Director of the Adult Bone Marrow Transplant Program at Jackson Memorial Hospital. Dr. Komanduri arrived in July 2008 after a nine-year tenure at the University of Texas MD Anderson Cancer Center, where he was Director of the Clinical Fellowship Program, one of the few fellowship programs dedicated to training oncologists and hematologists in all aspects of bone marrow transplantation. The applicant includes Dr. Komanduri’s resume (Vol. 3 – Tab 10/Additional Information, Physicians).

3. **A staff with experience in the special needs of children if pediatric transplantations are performed.**

This criterion is not applicable. The application is for an adult bone marrow transplantation program.

4. **A staff of nurses, and nurse practitioners with experience in the care of chronically ill patients and their families.**

The applicant states its existing operations include a site disease group of nurses, comprehensive treatment unit nurses and a range of inpatient nursing services, with practitioner staff experienced in caring for chronically ill patients and their families. The applicant names 13 registered nurses and one advanced registered nurse practitioner the applicant advises will serve the planned bone marrow program. The applicant states all these practitioners are current University of Miami Hospital and Clinics staff.
5. **Contractual agreements with consultants who have expertise in blood banking and are capable of meeting the unique needs of transplant patients on a long-term basis.**

The applicant advises it is in the process of creating a blood bank, which will be directed by Sherry Shariatmadar, MD, who is currently said to be the consultant for the blood bank at the University of Miami. According to the applicant, Dr. Shariatmadar is board-certified in Blood Banking Transfusion Medicine and an Associate Professor at the University of Miami/Miller School of Medicine. Dr. Shariatmadar is stated to have over 10 years of experience in blood banking, transfusion medicine, stem cell collection, processing and cryopreservation.

The applicant states it has contracts with Community Blood Centers of South Florida to provide blood and blood products.

6. **Nutritionists with expertise in the nutritional needs of transplant patients.**

The applicant indicates it has nutrition consultants to provide customized nutrition information on the bone marrow unit and cites the expertise of Karen Rzad, registered dietitian, Medical Nutrition Services Manager, University of Miami Hospital and Clinics. The applicant indicates Ms. Rzad has held this position since 2004 and is also a Certified Diabetes Educator, Insulin Pump Therapist, Stress Management Coach HeartMath®, and has completed the Living Healthy with Chronic Diseases, Stanford University Program. She is also stated to be an active member in the American Dietetic Association, the American Diabetes Association.

The applicant states that the dietician’s role on the bone marrow unit will include assessment of nutritional status, recommendations for total parenteral nutrition and oral feeding, documentation, and patient counseling and education.
7. **Respiratory therapists with expertise in the needs of transplant patients.**

The applicant provides inpatient respiratory therapy (RT) services. Its RTs are familiar with the respiratory services needs of those receiving aggressive treatment, particularly those patients experiencing immunosuppression, such as those suffering with pneumocystis carinii pneumonia and cytomegaviruses pneumonia. The applicant advises its staff is familiar with prompt and effective ventilator support, when needed. The applicant states that it will ensure that sufficient numbers of ventilators and respiratory staff are available to provide the necessary level of care to patients, if required. Per the applicant, its respiratory staff will receive in-service training on the latest in the management of patients undergoing bone marrow and peripheral stem cell transplantation, all in a team approach context. The applicant notes existing staff of Frederick F. Gillespie, RCP, CRT, CPFT, Director of Respiratory Care Services, University of Miami Hospital and Clinics (since 1990). In addition, the applicant notes pulmonary technologists Nick Marini, RRT, RPFT and Francisco L. Padron, RPFT.

8. **Social workers, psychologists, psychiatrists, and other individuals skilled in performing comprehensive psychological assessments, counseling patients, and families of patients, providing assistance with financial arrangements, and making arrangements for use of community resources.**

The applicant references its existing Courtelis Center for Psychosocial Oncology, consisting of what it describes as a multidisciplinary team of mental health professionals trained to identify and address the broad range of psychosocial needs of patients throughout the acute and chronic process of bone marrow transplantation. Per the applicant, the three phases of the bone marrow transplantation process includes pre-transplantation; hospitalization; and post-transplantation and that each phase highlights specific psychosocial variables and needs that are targeted in psychosocial assessment.
The applicant notes that professional staff at Courtelis Center, includes two psychiatrists, a nurse practitioner, a psychologist, five social workers, a chaplain, and an acupuncturist. The medical director, Beatriz Currier, MD, and the associate medical director, Martha Kato, MD are psychiatrists who are board-certified in psychiatry and the psychiatric subspecialty, psychosomatic medicine. Jeannette Garcia-Slanker, ARNP, Director of the Courtelis Center, is stated to have seven years of clinical experience with bone marrow patients. Elizabeth Thomas, Ph.D, is stated to have eight years of experience working with bone marrow patients. Rosa Caiseda, MSW is stated to have over 12 years of experience with bone marrow patients. The Courtelis Center psychosocial oncology multidisciplinary team is said to provide bone marrow psychosocial assessments, patient and family counseling, and coordinates the community resources for bone marrow patients, as needed.

c. **Data Reporting Requirements.** Chapter 59C-1.044(5), Florida Administrative Code states that facilities with organ transplantation programs shall submit data regarding each transplantation program to the agency or its designee twice a year. The first submission shall be by August 1 of each year, and shall cover the period between January 1 through June 30 of the same calendar year. The second submission shall be by February 1 of each year, and shall cover the period between July 1 through December 31 of the preceding year. The following data shall be provided for each type of organ transplanted.

1. The number of patients by county origin and zip code
2. The average gross revenue per admission.
3. The average length of stay.
4. Mortality rates

The applicant advises it cooperates fully with submitting applicable reporting requirements and will continue this practice.

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(1)(a) and (b), Florida Statutes.
Access

There are currently two adult bone marrow transplantation service provider in Transplant Service Area 4; these providers are Good Samaritan Medical Center (Palm Beach County) and Jackson Memorial Hospital (Miami-Dade County). Transplant Service Area 4 is comprised of the following counties: Miami-Dade and Monroe (District 11); Broward (District 10); Palm Beach (a portion of District 9) and Collier (a portion of District 8). Florida adult bone marrow transplant providers are located as follows: in Transplant Service Area 1 - Mayo Clinic and Shands at the University of Florida; in Transplant Service Area 2 - H. Lee Moffitt Cancer Center; in Transplant Service Area 3 – Florida Hospital/Orlando and Transplant Service Area 4 – Good Samaritan Medical Center and Jackson Memorial Hospital.

According to the Agency inpatient database for the 12-month period prior to the deadline of the current “other beds and service” batching cycle (July 2007 through June 2008), 479 of 507 (or 94.48 percent) of adult bone marrow transplants performed in authorized Florida hospitals were performed for Florida residents. Transplant Service Area 4 residents accounted for 88 of the 507 procedures, representing 17.36 percent of all DRG 009 [October 2007 through June 2008] and DRG 438 [July through September 2007] bone marrow procedures performed in authorized Florida hospitals. Forty-five (or approximately 51.14 percent) Transplant Service Area 4 residents received their transplants in Service Area 4. The remaining 43 residents, or approximately 48.86 percent received the procedures in other service areas, primarily Transplant Service Area 2 (H. Lee Moffitt Cancer Center treated 39 Service Area 4 residents).

The applicant estimates 35, 44, 52 and 60 bone marrow transplants for the first four years of operation, respectively. Approximately 50 percent are anticipated to be autologous transplants, using the patients own stem cells while approximately 40 percent are anticipated to be allogeneic, with about half using matched-related donor cells and about half matched-unrelated donor cells. The remaining 10 percent would account for other alternatives, such as cord blood transplants. It is likely that the applicant’s estimates would compromise the payer mix and patient count at Jackson Memorial in the near future, if it was not for the relatively substantial out-migration rate (43 such procedures being provided to Transplant Service Area 4 residents at non-Transplant Service Area 4 facilities for the year ending June 30, 2008). It appears that if the applicant’s estimates are realized and if demand trends continue upward, the payer mix and patient count at Jackson Memorial should not be markedly compromised.
The applicant proposes a 76-page need argument (CON #10041, E.1 Need Analysis). The applicant presents itself as expanding and augmenting the bone marrow program at Jackson Memorial (due to the ongoing relationship and physical proximity between the two providers). The applicant advises its proposal expands space and resources, affords greater treatment flexibility, promotes greater research and physician training and also avoids the complications of travel and aftercare. It is stated that patient care will be improved and out-migration will be reduced (such as relatively appreciable out-migration to H. Lee Moffitt Cancer Center). The applicant indicates its reasons for requesting the project, an analysis of the need, adverse impact and a description of itself. These are described below.

The applicant describes space limitations at Jackson Memorial (E.1. Need Analysis, page #4) and that there is currently no outpatient management of transplant patients there. There is an emphasis the project would enhance and promote expansion of the hematology and oncology programs at the University of Miami. According to the applicant the project would enhance nine shared research resources.

The applicant describes reduced access and availability for patients to bone marrow transplantation within Transplant Service Area 4 (E.1. Need Analysis, page #14). In the applicant's Table 1-2, it is stated that for calendar year 2007, that of 490 Transplant Service Area 4 residents that sought bone marrow procedures, only 48 received it in Transplant Service Area 4 and that this represents 9.8 percent of residents in the transplant service area that received these procedures, with 233 obtaining it at H. Lee Moffitt Cancer Center. The applicant advises that advances in bone marrow research and practice are cutting edge, that such is the practice at the University of Miami and that Jackson Memorial lags in keeping up-to-date with trending research in this area. A support letter by the lead researcher in this area of study at the University of Miami, Krishna Komanduri, MD, supports this claim.

Regarding adverse impact on existing Transplant Service Area 4 bone marrow transplantation providers, the applicant believes demand will be sufficient to maintain adequate demand to promote three programs (the applicant and the two existing bone marrow transplantation providers in the transplant service area). The applicant points out that neither existing provider's volume has grown over time and the applicant is replete with reference to cutting edge and trending research data that shows that bone marrow procedures are the only viable cancer cures in certain cancers and that the South Florida age growth rate is expected to place bone marrow treatment at an ever increasing rate of demand.
b. Does the applicant have a history of providing quality of care? Has the applicant demonstrated the ability to provide quality care? ss. 408.035(1)(c), Florida Statutes.

The applicant reports Florida licensure (Exhibit 2-1/University of Miami Hospital and Clinics License), accreditation by the Commission on Cancer (Exhibit 2-10/Accreditation from the Commission on Cancer) and the Joint Commission.

Agency complaint data indicates that the University of Miami Hospital and Clinics received 11 confirmed complaints and three confirmed complaints without deficiency for the three-year period ending January 28, 2009. The applicant’s complaint history is itemized below.

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<tr>
<th>Hospital Confirmed and Confirmed Without Deficiency Complaint Totals</th>
<th>University of Miami Hospital and Clinics</th>
<th>University of Miami Hospital and Clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complaint Category</td>
<td>Confirmed Total = 11</td>
<td>Confirmed W/O Deficiency Total = 3</td>
</tr>
<tr>
<td>Call Lights</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Emergency Access</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Lack of Assessment</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Nursing Service</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Patient Rights</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Physical Plant</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Plan of Care</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Pressure Sores</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: Agency for Health Care Administration Complaint Review Records

Other accreditations or certifications the applicant notes are with the American College of Surgeons, Commission on Laboratory Accreditation of the College of American Pathologists and radiology certifications.

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(1)(d) Florida Statutes

The financial impact of the project will include the project cost of $10,678,362 and year two incremental operating costs of $6,208,901.
The audited financial statements of the applicant for the periods ending May 31, 2007 and 2008 were analyzed for the purpose of evaluating the applicant’s ability to provide the capital and operational funding necessary to implement the project. The audit did not clearly separate current and non-current assets and liabilities. The Agency made estimates of the amounts of current and non-current assets and liabilities based on the notes in the audit.

**Short-Term Position:**
The applicant’s current ratio of 2.9 is well above average and indicates current assets are almost three times current liabilities, a strong position. The ratio of cash flows to current liabilities of 0.0 is well below average and indicates virtually no operating cash flow to cover current liabilities, a weak position. The working capital (current assets less current liabilities) of $1 billion is a measure of excess liquidity that could be used to fund capital projects. Overall, the applicant has an adequate short-term position. (See Table below).

**Long-Term Position:**
The ratio of long-term debt to net assets of 0.5 indicates long-term debt is less than equity. This is slightly lower than the Florida acute care hospital average and a good position. The ratio of cash flow to assets of 0.4 percent is well below average and illustrates a relatively low cash flow and is considered a weak position. In fiscal year end 2008 the applicant had $5 million in operating revenue in excess of expenses which resulted in a margin of 0.3 percent. Overall, the applicant has an adequate long-term position. (See Table below).

**Capital Requirements:**
Schedule 2 indicates the applicant has $44 million in capital projects. Schedule 2 did not include $22.2 million in maturities of long-term debt due prior to the completion of this project.

**Available Capital:**
The applicant indicates that funding for this project will be provided by cash on hand. Operating cash flows for the most recent year was $14.1 million and working capital is $147.3 million.

**Staffing:**
Currently, the applicant does not provide any transplant services and approval would result in a new product line. However, the applicant’s existing hospital has staff with expertise and experience regarding adult bone marrow transplantation and related skill and know-how. According to Schedule 6A, the applicant dedicates 11.0 FTEs for this project for
year one (ending December 31, 2011) and for each of the remaining three years (ending December 31, 2014).

**Conclusion:**
The applicant appears to have the financial resources necessary to fund this project and all capital projects listed on Schedule 2.

<table>
<thead>
<tr>
<th>CON Application 10041 - University of Miami</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>5/31/2008</strong></td>
</tr>
<tr>
<td>Current Assets</td>
</tr>
<tr>
<td>Cash and Current Investment</td>
</tr>
<tr>
<td>Board Designated Funds</td>
</tr>
<tr>
<td>Total Assets</td>
</tr>
<tr>
<td>Current Liabilities</td>
</tr>
<tr>
<td>Total Liabilities</td>
</tr>
<tr>
<td>Net Assets</td>
</tr>
<tr>
<td>Total Revenues</td>
</tr>
<tr>
<td>Interest Expense</td>
</tr>
<tr>
<td>Excess of Revenues Over Expenses</td>
</tr>
<tr>
<td>Cash Flow from Operations</td>
</tr>
<tr>
<td>Working Capital</td>
</tr>
</tbody>
</table>

**FINANCIAL RATIOS**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5/31/2008</strong></td>
</tr>
<tr>
<td>Current Ratio (CA/CL)</td>
</tr>
<tr>
<td>Cash Flow to Current Liabilities (CFO/CL)</td>
</tr>
<tr>
<td>Long-Term Debt to Net Assets (TL-CL/NA)</td>
</tr>
<tr>
<td>Times Interest Earned (NPO + Int/Int)</td>
</tr>
<tr>
<td>Net Assets to Total Assets (TE/TA)</td>
</tr>
<tr>
<td>Operating Margin (ER/TR)</td>
</tr>
<tr>
<td>Return on Assets (ER/TA)</td>
</tr>
<tr>
<td>Operating Cash Flow to Assets (CFO/TA)</td>
</tr>
</tbody>
</table>

d. **What is the immediate and long-term financial feasibility of the proposal?** ss. 408.035(1)(f), Florida Statutes.

A comparison of the applicant’s estimates to the control group values provides for an objective evaluation of financial feasibility, (the likelihood that the services can be provided under the parameters and conditions contained in Schedules 7 and 8), and efficiency, (the degree of economies achievable through the management skills of the applicant). In general, projections that approximate the median are the most desirable, and
balance the opposing forces of feasibility and efficiency. In other words, as estimates approach the highest in the group, it is more likely that the project is feasible, because fewer economies must be realized to achieve the desired outcome. Conversely, as estimates approach the lowest in the group, it is less likely that the project is feasible, because a much higher level of economies must be realized to achieve the desired outcome. These relationships hold true for a constant intensity of service through the relevant range of outcomes. As these relationships go beyond the relevant range of outcomes, revenues and expenses may either go beyond what the market will tolerate, or may decrease to levels where activities are no longer sustainable.

Comparative data were derived from hospitals in peer groups that reported data in 2007; the applicant will be compared to the hospitals in Peer Group 14 (Acute Care Specialty Hospital Group). The Agency also evaluated the projected cost of the bone marrow program on a stand-alone basis. Comparative data for the bone marrow program on a stand-alone basis were derived from hospitals with approved and operational bone marrow programs in 2007. Peer Group 14 has a total of 6 facilities including the facility where this project will be located. Per diem rates are projected to increase by an average of 3.5 percent per year. Inflation adjustments were based on the new CMS Market Basket, 3rd Quarter, 2008.

Gross revenues, net revenues, and costs were obtained from Schedules 7 and 8 in the financial portion of the application. These were compared to the control group as a calculated amount per adjusted patient day. In order to calculate adjusted patient days, the Agency needs a breakdown of inpatient and outpatient revenue. The applicant included this for the program only on Schedule 7A and for the hospital “without the project” in a supplementary schedule to Schedule 8A. The Agency noted that the hospital “without the project” revenue figures in the supplementary schedules were $13.2 and $14.3 million more than the “without the project” revenue on Schedule 8A for years one and two respectively. The expenses were off by the same amounts so the total margin was the same on Schedule 8A and the supplementary schedule. We decided to use the revenue figures in Schedule 8A for our analysis. Because 8A does not include a breakdown of inpatient and outpatient data, the Agency used the project only data on Schedule 7A and the “without the project” data in the supplementary schedules to calculate the adjustment factor. Based on this analysis adjusted patient days are projected at 52,747 in year one and 54,331 in year two.
Projected net revenue per adjusted patient day (NRAPD) of $5,214 in year one and $5,333 in year two is above the control group highest value of $5,076 in year one, and $5,218 in year two. (See Table below). Typically when net revenues per adjusted patient day fall above the highest values, the projected revenue are considered overstated. However, the applicant’s hospital had the highest NRAPD in the peer group in 2007. Since the applicant is adding a high acuity level service it would be expected that cost and revenue would increase slightly faster than inflation. The applicant’s NRAPD in fiscal year 2007 was reported as $4,349. The difference in the NRAPD reported in 2007 and the year two projected NRAPD of $5,333 results in an average compound annual increase of approximately 4.2 percent. This level of increase is greater than the inflation percentage outlined in the CMS Market Basket, 3rd Quarter, 2008, index. Net revenues appear to be slightly overstated.

Projected cost per adjusted patient day (CAPD) of $4,537 in year one and $4,678 in year two is between the control group median and highest values of $3,639 and $4,753 in year one, and $3,741 and $4,886 in year two. With CAPD between median and the highest in the peer group, costs are considered feasible. (See Table below). The applicant’s CAPD in year 2007 was reported as $4,073. The difference in the CAPD reported in 2007 and the year two projected CAPD of $4,678 results in an average compound annual increase of approximately 2.8 percent. This level of increase is below the inflation percentage outlined in the CMS Market Basket, 3rd Quarter, 2008, index. CAPD appear to be understated.

It should be noted that the transplant group data only includes inpatient costs. The applicant is projecting a significant level of outpatient costs. In order to compare the applicant’s projections to the group, the Agency calculated costs on an adjusted patient day basis utilizing an adjustment factor for the transplant program of 0.476. The year two projected CAPD for the transplant patients is $3,263. The incremental CAPD falls between the control group median and lowest values of $2,583 and $3,510. The projected cost appears efficient when compared to the group.
The applicant proposed a condition to provide 9.5 percent of its patient days for the project to Medicaid patients. In 2007 approximately 15 percent of the patient days in Organ Transplant Service Area 4 were Medicaid days. The applicant’s proposed condition appears achievable.

The year two operating profit for the hospital of $35.6 million computes to an operating margin per adjusted patient day of $655 (12.3 percent) which is well above the peer group’s highest value of $276. The applicant’s facility had the highest operating margin in the peer group. It should be noted that the Agency received this hospital’s 2008 operating results (via the FHURS report) which was reviewed and approved by the Financial Analysis Unit. The operating margin percentage in the 2008 fiscal year is consistent with the applicant’s projections. The project is expected to operate at a net loss for the first two years; however, this loss is not expected to have a materially negative impact to the hospital’s overall operations.

**Conclusion:**
This project appears to be financially feasible as part of the overall hospital operations.
### University of Miami

**CON Application #10041**

**2007 DATA  Peer Group 14**

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>Dec-12</th>
<th>YEAR 2 ACTIVITY</th>
<th>VALUES ADJUSTED FOR INFLATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td>Highest</td>
</tr>
<tr>
<td>Routine Services</td>
<td>289,768,307</td>
<td>5,333</td>
<td>2,446</td>
</tr>
<tr>
<td>Inpatient Ambulatory</td>
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<td>0</td>
<td>140</td>
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<tr>
<td>Inpatient Surgery</td>
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<td>0</td>
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<tr>
<td>Inpatient Ancillary Services</td>
<td>0</td>
<td>0</td>
<td>4,480</td>
</tr>
<tr>
<td>Outpatient Services</td>
<td>0</td>
<td>0</td>
<td>11,597</td>
</tr>
<tr>
<td>Total Patient Services Rev.</td>
<td>289,768,307</td>
<td>5,333</td>
<td>13,988</td>
</tr>
<tr>
<td>Other Operating Revenue</td>
<td>0</td>
<td>0</td>
<td>295</td>
</tr>
<tr>
<td><strong>Total Revenue</strong></td>
<td>289,768,307</td>
<td>5,333</td>
<td>14,043</td>
</tr>
</tbody>
</table>

| Deductions from Revenue           | 0       | 0               | 0       | 0      | 0      |

| **Net Revenues**                  | 289,768,307 | 5,333          | 5,218   | 3,922  | 2,342  |

<table>
<thead>
<tr>
<th>Expenses</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine</td>
<td>29,478,523</td>
<td>543</td>
<td>637</td>
<td>188</td>
<td>117</td>
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<tr>
<td>Ancillary</td>
<td>91,208,240</td>
<td>1,679</td>
<td>1,773</td>
<td>959</td>
<td>901</td>
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<tr>
<td>Ambulatory</td>
<td>3,222,893</td>
<td>59</td>
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<tr>
<td>Total Patient Care Cost</td>
<td>123,909,656</td>
<td>2,281</td>
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<td>Admin. and Overhead</td>
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<td>0</td>
<td>0</td>
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<tr>
<td>Property</td>
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<td>Total Overhead Expense</td>
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<td>2,571</td>
<td>1,782</td>
<td>1,034</td>
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<tr>
<td>Other Operating Expense</td>
<td>0</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Expenses</strong></td>
<td>254,183,224</td>
<td>4,678</td>
<td>4,886</td>
<td>3,741</td>
<td>2,293</td>
</tr>
</tbody>
</table>

| Operating Income                  | 35,585,083 | 655            | 276     | 98    | 52    |

| Patient Days                      | 9,615     | 12.3%          |
| Adjusted Patient Days             | 54,331    |                |
| Total Bed Days Available          | 21,170    |                |
| Adj. Factor                       | 0.1770    |                |
| Total Number of Beds              | 58        |                |
| Percent Occupancy                 | 45.42%    |                |

<table>
<thead>
<tr>
<th>Payer Type</th>
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<th>% Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self Pay</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Medicaid HMO</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Medicare</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Medicare HMO</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Insurance</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>HMO/PPO</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Other</td>
<td>9,615</td>
<td>100.0%</td>
</tr>
<tr>
<td>Total</td>
<td>9,615</td>
<td>100%</td>
</tr>
</tbody>
</table>
e. **Will the proposed project foster competition to promote quality and cost-effectiveness? ss. 408.035(1)(g), Florida Statutes.**

Competition to promote quality and cost-effectiveness is driven primarily by the best combination of high quality and fair price. Competition forces health care facilities to increase quality and reduce charges/cost in order to remain viable in the market.

This project is unique from other transplant applications in that an existing provider (Jackson Memorial Hospital) is less than one mile away from the applicant’s proposed program. Because of the close proximity of these two facilities, any consideration in choosing a provider based on location and or ease of physical access is mitigated. Transplant programs need to maintain a minimum level of procedures to remain proficient and ensure quality of outcomes. Therefore, these programs would need to attract a minimum number of patients. With the limits on price-based competition and the removal of location as a consideration, these two programs would likely have to focus on promoting increased quality to differentiate themselves from one another in order to attract patients.

**Conclusion:**
Although price-based competition for the transplant program is limited, the potential for provider-based competition exists in this case. The introduction of a new provider could lead to competition and reduce the current large out-migration of service area patients seeking adult bone marrow transplantation.

f. **Are the proposed costs and methods of construction reasonable? Do they comply with statutory and rule requirements? ss. 408.035(1)(h), Florida Statutes and Ch. 59A-3 or 59A-4, Florida Administrative Code.**

The applicant proposes to develop an adult autologous and allogeneic bone marrow transplantation program at University Hospital & Clinics, describing the new service as an expansion and augmentation of existing services at nearby Jackson Memorial Hospital. The program would be collaboration between University Hospital & Clinics and Sylvester Comprehensive Cancer Center.

The physical plant improvements required to accommodate the new program would be part of a larger expansion and renovation project that includes 14,400 square feet of new construction and 27,641 square feet of renovation, with 18 additional beds. Slightly over a quarter of the
construction would be for the new bone marrow unit. Part of the project would convert 30 semi-private rooms to private rooms. The applicant’s Schedule 9 indicates that the bone marrow transplantation project involves 1,875 GSF of new construction and 11,691 GSF of renovation at a construction cost of $3,617,060.

Although renovation work and addition would take place on all four floors of the hospital, only work on the second and fourth floor is directly related to the new bone marrow program. The second floor would house two procedure rooms and 11 infusion therapy stations. The procedure rooms would be used for extracting cells to be used in the process. Renovation would be made to the existing laboratory on the second floor for processing the extracted cells for both medical use and research. Additions and renovation would also take place on the fourth floor to create 12 new patient beds for inpatient bone marrow recipients. These rooms are generously sized and exceed minimum size requirements. It appears that some of the rooms will need to be modified to accommodate accessible toilet/shower rooms as required by Chapter 11 of the Florida Building Code. Also the narrative indicates that the patient rooms will have the capability of switching from a positive pressure environment to a negative pressure environment. This arrangement is prohibited by the AIA Guidelines for Design and Construction of Health Care Facilities (2.1-10.2.2.2(5)).

The schematic plans provide a partial list of applicable codes including the National Fire Protection Association, Life Safety Code and the Florida Building Code. Given the timeline, the project would be reviewed under more recent editions of many of the codes. A complete listing of applicable codes and dates of the codes will be required for future submissions.

The cost estimate for construction appears to be reasonable.

The schedule for construction from the time of building permit to final inspection is reasonable.

The design provides all of the functional spaces required for the patients and staff for the new program. Additionally the larger project would improve the physical plant of the hospital by providing spacious private rooms. Some modifications will be required to make at least 10 percent of the patient rooms and toilet/showers rooms accessible, but the generous room size will accommodate the necessary changes.
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 and propose the provision of health services to Medicaid patients and the medically indigent? ss. 408.035(1)(i), Florida Statutes.

The applicant reports its history of providing charity care. It states that from 2002 through 2006, its highest charity percentage was in 2003 (0.37 percent) and its highest Medicaid percentage for the period was in 2006 (4.98 percent).

Projected revenues on the applicant’s Schedule 7A indicate that operating year one would provide a payer mix of 4.8 percent self-pay and 12.6 percent combined Medicaid and Medicaid HMO. A total of 1.8 percent is “other payers”. A total of 17.4 percent is reached when self-pay, Medicaid and Medicaid HMO are combined. Combined, for remaining three years, these percentages change. Year one indicates a charity care deduction from revenue of $315,455 increasing to $328,108 for year two, $341,232 for year three and $354,882 for year four.

The applicant conditions approval to provide bone marrow transplantation for at least one charity care patient per year and to provide 9.5 percent of program’s total days to Medicaid recipients each year.

F. SUMMARY

University of Miami (CON #10041) proposes to establish an adult autologous and allogeneic bone marrow transplantation program in Organ Transplant Service Area 4 and is projected to have total project costs of $10,678,362, included in this figure are construction costs at $3,617,060 with $656,250 in new construction and renovation cost of $2,960,810. The project includes 1,875 GSF of new construction and 11,691 GSF of renovated space.

The applicant states that the project will expand and augment existing adult bone marrow transplantation services already operational at Jackson Memorial Hospital, due to its ongoing interwoven relationship with Jackson Memorial and the physical proximity between the two hospitals.
In weighing and balancing the review criteria, the following relevant factors are noted:

**Need**

There is no fixed need pool publication for adult bone marrow transplantation programs. It is the applicant’s responsibility to demonstrate the need for the project.

There are presently two adult bone marrow programs in Transplant Service Area 4 (Good Samaritan Medical Center [Palm Beach County] and Jackson Memorial Hospital [Miami-Dade County]).

The applicant estimates 35, 44, 52 and 60 bone marrow transplants for the first four years of operation, respectively (first year ending December 31, 2011). Agency database records for the 12-month period ending June 30, 2008 show a relatively high out-migration rate for patients seeking the service the applicant is proposing. Given existing demand for this transplantation service by Transplant Service Area 4 residents, the count of procedures of this transplantation service by existing Transplant Service Area 4 providers and the relatively high out-migration rate of Transplant Service Area 4 residents to non-Transplant Service Area 4 bone marrow transplant providers from June 2007 through July 2008 (with most out-migration to H. Lee Moffitt Cancer Center/Transplant Service Area 2), along with the likely anticipated South Florida elderly growth rate within the next several years, adequate demand is sufficient and proposed supply is reasonable enough to likely support the project.

The applicant provided data which indicates that 52 of the 98 service area residents or approximately 53.06 percent who received bone marrow transplantation in CY 2007, left the service area for the procedure. Agency data for the 12 months ending June 30, 2008, indicates that 43 of 88 or approximately 48.86 percent of the Transplant Service Area 4 residents that needed bone marrow transplant left the service area for the procedure.

The project will duplicate services that are in existence and that the applicant is a partner in providing. However, there is an argument supporting need for the project based on out-migration, medical advances and projected population growth. Jackson Memorial which is the current provider indicates that it will be expanding its program apparently in response to the concerns expressed by the applicant as Jackson’s program has averaged 47.4 procedures over the last five-year period ending June 30, 2008. The applicant provides utilization
projections that show its project will not match volume projected for Jackson until year four when both are projected to provide 60 procedures.

**Quality of Care**

The applicant reasonably demonstrated it met the rule requirements per Chapter 59C-1.044, Florida Administrative Code, with regard to the provision of quality of care for transplant programs and also demonstrated quality of care measures and appropriate policies and protocols to accommodate the proposed project.

Agency complaint data indicates that the University of Miami Hospital and Clinics received 11 confirmed complaints and three confirmed complaints without deficiency for the three-year period ended January 28, 2009.

**Cost/Financial Analysis**

The applicant has an adequate short-term and an adequate long-term position and overall appears to have the financial resources necessary to fund the project and all capital projects listed on Schedule 2.

This project appears to be financially feasible as part of the overall hospital operations and regarding the effect of competition, the existing regulatory environment and payment structure will likely have a greater impact than competition.

**Medicaid/Charity Care Commitment**

The applicant conditions to provide bone marrow transplantation for at least one charity care patient per year and to provide 9.5 percent (at a minimum) of the project’s total days to Medicaid recipients each year. Year one indicates a charity care deduction from revenue of $315,455 increasing to $328,108 for year two, $341,232 for year three and $354,882 for year four.

**Architectural Analysis**

Schedule 9 indicates that the bone marrow transplantation project involves 1,875 GSF of new construction and 11,691 GSF of renovation at a construction cost of $3,617,060.
Additions and renovation would also take place on the fourth floor to create 12 new patient beds for inpatient bone marrow recipients. The project narrative indicates the patient rooms will have the capability of switching from a positive pressure environment to a negative pressure environment. This arrangement is prohibited by the AIA Guidelines for Design and Construction of Health Care Facilities (2.1-10.2.2.2(5)).

The cost estimate for construction appears to be reasonable and the time of building permit to final inspection is reasonable.

G. **RECOMMENDATION**

Approve CON #10041 to establish an adult autologous and allogeneic bone marrow transplantation program at the University of Miami Hospital & Clinics in Miami, Florida, Transplant Service Area 4. The project involves a total project cost of $10,678,362. The project involves 1,875 gross square feet (GSF) of new construction and 11,691 GSF of renovation at a construction cost of $3,617,060.

CONDITIONS:

1. The applicant proposes to condition the project to the specific location being the University of Miami Hospital & Clinics.
2. Provide adult bone marrow transplantation to at least one charity care patient per year.
3. 9.5 percent of the program’s total patient days shall be provided to Medicaid patients.
AUTHORIZATION FOR AGENCY ACTION

Authorized representatives of the Agency for Health Care Administration adopted the recommendation contained herein and released the State Agency Action Report.

DATE: ____________________

__________________________________________
James B. McLemore
Health Services and Facilities Consultant Supervisor
Certificate of Need

__________________________________________
Jeffery N. Gregg
Chief, Bureau of Health Facility Regulation