

## State of New Hersev DEPARTMENT OF HEALTH

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MARY E. O'DOWD, M.P.H. Commissioner

May 4, 2015

## VIA UNITED PARCEL SERVICE

Leslie Hirsch President/Chief Executive Officer Saint Clare's Health System 25 Pocono Road Denville, New Jersey 07834

> Re: Transfer of Ownership -Saint Clare's Hospital Denville CN# FR 130701-14-01 Acquisition Cost: \$74,729,000

Expiration Date: May 4, 2020

Dear Mr. Hirsch:

I am approving your certificate of need (CN) application submitted on July 1, 2013, pursuant to N.J.A.C. 8:33-3.1, for the transfer of the ownership of St. Clare's Hospital Denville (St. Clare's Denville), a New Jersey non-profit corporation to Prime Healthcare Services - St. Clare's LLC (Prime St. Clare's), a Delaware Limited Liability Company. Prime Healthcare Services, Inc. (PHSI) is the sole member of Prime St. Clare's, as described in the corporate ownership structure presented in the application. For the purposes of this review, the application was deemed a transfer of ownership of a licensed facility currently offering health care services and not a reduction, elimination, or relocation of a health care service. A transfer of ownership of an entire general hospital is subject to the full CN review process. (N.J.A.C. 8:33-3.3(a)1). I evaluated this application for a transfer against standards set forth in statute (N.J.S.A. 26:2H-1 et seq.) and by administrative rule (N.J.A.C. 8:33). I am satisfied that the application submitted by Prime St. Clare's is consistent with those requirements. The application is being approved at the acquisition cost noted above.

This CN approval is limited to the transfer of ownership of St. Clare's Denville, a general acute care hospital with 306 beds. Categorically, the bed composition would continue to reflect 202 Medical/Surgical beds, 23 OB/GYN beds, 20 Pediatric beds, 19 Adult ICU/CCU beds, 20 Adult Open Acute Psychiatric beds, and 22 Adult Closed Acute Psychiatric beds. These 42 psychiatric beds are located at the St. Clare's Hospital-

Boonton campus. The hospital's service complement would include the existing 6 Inpatient Operating Rooms (ORs), 2 Same Day Surgery ORs, 1 Cystoscopy room, 1 Cardiac Catheterization laboratory for adults, Acute Hemodialysis services, 2 Linear Accelerators, 2 CT units, and 1 Fixed MRI unit. In addition, the hospital is committed to continuing its designations as both a Community Perinatal Center – Intermediate with 8 bassinets and a Primary Stroke Center.

St. Clare's Hospital-Boonton will be included in the transfer of ownership. Categorically, that hospital's bed composition would continue to reflect 16 Adult Intermediate Psychiatric beds, 28 Child/Adolescent Acute Psychiatric beds, 44 Inpatient Alcohol Detoxification beds and 16 Inpatient Drug Detoxification beds. There are a total of 146 psychiatric beds at St. Clare's Hospital-Boonton, inclusive of the 42 psychiatric beds which appear on the license of St. Clare's Denville.

Additionally, two hospital-based off site facilities, Saint Clare's Imaging Center at Parsippany and Saint Clare's at Sussex Ambulatory Care Facility, along with the Visiting Nurse Association of Saint Clare's, Inc., and two MRI facilities, Magnetic Imaging of Morris, P.A. and MRI of West Morris, will be included in the transfer of ownership of St. Clare's Denville.

As set forth in the CN application, Prime St. Clare's agrees to operate the hospital as a general acute care hospital following the transfer of ownership. It also agrees to continue all existing medical services offered by St. Clare's Denville, and maintain the existing licensed bed capacity, service complement and programs at the hospital's existing location in Morris County. In addition, Prime St. Clare's agrees to hire substantially all hospital employees who are employed at St. Clare's Denville at the time of the transfer of ownership.

For the reasons that follow I am approving, with conditions, the application submitted for the transfer of ownership of St. Clare's Denville to Prime St. Clare's. My decision to approve this CN application is consistent with the recommendation of the State Health Planning Board (SHPB), which unanimously recommended approval of CN# FR 130701-14-01 at its August 7, 2014 meeting. In reaching this decision, I considered the CN application for the transfer of ownership of St. Clare's Denville, completeness questions and responses, public hearing transcripts, written comments, exhibits, Department of Health (Department) staff recommendations, and SHPB recommendations. The referenced materials are incorporated and made a part of this final decision.

N.J.S.A. 26:2H-8, as well as N.J.A.C. 8:33-4.9(a), provide for the issuance of a CN only where the action proposed in the application for such certificate is necessary to provide required health care in the area to be served, can be economically accomplished and maintained, will not have an adverse economic or financial impact on the delivery of health services in the region or statewide, and will contribute to the orderly development of adequate and effective health care services. In making such

determinations, I must take into consideration: (a) the availability of facilities or services which may serve as alternatives or substitutes; (b) the need for special equipment and services in the area; (c) the possible economies and improvement in services to be anticipated from the operation of joint central services; (d) the adequacy of financial resources and sources of present and future revenues; (e) the availability of sufficient manpower in the several professional disciplines; and (f) such other factors as may be established by regulation.

St. Clare's Health System (St. Clare's) has been financially distressed for several years and has received significant financial support from the State of New Jersey. Since 2009, St. Clare's has received \$14.3 million in stabilization grants from the Department. As a condition to stabilization funding, St. Clare's was required to search for a strategic partner or association with another health care system. Overall operating costs and reduced patient volume at Saint Clare's Denville account for the decision to transfer ownership to Prime St. Clare's. Les Hirsch, President and CEO of St. Clare's Health System, detailed the search for a capital partner, which began more than three years ago, and noted PHSI's commitment to patient safety and quality care. He said that St. Clare's Denville will continue to service the vulnerable and those who are really most in need, and that PHSI has convinced St. Clare's Health System that they will serve the community and be good stewards and good corporate citizens as the operator and owner of St. Clare's Denville. (Transcript of July 23, 2014 Public Hearing, 7/23/14 Tr. at 48:12-49:3).

The proposed transfer appears to be a feasible option, and the only option presented to the SHPB by the Board of Trustees and management of St. Clare's Denville, for ensuring that this hospital continues to provide health care services to the community. If St. Clare's Denville were to continue to operate as an independent community hospital, significant financial pressure would be exerted on its limited resources, increasing its operating losses and likely leading to either a significant reduction of acute care services or an unplanned hospital closure.

As part of the review process, the SHPB is required to hold at least one public hearing in the service area of the health care facility within 30 days of the application being declared complete by the Department. A public hearing took place at the Township of Denville Municipal Building, 1 Saint Mary's Place, in Morris County on July 23, 2014, with approximately 100 people in attendance. Forty- seven speakers provided comments. The Staff recommendations briefly summarize the overall tone of the comments from the transcript and show significant support for the applicant's acquisition of the hospital. The application received opposition from one speaker representing New Jersey Citizen Action, who expressed concerns regarding the fitness of PHSI to operate St. Clare's Denville, citing Prime's ongoing federal investigations, litigation regarding access to primary care physicians, a history of staffing and services reductions, and its cancellation of insurance carrier contracts. 07/23/14 Tr. at 64:15-66-23. That speaker also asked that the Department appoint a monitor to oversee PHSI's handling of the hospital and the community's needs. 07/23/14 Tr. at 65:17-21.

As to the specifics of this application, N.J.S.A. 26:2H-8(a) requires that I consider the availability of facilities or services which may serve as alternatives or substitutes. The applicant has demonstrated that while there are alternative hospitals with market share within the primary service area of St. Clare's Denville, Morris County, residents would likely experience substantial reductions in access to health care services if St. Clare's Denville were to close or significantly downsize. The Acquisition of the hospital by Prime St. Clare's will preserve health care services in the area. I have taken into consideration the decision of the Board of Trustees and their fiduciary accountability to the community served by St. Clare's Denville. At the public hearing, Les Hirsch stated that the Board of Trustees conducted a robust due diligence process, which included the careful review and thorough analysis of proposals, and serious discussions with notfor-profit, religious and also for-profit healthcare organizations. 7/23/14 Tr. at 47:16-48:6. In its application, Prime St. Clare's stated that it had no intentions to downsize services or reduce availability to any service currently provided at St. Clare's Denville, and this will provide for accessibility and continuity of health care in this community. I have also taken into consideration that there are other hospitals in Morris County that offer comparable or expanded capabilities to St. Clare's Denville, but find that this transfer of ownership will not significantly alter the relationship of these hospitals to coexist, or adversely impact the current level of care or services in the area.

I agree that the proposed transfer of ownership, as opposed to the potential reduction of services or closure of St. Clare's Denville, will preserve appropriate access to health care services for the community, including the medically indigent and medically underserved population. Elected officials from this community spoke of the importance of the hospital in the community as a provider of health care, a major employer, and as being critical to redevelopment. They highlighted St. Clare's Denville's role in the community, its importance as a healthcare institution, and the adverse impact on the community if the hospital closed. Thus, I am satisfied that this criterion is met.

I also find that the requirement at N.J.S.A. 26:2H-8(b) to consider the need for special equipment and services in the area would be met in this case. Prime St. Clare's agrees to offer the same services that are currently licensed at the present facility. Prime St. Clare's would only make future adjustments in the provision of their general services based on health need assessments of the region and would make changes if results of such assessments warranted this type of action. More specialized services, either inpatient or outpatient, would only be added to address identified gaps in service or the expansion of existing service gaps. PHSI intends to bring its national experience to Prime St. Clare's in order to improve the quality and delivery of existing health services and programs previously operated by the owners of St. Clare's Denville.

With respect to N.J.S.A. 26:2H-8(c) regarding the possible economies and improvement in services to be anticipated from the operation of joint central services, I find that the applicant plans to introduce its national management techniques at Prime

St. Clare's as a means to control expenses, improve efficiencies, and integrate more effective care delivery.

During the public comment portion of the SHPB meeting, the Vice President of Strategic Transactions for Catholic Health Initiatives (CHI), Mark Parrington, noted "St. Clare's joined CHI in 2008. A lot of progress has been made in the operations of St. Clare's over that time period, primarily due to the commitment of the board and management team and staff. It's our trust that Prime Healthcare will continue this work and enhance the work over the next period of time." 8/7/14 Tr. at 45:9-18. Dr. Edward McManus, a physician and Chairman of the Board, stated the medical staff is "really excited to see it [the transfer ownership] move forward . . . with some ability to make some decisions and move on." 8/7/14 Tr. at 87:1-3. Luis Leon, President of Operations for PHSI, stated that PHSI will build on St. Clare's unique culture and infrastructure. 8/7/14 Tr. at 87:17-20. "We will learn what it is that they [the staff] do best and use that to expand and build upon. We are anticipating things that we can bring to the community, things that we can do better. And we're really looking forward to it." 8/7/14 Tr. at 89:11-25.

The applicant will implement its system wide operational strategies such as decreasing wall time (time paramedics and EMTs are required to wait in the Emergency Department) to increase the number of patients seen at Prime St. Clare's and establishing a community outreach program to meet the primary care needs of the community to reduce unnecessary Emergency Department visits. These along with other tested and proven measures could potentially stimulate an increase in the utilization of services at Prime St. Clare's, as the applicant indicates has occurred at their other out-of-state hospitals. The applicant's objective is to restore the reliability of St. Clare's Denville as a cornerstone of the community healthcare system and renew patient confidence in their services.

There are also economies of scale to be realized by this acquisition. For example, PHSI has significant expertise in providing operating efficiencies at their acute facilities, which includes group purchasing, accounting practices, dietary and nutrition services, radiology services, and information technologies. With the advice and recommendations of the Local Governing Board from St. Clare's Denville, Prime St. Clare's expects to be able to identify and coordinate possible economies and improvements that will be of greatest benefit to the primary and secondary service areas of St. Clare's Denville as well as the region.

N.J.S.A. 26:2H-8(d) requires me to examine the adequacy of financial resources and sources of present and future revenues. Financial analysis of the St. Clare's application undertaken by the Department indicates that PHSI possesses adequate financial resources to accomplish the proposed project. According to unaudited financial statements for the period ending 12/31/14 provided by the applicant, PHSI reported an excess of revenues over expenses of \$177.4 million, which translates to a profit margin of 7.4%. Unrestricted cash as of 12/31/14 was \$149.8 million, which

translates to about 25 days cash on hand. In addition, Prime has secured commitments from lenders to provide additional capital to support the acquisition of St. Clare's. For the same period, St. Clare's reported a profit margin of negative 29.5% and days cash on hand of 2 days. I am convinced that if the operating losses at St. Clare's were to continue, the hospital's operating future could be put at risk and possibly cease to exist.

With respect to N.J.S.A. 26:2H-8(e), regarding the availability of sufficient manpower in the several professional disciplines, I am satisfied that there will be sufficient qualified personnel because PHSI has agreed to operate the existing beds and services presently at St. Clare's Denville and retain substantially all of the current employees when the transfer of ownership is completed. PHSI does not anticipate any changes in the current contracts with professional staff subsequent to this transfer of ownership. PHSI plans to implement a number of measures to enhance the hospital's ability to recruit and sustain the appropriate complement of physicians, clinical staff, and support personnel to ensure the long term viability of St. Clare's Denville. This may include upgrading medical equipment and information technology depending on need, maintaining an open medical staff and honoring the medical staff privileges of all physicians on staff as of the closing, as well as incorporating medical staff members on the hospital's governing board.

N.J.S.A. 26:2H-8(f) requires consideration of such other factors as may be established by regulation. Therefore, I have taken into consideration the applicable administrative rules governing the services subject to full review (i.e., N.J.A.C. 8:33-1.1 et seq.). Prime St. Clare's is in compliance with the access requirements set forth in N.J.A.C. 8:33-1.1 et seq. and N.J.A.C. 8:33-4.10(a). Specifically, Prime St. Clare's plans no changes to the care or services currently provided at St. Clare's Denville following this transfer of ownership, and it will promote access to low income persons, racial and ethnic minorities, women, disabled persons, the elderly, persons with HIV infections, and other persons who are unable to obtain care. Furthermore, Prime St. Clare's will continue to maintain its commitment to the community to preserve access to health care for the residents, including the medically indigent and medically underserved population. The applicant states that it will provide care in accordance with N.J.S.A. 26:2H-18.64 and N.J.A.C 8:43G-5.2(c) regarding the provision of healthcare services regardless of the patient's ability to pay or payment source and that the amount of charity care shall not be limited to, nor substantially less than, the amount of charity care provided historically by St. Clare's Denville.

I agree with the SHPB on the recommended conditions, although I emphasize that Prime St. Clare's must take all appropriate measures to ensure that patients receiving services at the facility are aware of the transfer of the license and that insurance coverage may change. Pursuant to Condition 18(c) below, Prime St. Clare's shall post on the hospital's website the status of all insurance contracts related to patient care between the hospital and insurance plans, and must proactively provide notices to patients concerning pricing and charges related to coverage during termination of plans or out-of-network admissions. The Affordable Care Act, section

2718(e) of the Public Health Service Act also requires that "[e]ach hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act." I rely on the representations made at the SHPB by Prime St. Clare's that it is committed to continuing and improving access to quality health care for the community and will work with all of the existing insurance carriers to ensure the continuation and availability of their services. In the event that plans are terminated or considered out-of-network, Prime St. Clare's shall provide patients with the necessary information to plan their care and make informed choices, including the ability to make a choice informed by costs. I anticipate that this information will be shared with the Community Advisory Group, established pursuant to Condition 13 below, and the Advisory Board, established pursuant to Condition 28 below. Although there is no mandatory format for the Annual Public Meeting, N.J.S.A. 26:2H-12.50, information concerning insurance coverage and network participation would be an appropriate discussion topic to share with the community.

N.J.A.C. 8:33-4.9(a) requires a demonstration by the applicant that this transfer of ownership shall not have an adverse impact on the population being served in regards to access and quality of care. The applicant indicates that the transfer of ownership of St. Clare's Denville, as opposed to any reduction in services or possible closure of the hospital, will preserve and enhance the financial viability of the hospital and allow it to continue as a general acute care hospital providing the same level of licensed beds and health care services in the community. Prime St. Clare's has made a commitment to maintain St. Clare's Denville as a general acute care hospital for at least five years following the transfer of ownership. The objective of this transfer of ownership is to reshape the healthcare delivery system at the existing St. Clare's Denville, and provide more efficient and effective services, without causing any disruption in the continuity of care for its patients. As a component of rebuilding the hospital's information infrastructure, Prime St. Clare's plans to upgrade the current IT services at St. Clare's Denville to conform to its existing nationwide IT system. This integration would enhance communication and more efficiently coordinate care through the electronic sharing of patient medical records. I also believe that the development of a comprehensive medical records system between their current and future institutions will cultivate a stronger working relationship and promote greater collaboration and decision making among the system's physicians.

Moreover, I find that Prime St. Clare's has provided an appropriate project description, which includes information as to the financial impact of the merger, operating costs and revenues, services affected, equipment involved, source of funds, utilization statistics, and justification for the proposed project (N.J.A.C. 8:33-4.10(b)), assurance that all residents of the area, particularly the medically underserved, will have access to services (N.J.A.C. 8:33-4.10(a)), and assurance that it will meet appropriate

licensing and construction standards (N.J.A.C. 8:43G-1.1 et seq. and N.J.A.C. 8:33-4.10(d)).

I am aware of concerns raised by New Jersey Citizen Action that PHSI's record in California and other states is suspect in a number of areas and should be taken into consideration by the Department and the SHPB during its review. 07/23/14 Tr. at 64:15-66-23. In accordance with factors set forth at N.J.A.C. 8:33-4.10, the Department analyzed PHSI's track record in various states. Hospital regulators in California, Nevada, Pennsylvania and Texas provided track record information for each PHSIowned hospital in these states. Department staff also consulted with Rhode Island as to its investigation of PHSI's track record. Department staff identified no track record violations sufficiently serious to warrant denial of the application. In response to completeness questions regarding facilities that PHSI acquired since the submission of Prime St. Clare's application, Prime St. Clare's submitted information to the Department attesting to the fact that it has no major track record issues in any states in which it operates. I also note that there have been no major track record issues at St. Mary's Hospital since ownership of that hospital was transferred to Prime Healthcare Services -St. Mary's Passiac, LLC. In order to complete my examination of the record, I reviewed media reports of accusations, investigations and/or legal proceedings involving PHSI, its subsidiaries and its healthcare facilities in the state of California and other states. The Department has acknowledged concerns raised as a result of these media reports in some of the recommended conditions found later in this letter. The Department also consulted with the New Jersey Office of Attorney General regarding its investigation of PHSI under the Community Health Care Assets Protection Act. I am aware of the settlement payment made by PHSI involving alleged violations of federal patient confidentiality laws. At this time, the record shows that PHSI took corrective action to ensure patient protections going forward. I am also aware of the ongoing investigation by the U.S. Department of Justice of PHSI's Medicare billing practices. The Department is unaware of any finding by any court or governmental body that a Prime entity or any of its principals are guilty of any criminal action related to the operation of hospitals in any state. Nevertheless, we will work with the New Jersey Office of the Attorney General and the State Comptroller Medicaid Fraud Division to monitor any and all cases pending in the federal courts involving a Prime entity or any of its principals.

Allegations of wrongdoing by PHSI also gave rise to a request for the appointment of a monitor. 07/23/14 Tr. at 65:17-21. Department staff supports requiring facilities to use consultants for particular purposes, but the use of a general monitor is not recommended. A health care monitor appointed by the Department would not have decision-making authority or the ability to mandate compliance. The Department is able to oversee compliance and monitor care through the following mechanisms: ongoing evaluation of compliance with CN conditions; regulatory enforcement, such as plans of correction, on-site revisits and civil monetary penalties, as necessary; on-site monitoring visits, which are unannounced; review of facility reporting, including financial performance; complaint investigations; and consultation with the Centers for Medicare and Medicaid Services, as necessary. In addition, the

Department has authority to place an appointee on the board of a financially stressed hospital to have direct input into fiscal and management decisions.

In order to actively engage the community, I have, through conditions, created a Community Advisory Group to involve patient advocates, local public health officers, labor union officials, community advocates, and local elected officials, to monitor Prime St. Clare's Denville's obligations to the community, including those obligations defined in the conditions below and in the application. In addition, Prime St. Clare's shall be required to annually report to the Department on a number of specific factors, including, but not limited to, investments made to the hospital and any transfers of funds from the hospital to any parent, subsidiary corporation, or corporate affiliate.

To ensure ongoing transparency and compliance with the CN conditions set forth in this letter and all applicable laws and rules, Condition 28 requires the designation of an independent Advisory Board that will monitor the hospital's performance and report in writing to the hospital and the Department semi-annually. I may name up to two members to the Advisory Board to review compliance with capital commitments, charity care, federal and state laws, and other reporting requirements. If the findings by this Advisory Board identify a failure by Prime St. Clare's to fulfill the commitments set forth in this letter, and they are confirmed by the Department, those failures may be considered a licensing violation subject to penalty and/or license revocation.

In addition, a member of the Advisory Board shall be an ex-officio member of the Local Governing Board. This condition for PHSI-owned hospitals in New Jersey represents an unprecedented level of oversight during the critical transition period subsequent to the transfer of ownership. I am confident that the conditions placed on the hospital through this CN, coupled with the Department's regulatory oversight, exceed the capabilities of a general monitor. In particular, the role of the Advisory Board and its ability to influence the Local Governing Board will ensure the facility's operational compliance in our State.

I believe the conditions contained below address the concerns raised in response to the Prime St. Clare's applications. In addition, I anticipate that Prime St. Clare's shall fully publically report on all information required in the conditions to the Community Advisory Group, the Department, and the Advisory Board.

Based on the foregoing, I am approving the application for the transfer of ownership of St. Clare's Denville. My decision to allow this transfer of ownership from St. Clare's Denville to Prime St. Clare's is based on the fact that the operation of St. Clare's Denville under the proposed new ownership would be beneficial to the population in its service area because it will preserve access to health care services for the community, including the medically indigent and medically underserved population. This transfer of ownership will strengthen the financial viability of St. Clare's Denville, making it more financially sound and better equipped to provide the essential health care services needed to serve the core population of its primary service area. I believe

that this approval will not have an adverse impact on the other existing hospitals in Morris County or the surrounding counties. There is no existing data to suggest that this transfer of ownership would alter St. Clare's Denville's relationship with the other existing Morris County/regional hospitals or adversely impact the health status of any of the communities served by all hospitals in Morris County and surrounding counties.

My decision to approve this application also factors in the applicant's plans to rebuild the healthcare delivery system at St. Clare's Denville by enhancing their medical and non-medical supportive technology, as well as creating a more structured physician and patient environment for better care. This transfer has the potential of promoting shared services and administrative efficiencies targeting improvements in patient outcomes.

The issue of the for-profit status of the applicant is one that has been raised in other hospital transfers. As I believe is appropriate, neither staff nor the SHPB has ever determined that the for-profit status of an entity is one that is fatal in the review of CN or licensing applications. In other areas of health care licensing, such as long-term care, we see primarily for-profit ownership. There is also no statutory or regulatory authority for treating for-profit and not-for-profit entities differently in CN or licensing reviews. In this particular case, it is clear that the hospital's current financial status is so precarious that its closure, along with the resulting health care service and economic disruptions, is a real possibility. Thus, in reviewing the only application before me that could avert closure, the fact that the acquiring entity is a for-profit organization is of no particular relevance. I also note that compliance with all CN and licensing requirements is equally enforced for all facilities, whether not-for-profit, for-profit or governmental.

Finally, I acknowledge that St. Clare's Denville has had a long standing commitment to the residents in its service areas and believe that this approval will better enable the hospital, under its new ownership, to maintain and enhance its commitment to the community into the foreseeable future. I also note that the management of Prime St. Clare's and St. Clare's Denville share the same values and vision for providing quality health care services to the communities they serve. For the reasons set forth in this letter and noting the approval of the SHPB, I am approving Prime St. Clare's application for the transfer of ownership of St. Clare's Denville subject to the following conditions, which I note were accepted by a representative of the applicant while addressing the SHPB:

- 1. The applicant completes the Office of Attorney General Community Health Care Assets Protection Act, N.J.S.A. 26:2H-7.10 et seq., review for the proposed transfer of the assets of St. Clare's Denville to Prime St. Clare's.
- 2. The applicant shall file a licensing application with the Department's Division of Certificate of Need and Licensing (the Division) to execute the transfer of the ownership of St. Clare's Denville to Prime St. Clare's, as well as all other licensed health care facilities described in the application and described as

included in the entire transaction between the applicant and Saint Clare's Health Care System.

- 3. The applicant shall notify the Division, in writing, of specifically who is responsible for the safekeeping and accessibility of all St. Clare's Denville's patients' medical records (both active and stored) in accordance with <a href="N.J.S.A.">N.J.S.A.</a> 26:8.5 et seq. and <a href="N.J.A.C.">N.J.A.C.</a> 8:43G-15.2.
- 4. The applicant, Prime St. Clare's, agrees to retain substantially all of the current employees at St. Clare's Denville and all of the current employees at St. Clare's Hospital-Boonton. Six months after licensure, Prime St. Clare's shall document to the Division the number of employees retained and provide the rationale for any workforce reductions.
- 5. For at least five years, Prime St. Clare's shall continue all inpatient and clinical services and all community health programs currently offered at St. Clare's Denville. Any changes in this commitment involving either a reduction, relocation out of St. Clare's Denville's current service area, or elimination of inpatient or clinical services or community health programs offered by St. Clare's Denville's former ownership shall require prior written approval from the Department and shall be subject to all applicable statutory and regulatory requirements. This condition shall be imposed as a contractual condition of any subsequent sale or transfer, subject to appropriate regulatory or legal review, by Prime St. Clare's within the five-year period.
- 6. Prime St. Clare's shall continue to operate its licensed ambulance services, including Basic Life Support/Mobility Assistance Vehicles (BLS/MAV), Mobile Intensive Care Unit (MICU) and Specialty Care Transportation Unit (SCTU), for at least five years from the date of licensure.
- 7. Prime St. Clare's shall continue compliance with N.J.A.C. 8:43G-5.21(a), which requires that "[a]II hospitals . . . provide, on a regular and continuing basis, outpatient and preventive services, including clinical services for medically indigent patients, in those services provided on an in-patient basis." Within 30 days of the issuance of the license and every six months thereafter for a period of five years, Prime St. Clare's shall submit documentation of compliance with this condition to the Division. Such documentation of clinical services shall include, but not be limited to, a list of all physician specialties, the number of physicians within each specialty and the number of those physicians within each specialty that accept Medicaid reimbursement.
- 8. Prime St. Clare's shall comply with federal EMTALA requirements, and provide care for all patients who present themselves at St. Clare's Denville without regard to their ability to pay or payment source in accordance with N.J.S.A. 26:2H-18.64 and N.J.A.C. 8:43G-5.2(c).

- 9. Prime St. Clare's shall provide care in accordance with N.J.S.A. 26:2H-18.64 and N.J.A.C. 8:43G-5.2(c), which shall be consistent with the needs of the uninsured and provide unimpaired access to all services offered by the hospital.
- 10. Within 60 days of licensing, Prime St. Clare's shall establish an effective Local Governing Board for the hospital responsible for (a) representing the acute care hospital in the community and taking into account the views of the community in its deliberations; (b) participating in Prime St. Clare's community outreach programs; (c) supervising the Hospital's charity care policies and practices; (d) monitoring financial indicators and benchmarks; (e) monitoring quality of care indicators and benchmarks; and (f) developing a Community Health Needs Assessment and approving its implementation, as discussed in Condition 13. The Local Governing Board shall adopt bylaws and maintain minutes of monthly meetings. Within six months of licensing, Prime St. Clare's shall submit to the Department a current working description of the Local Governing Board's authorities, policies governing Board composition, roles and responsibilities, governance authority, and shall clearly define those in comparison to its working relationship with the national PHSI Board. On an annual basis, Prime St. Clare's shall provide the Department with the Board's roster and advise the Department of any significant changes to the Local Governing Board's policies governing Board composition, governance authority and Board appointments made during each year that the hospital is in operation. The Local Governing Board shall maintain suitable representation of the residing population of Prime St. Clare's service area who are neither themselves employees of, nor related to employees or owners of, any parent, subsidiary corporation or corporate affiliate. A member of the Advisory Board established pursuant to Condition 28 shall be an ex-officio member of the Local Governing Board.
- 11. Within 30 days of licensing, PHSI shall provide the Department with an organizational chart of the hospital and each service that shows lines of authority, responsibility, and communication between PHSI and hospital management and the Local Governing Board. PHSI, as licensee operating Prime St. Clare's, shall be responsible for compliance.
- 12. Every six months for the next five years, starting on the date a license is issued to Prime St. Clare's, Prime St. Clare's shall report the progress on the implementation and measured outcomes of the following initiatives noted in the application to improve the operational efficiency and quality of care at Prime St. Clare's:
  - a. The institution of a physician recruitment effort, primary care and specialty, to support Prime St. Clare's;

- The institution of a measure to decrease "wall time" (time paramedics and EMT's are required to wait in the Emergency Department);
- c. The institution of a community outreach program to meet the primary care needs of the community reducing unnecessary Emergency Department visits; and
- d. The institution of a Clinical Systems Improvement initiative capable of improving health outcomes and increasing productivity.
- 13. Within three months of licensure approval, Prime St. Clare's shall develop and participate in a Community Advisory Group (CAG) to provide ongoing community input to the hospital's CEO and the hospital's Local Governing Board on ways that Prime St. Clare's can meet the needs of the residents in its service area. This would include participating in the development and updating of the Community Health Needs Assessment (CHNA).
  - a. Subject to the provisions below, Prime St. Clare's shall determine the membership, structure, governance, rules, goals, timeframes, and the role of the CAG in accordance with the primary objectives set forth above, and within 60 days from the date of formation of the CAG, shall provide a written report setting forth same to the hospital's Local Governing Board, with a copy to the Department and subject to the Department's approval.
  - b. Prime St. Clare's shall minimally seek participation from each town in its service area by offering a seat on the CAG to each town's mayor or his/her designee. Membership on the CAG shall include patient advocates, local public health officials, clinical practitioners whose mission is to ensure that New Jersey residents are provided fully-integrated and comprehensive health services, labor union officials and community advocates. Prime St. Clare's shall designate co-chairs of the CAG, one of whom shall be a member of the hospital's Local Governing Board and one of whom shall be a community member who is neither an employee of, nor related to employees or owners of, any parent, subsidiary corporation or corporate affiliate.
  - A CAG representative shall be given a seat, ex-officio with voting privileges, on the hospital's Local Governing Board.
  - d. The co-chairs of the CAG shall jointly submit to the hospital's Local Governing Board, with a copy to the Department, a semi-annual report of the progress toward the goals of the CAG.

- e. The co-chairs of the CAG shall jointly transmit to the hospital's Local Governing Board, with a copy to the Department, quarterly and any special reports relative to the implementation of these conditions.
- f. Each member of the CAG shall be required to publicly disclose any and all conflicts of interest to the CAG members and the hospital's Local Governing Board.
- g. Prime St. Clare's may petition the Department to disband the CAG not earlier than three years from the date of licensure and on a showing that all of the above conditions have been satisfied for at least one year.
- 14. Prime St. Clare's shall submit annual reports to the Department for the initial five years following the transfer of ownership, or upon request, detailing:
  - a. The investments it has made during the previous year at the hospital. Such reports shall also include a detailed annual accounting of any long- or short-term debt or other liabilities incurred on the hospital's behalf and reflected on the Prime St. Clare's balance sheet;
  - b. The transfer of funds from the hospital to any parent, subsidiary corporation, or corporate affiliate and indicating the amount of funds transferred to document that assets and profits reasonably necessary to accomplish the healthcare purposes remain with the hospital. Transfer of funds shall include, but not be limited to, assessments for corporate services, transfers of cash and investment balances to centrally controlled accounts, management fees, capital assessments, and/or special one-time assessments for any purpose;
  - c. All financial data and measures required pursuant to N.J.A.C. 8:31B and from the financial indicators monthly reporting; and,
  - d. A list of completed capital projects itemized to reflect both the project and its expenditure.

In addition, Prime St. Clare's shall provide its Audited Annual Financial Statements to the Department and post them to its website within 180 days of the end of its fiscal year.

- 15. Within 15 business days of approval of this application, Prime St. Clare's shall provide a report to the Division detailing the communication plan to St. Clare's Denville staff, the community, including but not limited to elected officials, clinical practitioners, and EMS providers, concerning the approval of the transfer of ownership and the availability of fully-integrated and comprehensive health services. This shall include reference to the outreach plan referenced in Condition 17 below.
- 16. Within 60 days of posting its Audited Annual Financial Statements to its website, Prime St. Clare's shall hold an annual public meeting in New Jersey pursuant to N.J.S.A. 26:2H-12.50, and shall make copies of those financial statements available at the annual public meeting. Prime St. Clare's shall develop mechanisms for the meeting that address the following:
  - a. An opportunity for members of the local community to present their concerns to Prime St. Clare's regarding local health care needs and hospital operations, and a procedure on how those concerns will be addressed by the hospital; and
  - b. A method for Prime St. Clare's to publicly respond to the concerns expressed by community members at the annual public meeting. Prime St. Clare's shall develop these methods within 90 days of approval of this application and share them with the Division.
- 17. An outreach plan shall be established to ensure that all residents of the hospital service area, especially the medically indigent, have access to the available services at the location. A self-evaluation of this effort shall be conducted on an annual basis for five years after licensure to measure its effectiveness. The evaluation shall be submitted to the Department within 20 business days after the conclusion of each year of licensure and presented to the public at the hospital's annual public meeting.
- 18. After the transfer is implemented:
  - a. Prime St. Clare's shall use its commercially reasonable best efforts to negotiate in good faith for in-network HMO and commercial insurance contracts, with commercially reasonable rates based on the rates that HMOs and commercial insurance companies pay to similarly situated in-network hospitals in the northern New Jersey region.
  - b. Prime St. Clare's shall convene periodic meetings with the Department and the Department of Banking and Insurance (DOBI) to review and evaluate all issues arising in contract negotiations within the first year of licensure and provide written documentation

to the Department on a monthly basis during that first year which shall include, but not be limited to, a description of the number and subject of telephone calls, correspondence and meetings with existing HMO and commercial insurance carriers, as well as follow-up telephone calls, correspondence and meetings. At a minimum, Prime St. Clare's shall have monthly contact with the existing HMO and commercial insurers. If the existing HMO and commercial insurers fail to respond to requests for negotiations, then Prime St. Clare's shall notify the Department and DOBI to request assistance.

- c. Within 10 days of licensure, Prime St. Clare's shall post on the hospital's website the status of all insurance contracts related to patient care between the hospital and insurance plans, including all insurance plans with which St. Clare's Denville contracted at the time of submission of this CN application, July 2013. Prime St. Clare's shall also provide notices to patients concerning pricing and charges related to coverage during termination of plans.
- d. Within the first year of licensure, Prime St. Clare's shall notify the Department of the status of notices to terminate any HMO or commercial insurance contract that will expand out-of-network service coverage. Prime St. Clare's shall meet with representatives from the Department and DOBI to discuss the intent to terminate such contract, willingness to enter into mediation, and shall document how it will provide notice to patients and providers, and the impact such action is reasonably expected to have on access to health care.
- e. For at least five years after licensure, Prime St. Clare's shall report annually to the Department on the hospital's payer mix and the number and percent of total hospital admissions that came through the emergency department.
- 19. In accordance with the provisions of N.J.S.A. 26:2H-18.59h, Prime St. Clare's shall "offer to its employees who were affected by the transfer, health insurance coverage at substantially equivalent levels, terms and conditions to those that were offered to the employees prior to the transfer." This condition does not prohibit good faith contract negotiations in the future.
- 20. Prime St. Clare's shall adopt a transitions-of-care program to prevent unnecessary hospital admissions and re-admissions. A yearly self-evaluation to measure the effectiveness of the program shall be completed by the applicant and filed with the Division for the first five years after licensure.

- 21. Prime St. Clare's shall maintain compliance with the United States Department of Health and Human Services Standards for Culturally and Linguistically Appropriate Services in Health and Healthcare. Compliance shall be documented and filed with the Division with annual licensing renewal.
- 22. For at least five years, Prime St. Clare's shall not enter into any contract or other service or purchasing arrangements, or provide any corporate allocation, or equivalent charge to affiliated organizations within PHSI, Prime Healthcare Holding, Inc. and Prime Healthcare Management, Inc. except for contracts or arrangements or allocation to provide services or products that are reasonably necessary to accomplish the healthcare purposes of the hospital and for compensation that is consistent with fair market value for the services actually rendered, or the products actually provided.
- 23. Prime St. Clare's shall institute or preserve the hospital's "hard-stop" initiative for the use of elective Caesarian Sections before 39 weeks and all elective deliveries under 39 weeks. "Hard stop" as defined by the March of Dimes means that a Labor and Delivery Unit that receives a request to schedule or admit a patient for delivery by either labor induction or C-section before 39 weeks without documented medical necessity would be denied based on the medical risks associated with such early deliveries.
- 24. Provided that Prime St. Clare's continues to offer inpatient obstetric and pediatric beds/services, it shall participate as a member in good standing in the regional Maternal and Child Health Consortium that serves the hospital's primary service area.
- 25. Prime St. Clare's shall submit any proposed plan including documented compliance with law and regulations as it relates to out-of-network cost sharing with patients to DOBI prior to implementation. Prime St. Clare's shall not implement any out-of-network cost sharing plans if DOBI objects thereto.
- 26. Prime St. Clare's shall annually document to the Division its work with the Federally Qualified Health Centers (FQHCs) within its service area to strengthen the primary care network by directing and encouraging patients seen in all of its ambulatory clinics, physician-owned practices, the emergency department and upon admission or discharge, to utilize the primary care services provided at the FQHCs for initial and follow-up care as appropriate.
- 27. Prime St. Clare's shall comply with requirements of the New Jersey Department of Labor and Workforce Development's (DOLWD) Division of Wage and Hour Compliance that address conditions of employment and the method and manner of payment of wages.

28. Prime St. Clare's shall agree to take steps to ensure transparency, provide quality care to patients, and provide assurances to the Department of its continued financial viability. St. Clare's Health Systems, Inc. shall designate a single Advisory Board to oversee and monitor the operation of both St. Clare's Denville and St. Clare's Dover by Prime St. Clare's. The Advisory Board shall be comprised of at least three individuals but no more than five. Three individuals shall be selected by St. Clare's Health Systems, Inc. prior to the closing of the transfers, and two individuals may be selected by the Commissioner of Health. The Advisory Board shall (a) review and supervise Prime St. Clare's compliance with the Capital Commitments, (b) review and supervise Prime St. Clare's compliance with the charity care policies, (c) review and supervise the Prime St. Clare's compliance with the ethical and religious directives, (d) review and supervise Prime St. Clare's compliance with maintenance of all pastoral services, and (e) Prime St. Clare's compliance with State and Federal laws, statutes, regulations, administrative rules and directives, and the impact on community health care access and quality, and report such findings to the Department.

The members of the Advisory Board shall: (i) be independent of any Prime entity, having no current or previous familial or personal relationship to any Prime entity, its principals, board members and/or managers, or be owned by any Prime entity in whole or in part and (ii) shall be acceptable to the Department. A member of the Advisory Board shall serve as an ex-officio, non-voting member of the Local Governing Board referenced above in Condition 10.

The Advisory Board shall also monitor the following, and these findings shall be reported semi-annually, in writing, to both the hospital's Local Governing Board and the Department:

- Levels of uncompensated care for the medically indigent;
- Emergency department admissions;
- Provision of clinic services;
- Compliance with standard practices related to coding of diagnoses;
- Rationale for termination of insurance contracts;
- Insurance participation and policies related to out-of-network services;
- Compliance with the Department licensing requirements related to staffing ratios and overtime, and DOLWD Wage and Hour requirements;
- Compliance with all other CN conditions within the required timeframes required by each condition.

The Advisory Board shall be active for a minimum period of at least two years and shall provide all reports, findings, projections, and operational or strategic

plans to the Department and Prime St. Clare's Local Governing Board for assessment. In the event Prime St. Clare's does not fulfill the commitments set forth in this approval, the failure may be considered a licensing violation subject to maximum penalty and/or license revocation.

- 29. Prime St. Clare's shall identify a single point of contact to report to the Division concerning the status of all of the conditions referenced within the timeframes noted in the conditions.
- 30. All the above conditions shall also apply to any successor organization to Prime St. Clare's who acquires St. Clare's Denville within five years from the date of CN approval.

Failure to satisfy any of the aforementioned conditions of approval may result in sanctions, including license suspension, monetary penalties and other sanctions in accordance with N.J.S.A. 26:2H-1 et seq. and all other applicable requirements. Acceptance of these conditions will be presumed unless written objections are submitted to the Department within 30 days of receipt of this letter. Upon receipt of such objections, this approval will be deemed suspended and the project shall be reexamined in light of the objections.

We look forward to working with you and helping you to provide a high quality of care to the patients of Prime St. Clare's. If you have any questions concerning this Certificate of Need, please do not hesitate to contact John Calabria, Director, at (609) 292-8773.

Sincerely.

Mary O'Dowd, M.P.H.

Commissioner

John A. Calabria, DOH

C: