State of New Jersey
**DEPARTMENT OF HEALTH**
PO BOX 358
TRENTON, N.J. 08625-0358
www.nj.gov/health

PHILIP D. MURPHY
*Governor*

TAHESHA L. WAY
*Lt. Governor*

KAITLAN BASTON, MD, MSc, DFASAM
*Commissioner*

August 28, 2024

**VIA ELECTRONIC & FIRST-CLASS MAIL**

Mohamed H. Nabulsi, Esq.
Mandelbaum Barrett PC
3 Becker Farm Road, Suite 105
Roseland, NJ 07068

Re: Hudson Regional Hospitals, LLC
CN FR # 2024-04353-09;01
Full Review – Transfer of Ownership
Completeness Questions – 4th Set

Dear Mr. Nabulsi:

The Department of Health (Department) requires additional information for the application referenced above, which was submitted on April 1, 2024. This request is being submitted in writing in accordance with N.J.A.C. 8:33-4.5(c), which provides that "Once an application has been submitted to the Department, no subsequent submission of information shall be accepted unless specifically requested in writing by the Department."

Enclosed please find subsequent Completeness Questions for your review and response. Please respond within ten business days of receipt of this letter. To facilitate the review of your response, it is requested that your response letter be presented in a question-and-answer format (i.e., re-state each question and follow with the appropriate response). Be advised that based on a review of your responses, additional questions and/or requests may be forthcoming.

If you have any questions concerning this matter, please do not hesitate to contact me at (609) 292-6552. I can also be reached via email at Joshua.Antunes1@doh.nj.gov.

Sincerely,

Joshua Antunes
Health Systems Specialist
Certificate of Need and Healthcare Facility
Licensure Program

Enclosure

C: A. Ventura, DOH
K. Gigliotti, DOH
N. Kifaieh, Hudson Regional Hospital

# FULL REVIEW - COMPLETENESS QUESTIONS

**NAME OF APPLICANT:** Hudson Regional Hospitals, LLC
**CERTIFICATE OF NEED NUMBER:** CN FR # 2024-04353-09;01
Transfer of Ownership

**NAME OF REVIEWER:** Joshua Antunes
**TELEPHONE NUMBER OF REVIEWER:** (609) 292-6552
**REVIEWER'S EMAIL:** Joshua.Antunes1@doh.nj.gov

A Certificate of Need – Full Review (CN FR) application has been submitted for Bayonne Medical Center, with a proposed transfer of ownership from IJKG Opco LLC to Hudson Regional Hospitals, LLC (as listed on page 1 of the application). The Applicant, Hudson Regional Hospitals, LLC, is a limited liability company, and the proposed sole ownership entity of this Facility.

The following are Completeness Questions from the Department of Health (hereinafter, "Department" or "DOH"):

1. The Department notes that a Certificate of Need – Full Review application for a proposed transfer of ownership requires the submission of an Operations Transfer Agreement (OTA) between both parties. **Confirm if the parties have finalized an OTA. If not, when do you propose that the Department will be provided with such Agreement?**

   **Please note that the Department may not approve an application for a transfer of ownership absent an operations transfer agreement between the parties.**

Note: Please be aware that as the CN FR application review continues, additional questions and/or requests may be forthcoming, including related to the Applicant's regulatory compliance/ track record.

**General Attestation Form for Track Record Chart - Applicant's Out-of-State Facilities**

*Instructions:* The attestation language below should be submitted on facility letterhead and dated and signed by the Applicant/Proposed Licensee or authorized representative of the Applicant/Proposed Licensee, who is an employee within the organization (e.g., the Administrator or other administrative staff within the organization).

I attest that I am an authorized representative of (INSERT APPLICANT/ PROPOSED LICENSEE'S NAME), and I have provided a complete list of the names and addresses of every facility or service similar to the services proposed in the submitted application, which is owned, operated or managed, in whole or in part, by (INSERT APPLICANT/ PROPOSED LICENSEE'S NAME). I confirm that the records of these facilities have been and will continue to be monitored so that all State regulatory compliance issues, and Federal compliance, if applicable, have been and will be identified on a continuous basis.

**This will also serve as an attestation that for the track record period specified prior to the date of the submission of the pending application to the Department of Health to the present, that all out-of-state facilities or services similar to those proposed in the submitted application which are owned, operated or managed, in whole or in part, by (INSERT APPLICANT/ PROPOSED LICENSEE'S NAME), which are not listed in the attached chart are in substantial compliance with applicable State licensure and Federal requirements, if applicable, in accordance with N.J.A.C. 8:33-4.10(d).** This verifies that, except as listed on the attached chart, there are: a) no significant compliance issue(s), which is defined as a situation, condition or circumstance that may pose serious risks to life, safety or quality of care for patients, residents or clients; b) no citation or notice of deficiencies posing actual harm, or immediate or serious risk of harm; and c) no findings of a substandard quality of care leading to enforcement actions against the facility license.

**I further attest that the attached chart only lists those facilities with significant compliance issues as defined above. I attest that the chart is accurate and complete and contains the name of any facility with substantial compliance issues, during the time period specified prior to the date of the submission of the pending application to the present.** I attest that the compliance issues identified in the chart have been corrected within time frames defined by the relevant jurisdiction.

**Finally, I agree that this attestation will be updated every 60 days from the date below to the date of the final determination of the pending application.** I understand it is the Applicant's responsibility to submit the updated attestation and chart, if compliance issues arise, every 60 days, and to continue to alert the Department of Health to any significant compliance issues until the final determination on the pending application.

Applicant/ Proposed Licensee or Authorized Representative - name and title (typed):

Applicant/ Proposed Licensee or Authorized Representative - signature:

Date: Date application submitted:

Track Record Time Frame:

Total number of facilities owned, managed or operated by Applicant:

Total number of facilities owned, managed or operated out-of-state:

Total number of facilities listed on DOH Track Record form with non-compliance issues:

## INSTRUCTIONS FOR DEPARTMENT OF HEALTH
## OUT-OF-STATE TRACK RECORD CHART FOR AMBULATORY SURGERY CENTERS

1. In making a determination as to the Applicant's capacity to operate a health care facility/ service, the Department of Health (DOH) will consider the Applicant's prior operating history, both in New Jersey and in other states. These are instructions for the chart that the Applicant will use to list the compliance record, or "track record", for their out-of-state Ambulatory Surgery Centers (ASCs).

   The purpose of this Track Record chart is for the Applicant to list any out-of-state ASCs they own, operate or manage, in whole or in part, that have compliance issues cited by the licensing agency or regulatory office. **Only ASCs with compliance issues for the track record period specified need to be listed in the chart**. The track record period should include the compliance history for the 12 months preceding the application submission.

   There is also an accompanying attestation to be completed by the Applicant that any ASC owned, operated or managed, in whole or in part, by the Applicant that is not listed on the chart, did not have any citations or other compliance issues as specified in these instructions from the licensing agency or regulatory office for the specified track record period.

   Again, the Applicant should complete the out-of-state track record chart, as well as the attestation related to the chart, and submit both documents to the Department of Health.

2. First, the Applicant should provide a list of all out-of-state ASCs they own, operate or manage, in whole or in part, to DOH to use as a reference in reviewing the chart.

3. The Applicant will then provide the information requested in the track record chart for those facilities with compliance issues as noted in these instructions and on the chart. After completing facility identifying information in the first four columns in the chart, the Applicant will specify the type of survey -- recertification, or complaint survey. Then for each column (highlighted in blue) with CMS Conditions for Coverage, enter an "**X**" in the column with deficiencies for that Condition.

4. The Applicant will enter "N/A" or number of events in columns for "*No. of Patient Hospitalizations*" and "*No. of Patient Deaths*" which are a *direct result* of the deficiency

(or deficiencies) which were entered in the prior columns. The Applicant will also provide an explanation of the event(s) related to patient hospitalizations and/or patient deaths in a separate narrative.

5. The Applicant will complete *"Corrective Actions and Date Completed"* for the citations listed.

6. The Applicant will also specify if there are *Curtailments of Admissions; State License Revocations*; or *Denial of Medicare Payments* in the column indicated. If this is not applicable, "N/A" would be entered.

7. For "*Ultimate Outcome*", the following responses would be entered: Licensed – Condition closed or Waiting for re-visit.

8. If there are no deficiencies for Conditions listed for any out-of-state facilities owned, managed or operated by the Applicant for the Track Record period specified, enter "Not Applicable for all facilities" in the first line on this chart, and confirm on the attestation form to accompany this chart.

9. The Applicant will submit the following to the assigned DOH Analyst via email:
   a) Completed DOH Track Record chart.
   b) DOH Attestation Form for the Track Record Chart signed by the Applicant. (A scan/copy of the Attestation may be sent in email to the DOH Analyst with the original, signed Attestation mailed to DOH for the file.)

***If additional information is needed on any track record item, DOH staff may request clarification as needed after the Applicant submits the above documents.***

**AMBULATORY SURGERY CTR** TRACK RECORD CHART: New Jersey Department of Health: Certificate of Need and Licensing APPLICATION#__________ APPLICANT NAME__________ Time Frame:

See instructions to complete this form. If there are no deficiencies for Conditions listed for any out-of-state facilities owned by the Applicant for the Track Record period noted above, enter "Not Applicable for all facilities" in the first line on this chart, and confirm on the attestation form to accompany this chart.

| CMS Provider # | State | Facility Name | Facility Address | Survey Date | Survey Type and Findings | 416.40 Compliance with State Licensure Law | 416.41 Governing Body and Management | 416.42 Surigcal Services | 416.43 Quality Assessment and Perf. Improvement | 416.44 Environment | 416.45 Medical Staff | 416.46 Nursing Service | 416.47 Medical Records | 416.48 Pharmaceutical Services | 416.49 Laboratory and Radiologic Svces | 416.50 Patient Rights | 416.51 Infection Control | 416.52 Patient Admission, Assessment & Discharge | 416.54 Emergency Preparedness | No. of Patient Hospitalizations which are a direct result of the citation(s) reported in prior column(s) | No. of Patient Deaths which are a direct result of the citation(s) reported in prior column(s) | Corrective Actions and Date Completed | Curtailments of Admissions, State License Revocations, or Denial of Medicare Payments | Ultimate Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *SAMPLE ENTRY - REMOVE TO COMPLETE FORM -* 01-1234 | VT | ABC Ambulatory Surgical Ctr | 123 Sunnyside Dr., Small Town, VT | 1/15/17 | Recertification Survey - 4 Conditions | | X | X | | | | | X | | X | | | | | N/A | N/A | QA/I review and action plan completed 5/15/17 | N/A | Waiting for re-visit |
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