

Rhode Island Department of Health, Center for Health Facilities Regulation and Nicole Alexander-Scott, MD, MPH, In Her Capacity as Director of Health



In the matter of:

Kent Hospital
License # HOS00125
455 Tollgate Road
Warwick, RI 02886

CONSENT AGREEMENT

This matter is before the Rhode Island Department of Health (“RIDOH”) pursuant to the authority conferred upon the Director of RIDOH (the “Director”) under provisions of Rhode Island Gen. Laws § 23-17-1 *et seq.*, (the “Act”) and the *Rules and Regulations for Licensing of Hospitals* (216-RICR-40-10-4) (the “Regulations”).

PURPOSE

This Agreement is being executed and implemented for the purposes of improving the delivery of quality health care to the community served by Kent Hospital (“Kent”), and resolving regulatory action regarding Kent’s compliance with the Act, the Regulations, and Kent’s written policies and procedures as set forth herein, and is intended to address and resolve regulatory and or compliance issues known to, investigated by and for which plans of correction have been submitted and accepted by RIDOH, as of the execution of this Agreement. RIDOH herein represents the compliance issues known to, investigated by and for which plans of correction have been submitted and accepted by RIDOH at this time, are set forth on page 2 herein.

FINDINGS OF FACT

Whereas, Kent is located at 455 Tollgate Road, Warwick, Rhode Island, and is licensed by RIDOH pursuant to the Act and the Regulations.

Whereas, as a condition of its license, Kent is required to comply with all rules and regulations regarding the provision of care and services provided to all patients in accordance with the prevailing community standard of care in a manner that maintains the health and safety of individuals.

Whereas, the prevailing community standards include, but are not limited to, the provision of care and services set forth in accordance with written policies and procedures pertaining to verification of procedure site/site and preventing unintended retained foreign objects (“URFOs”).

Whereas, after receiving reports from Kent of the incidents noted as 1 and 2, RIDOH investigated the facility self-reported incidents during unannounced Centers for Medicare and Medicaid Services (“CMS”) and State licensure surveys, and RIDOH discovered incidents of potential immediate jeopardy and subsequently issued Federal and State deficiency statements.

Whereas, Kent timely responded to the deficiencies relating to verification of procedure site/site and by letter dated April 17, 2018, RIDOH acknowledged receipt and acceptance of the provisions and time frames for corrective action.

Whereas, during the time that Kent was implementing the verification of procedure site/site corrective actions and enhanced policies and procedures, two unrelated URFOs occurred at Kent and were immediately self-reported to RIDOH.

Whereas, upon said investigations RIDOH determined that Kent failed to implement and sustain processes and systems to provide care and services in accordance with its written policies and procedures pertaining to verification of site/site and prevention of URFOs.

1. On 12/6/2017, Patient #1 underwent a re-excision of the right breast which was performed on the wrong area of the breast.
2. On 3/14/18, Patient #2 underwent an incision on the left abdomen for a nephrectomy which was intended to be done on the right abdomen.
3. On 4/10/18, Patient #3 underwent insertion of a catheter with use of a guidewire that was subsequently found to be retained in the patient following the procedure.
4. On 5/20/18, Patient #4 underwent insertion of a catheter with use of a guidewire that was subsequently found to be retained in the patient following the procedure.

Whereas, at a meeting with RIDOH on June 13, 2018, Kent presented a 100-day turnaround plan that Kent had voluntarily initiated in March 2018 following incident 2 and was subsequently expanded to address URFOs and overall hospital wide procedures to ensure patient safety and compliance with the plans of correction and applicable federal and state standards.

Whereas, RIDOH takes administrative notice that Kent has represented and verified that it has incurred, and will incur, costs relating to such turnaround plan of at least \$1,700,000 to improve its patient quality and safety.

NOW THEREFORE, in lieu of regulatory action regarding the above-referenced matter, and in exchange for and in consideration of the mutual terms, conditions, promises, and covenants set forth by this Agreement, Kent and RIDOH agree as follows:

1. The term of this Agreement is effective upon the last date signed and shall remain in effect for a period of one (1) year or until all requirements of this Agreement are completed, whichever date is later.

2. RIDOH agrees to forgo regulatory action against Kent's License No. HOS00125 regarding the four events described above, subject to Kent taking the actions set forth herein at its own expense.

3. Kent will otherwise remain in full compliance with all applicable laws and regulations.

4. Kent agrees to commit a minimum of \$1,000,000 (which is understood to be part of the voluntary \$1,700,000 commitment referenced above) in remediation investments to improve its systems pertaining to verification of procedure site/site, and preventing URFOs. Such remediation investments shall be applied first to costs Kent incurs that are directly related to conditions imposed herein, including but not limited to any requirements and/or recommendations by the Joint Commission ("TJC"). Kent may include as remediation investment expenditures a maximum of \$330,000 in salary costs for training/re-training existing staff in its systems related to verification of procedure site/site and preventing URFOs. This amount is not intended to limit or direct the amount Kent may otherwise invest in training/retraining of existing staff.

5. Kent shall report the four events listed above to TJC Office of Quality and Patient Safety ("OQPS") within ten (10) business days of receipt of notification from CMS that their deemed status has been restored, and shall request written recommendations from the OQPS.

- a. Kent shall accept, and fully participate in implementing, actions recommended by the OQPS, which may include but are not limited to participation in further analysis of the cause(s) of the events and/or a facility site survey.
- b. Kent shall, upon receipt of recommended actions from the OQPS, provide RIDOH with a copy of all such recommendations, including a timeline for implementation approved by the OQPS.
- c. Kent shall begin implementation of the OQPS recommended actions no later than thirty (30) business days from the date received by Kent, unless otherwise agreed upon by Kent and TJC.
- d. Kent shall implement one or more of the Joint Commission Center for Transforming Healthcare ("JCCTH") Targeted Solutions Tools ("TST") pursuant to a separate agreement between Kent and the JCCTH. The JCCTH is an independent, non-profit organization that uses a systematic approach to analyze specific breakdowns in care and discover their underlying causes, to develop targeted solutions that solve complex problems.
 - i. Kent shall accept JCCTH recommendations regarding the specific TST(s) to be implemented and shall work collaboratively with JCCTH staff to implement such recommendations in a way that supports ongoing, sustainable improvement.
 - ii. Kent will share all TST data, reports, and findings with the OQPS.

- iii. Kent will provide RIDOH with written monthly monitoring/progress reports through completion of the TST implementation(s).
6. Kent shall immediately contract with, and pay for, an independent expert compliance contractor and/or organization, acceptable to RIDOH in scope of work and time commitment, to provide monitoring and oversight:
 - a. Engage a dedicated resource by August 1, 2018 to monitor compliance with all terms and conditions contained herein.
 - b. Monitoring shall remain in place for a minimum of one year or until all terms and conditions referenced herein are completed, whichever date is later.
7. Kent shall share all survey-related documents with RIDOH including, but not limited to, accreditation survey reports, plans of corrections, and evidence of compliance with hospital standards. During the term of this Agreement, should CMS request that RIDOH, (as the State Agency for CMS), perform a validation survey of Kent, prior to performing such validation survey RIDOH shall disclose to CMS that it is in possession of such survey-related documents.
8. Kent executive leadership shall report all plans of corrections and progress of the TST implementation to the Kent Board of Trustees, and submit proof thereof to RIDOH.
9. Kent shall provide RIDOH with copies of all invoices and proof of payment regarding all remediation investment expenditures. Kent shall obtain RIDOH approval for all expenditures proposed to contribute to the remediation investment expenses referenced herein.
10. Kent's failure to meet any terms of this Agreement will constitute a breach. If such a breach occurs, RIDOH may exercise its authority to utilize all rights and remedies available under state law. RIDOH reserves the right to terminate this Agreement if it finds that Kent has not fully disclosed material information about Kent's activities, patient safety, and patient outcomes as they relate to the terms of this Agreement. If RIDOH finds that Kent has reduced or discontinued the level of commitment needed to implement this Agreement without good cause, as determined by RIDOH, RIDOH will treat this finding as a breach of this Agreement.
11. This Agreement supersedes any and all prior discussions or compacts, oral or written, between RIDOH and Kent and represents the totality of the understanding with regard to the subject matter herein.
12. The terms and conditions of this Agreement are in addition to the terms, conditions, and requirements contained within the State plans of correction submitted by Kent dated 1/26/2018 and, 4/16/2018, as well as those patient safety initiatives presented to RIDOH on 6/15/18, which are incorporated by reference as if fully set forth herein.
13. By signing this Agreement, RIDOH and Kent acknowledge and agree that the plans of corrections submitted to and accepted by RIDOH prior to the execution of this Agreement are enforceable separate and apart from this Agreement and do not vitiate or modify any of the terms and conditions set forth herein.

14. The parties recognize that this is a public document and may be released by RIDOH in accordance with applicable laws and regulations.

15. The terms of this Agreement may be modified or amended at any time by written consent of all parties. Modifications to this Agreement shall have no force and effect unless such modifications are reduced to writing and signed by the authorized representative of each participating party.

16. If any provision of this Agreement shall be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

17. The terms and conditions of this Agreement will inure to the benefit of, and be binding upon, RIDOH and Kent, their successors and assigns.

18. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same document.

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CONSENTED AND AGREED TO BY:



Raymond O. Powrie, MD
President, Kent Hospital

6.22.18

Date

James E. Fanale, MD
President, CEO and Chief Clinical Officer
Care New England

Date



Nicole Alexander-Scott, MD, MPH
Director, Rhode Island Department of Health

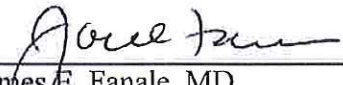
6/22/18

Date

CONSENTED AND AGREED TO BY:

Raymond O. Powrie, MD
President, Kent Hospital


Date



James E. Fanale, MD
President, CEO and Chief Clinical Officer
Care New England

6/21/18

Date



Nicole Alexander-Scott, MD, MPH
Director, Rhode Island Department of Health

6/22/18

Date

