

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:

Rhode Island Hospital
License # HOS00121
593 Eddy Street
Providence, RI 02903

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 Rhode Island Hospital (“RIH”), and resolving regulatory action regarding RIH’s compliance with the Act, the Regulations, and RIH’s written policies and procedures as set forth herein, and is intended to address and resolve any and all regulatory and or compliance issues known to and investigated by RIDOH as of the execution of this Agreement. RIDOH herein represents the compliance issues known to and investigated by RIDOH at this time are set forth herein on page 2 of this Agreement.

FINDINGS OF FACT

Whereas, RIH is located at 593 Eddy Street, Providence, Rhode Island, and is licensed by RIDOH pursuant to the Act and the Regulations.

Whereas, as a condition of its license, RIH 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 in accordance with written policies and procedures pertaining to patient identification and verification, verification of procedure site/side, and provider orders for diagnostic imaging services.

Whereas, after investigating multiple facility-reported incidents during an unannounced combined Federal Centers for Medicare and Medicaid Services (“CMS”) and State licensure survey, RIDOH discovered incidents of potential immediate jeopardy and subsequently issued Federal and State deficiency statements dated March 29, 2018.

Whereas, upon said investigations RIDOH determined that RIH failed to implement and sustain processes and systems to provide care and services in accordance with its written policies and procedures pertaining to patient identification and verification, verification of procedure site/side, and provider’s orders for diagnostic services in the following cases:

1. On 2/21/2018, Patient ID #2 underwent a computed tomography angiography of the brain and neck intended for another patient.
2. On 2/26/2018, Patient ID #1 was not correctly identified and as a result underwent an angiogram intended for another patient.
3. On 3/12/2018, Patient ID #3 underwent a surgical vertebroplasty on Patient ID #3’s C-6 which was intended to be done on C-7.
4. On 3/16/2018, Patient ID #8 underwent a mammogram of the right breast intended for another patient.

Whereas, RIH has failed to conform with all requirements established under the Act and Regulations.

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, RIH 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 RIH’s License No. HOS00121 regarding the four events described above, subject to RIH taking the actions set forth herein at its own expense.
3. RIH will otherwise remain in full compliance with state law and regulation.
4. RIH agrees to commit a minimum of \$1,000,000 in remediation investments to improve its systems pertaining to patient identification and verification, verification of procedure site/side, and provider’s orders for diagnostic services. Such remediation investments shall be applied first to costs RIH incurs that are directly related to conditions imposed herein, including but not limited to any requirements and/or recommendations by the Joint Commission (“TJC”). RIH 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 patient identification and

verification, verification of procedure site/side, and providers' orders for diagnostic services. This amount is not intended to limit or direct the amount RIH may otherwise invest in training/retraining of existing staff.

5. RIH shall report the four events listed above to TJC Office of Quality and Patient Safety ("OQPS") within ten (10) business days of the effective date of this Agreement and shall request written recommendations from the OQPS.

- a. RIH 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. RIH 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. RIH shall begin implementation of the OQPS recommended actions no later than thirty (30) business days from the date received by RIH, unless otherwise agreed upon by RIH and TJC.
- d. RIH shall implement one or more of the Joint Commission Center for Transforming Healthcare ("JCCTH") Targeted Solutions Tools ("TST") pursuant to a separate agreement between RIH 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. RIH 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. RIH will share all TST data, reports, and findings with the OQPS.
 - iii. RIH will provide RIDOH with written monthly monitoring/progress reports through completion of the TST implementation(s).

6. As it relates to Patient ID #2, RIH shall decrease electronic order entry errors by implementing the following:

- a. Within sixty (60) business days of the effective date of this Agreement, develop and provide RIDOH with a copy of a detailed Excel report showing the titles of all current active users having access to patient electronic records and indicating for each individual user the maximum number of patient records that can be open/accessed/edited simultaneously. If the number of records a user can open/access/edit simultaneously changes based on work assignment or department assignment or otherwise, the report shall list individual user access information for each separate assignment.
- b. Within sixty (60) business days of the effective date of this Agreement, provide RIDOH with a copy of all policies and procedures, including clear guidance, outlining the criteria used, justification required and approvals needed to assign users the ability to open/access/edit more than one patient record simultaneously.

- c. Within one hundred twenty (120) business days of the effective date of this Agreement and subject to RIDOH approval, RIH shall conduct mandatory, system-wide in-person training pertaining to patient identification and verification, verification of procedure site/side, and providers' orders for diagnostic services.
7. Obtain provider, staff, and community provider Emergency Medical Services ("EMS") feedback about hospital policies and procedures pertaining to patient identification and verification to prevent patient misidentification by implementing the following:
 - a. Within thirty (30) business days of the effective date of this Agreement, schedule a series of interdisciplinary meetings for all emergency department and interventional radiology nurses, providers, support staff, and community EMS provider representatives involved in identifying patients arriving via emergency medical services to actively solicit input on the strengths, weaknesses, and opportunities for improvement in the existing policies and procedures designed to prevent misidentification of patients, including those that may be unique for which current policies may not be optimal. These meetings must be concluded within sixty (60) days of the effective date of this Agreement, after which RIH shall review and revise its policy and procedures relative to patient identification and verification and provide a copy of the revised policy and procedure to RIDOH on or before August 30, 2018.
8. RIH 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 July 20, 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.
9. RIH 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. In the unlikely event that CMS requests that RIDOH perform a validation survey of RIH during the term of this Agreement, RIDOH shall (a) disclose to CMS that it is in possession of such survey-related documents and (b) request not to perform that validation survey, given RIDOH's possession of such survey-related documents and the expectation for validation surveyors to be independent.
10. RIH executive leadership shall report all plans of corrections and progress of the TST implementation to the RIH Board of Trustees, and submit proof thereof to RIDOH.

11. RIH shall provide RIDOH with copies of all invoices and proof of payment regarding all remediation investment expenditures. RIH shall obtain RIDOH approval for all expenditures proposed to contribute to the remediation investment expenses referenced herein.

12. RIH'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 RIH has not fully disclosed material information about RIH's activities, patient safety, and patient outcomes as they relate to the terms of this Agreement. If RIDOH finds that RIH 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.

13. This Agreement supersedes any and all prior discussions or compacts, oral or written, between RIDOH and RIH and represents the totality of the understanding with regard to the subject matter herein.

14. The terms and conditions of this Agreement are in addition to the terms, conditions, and requirements contained within the State plan of correction submitted by RIH dated May 14, 2018, which is incorporated by reference as if fully set forth herein. By signing this Agreement, RIDOH agrees to (a) accept the May 14, 2018 plan of corrections, (b) communicate such acceptance to CMS as soon as is practicable, and (c) provide evidentiary support for such communication to RIH.

15. The parties recognize that this is a public document and may be released by RIDOH in accordance with State law.

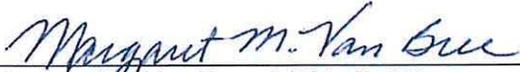
16. The terms of this Agreement may be modified or amended at any time by written consent of all parties. Modifications to this Agreement shall have no force and effect unless such modifications are reduced to writing and signed by the authorized representative of each participating party.

17. 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.

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

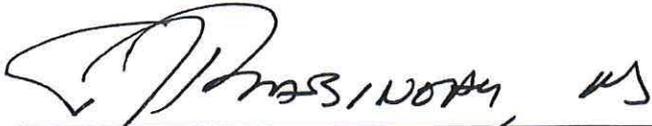
19. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same document.

CONSENTED AND AGREED TO BY:



Margaret M. Van Bree, MHA, DrPH
President, Rhode Island Hospital

6.4.18
Date



Timothy J. Babineau, MD
President and CEO, Lifespan

6.4.18
Date



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

6/4/18
Date