

Department of Health & Human Services
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2325
Boston, MA 02203



Northeast Division of Survey & Certification

June 11, 2018

Peter Holden, President
St Mary's Regional Medical Center
93 Campus Avenue
Lewiston, ME 04240

**Re: CMS Certification Number: 200034
Survey ID: W11Y11, 05/22/2018**

Dear Mr. Holden:

Section 1865 of the Social Security Act (the Act) and Centers for Medicare & Medicaid Services (CMS) regulations provide that a provider or supplier accredited by a CMS-approved Medicare accreditation program will be "deemed" to meet all of the Medicare Conditions of Participation (CoPs) for hospitals. In accordance with Section 1864 of the Act, State Survey Agencies may conduct at CMS's direction, surveys of deemed status providers on a selective sampling basis, in response to a substantial allegation of noncompliance, or when CMS determines a full survey is required after a substantial allegation survey identifies substantial noncompliance. CMS uses such surveys as a means of validating the accrediting organization's survey and accreditation process.

A survey conducted by the Maine Department of Health and Human Services (State Survey Agency) at St Mary's Regional Medical Center on May 22, 2018 found that the facility was not in substantial compliance with the following Condition of Participation (CoPs) for hospitals.

42 C.F.R. §482.12 – Governing Body

As a result, effective May 22, 2018, your facility's deemed status is being removed and survey jurisdiction has been transferred to the State Survey Agency.

A listing of all deficiencies found is enclosed (Form CMS-2567, Statement of Deficiencies and Plan of Correction). You are not required to submit a plan of correction (PoC) for these deficiencies, but you may do so voluntarily. Copies of the Form CMS-2567, including copies containing a facility's PoC, are releasable to the public in accordance with the provisions of Section 1864(a) of the Act and 42 C.F.R.

§401.133(a). As such, if you choose to submit a PoC, it should not contain personal identifiers, such as patient names, and you may wish to avoid the use of staff names.

The State Survey Agency will conduct an unannounced full survey of your facility to assess compliance with all the applicable Medicare conditions. If that survey indicates your facility is in substantial compliance with all of the applicable conditions, CMS will restore your deemed status and notify you in writing of this. If that survey indicates your facility is not in substantial compliance with one or more of the applicable conditions, then CMS will initiate action to terminate your Medicare agreement and will notify you in writing of this, including your opportunity to make timely correction of deficiencies identified.

In accordance with 42 CFR §498.3(d), this notice of findings is an administrative action, not an initial determination, and therefore formal reconsideration and hearing procedures do not apply.

If you have any questions, please contact Nancy Hannah at (617) 565-1327.

Sincerely,

A handwritten signature in black ink, appearing to read "Hyosim Seon-Spada".

CAPT Hyosim Seon-Spada, DNP, USPHS
Branch Manager, Survey Branch

Enclosure: CMS-2567

cc: State Survey Agency
DNV-GL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 06/11/2018
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 200034	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 05/22/2018
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NAME OF PROVIDER OR SUPPLIER ST MARY'S REGIONAL MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 93 CAMPUS AVENUE - PO BOX 291 LEWISTON, ME 04243
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A 000	<p>INITIAL COMMENTS</p> <p>Federal Complaint #27958</p> <p>During an EMTALA investigation, issues related to the hospital's compliance related to the Condition of Participation: Governing Body were identified. On May 21, 2018, CMS authorized a review to evaluate compliance with 42 Code of Federal Regulations Part 482, Condition of Participation: Governing Body (§482.12). This survey determined the hospital was not in compliance with 42 Code of Federal Regulations Part 482.12, Condition of Participation: Governing Body. The following requirements have not been met:</p>	A 000		
A 043	<p>GOVERNING BODY CFR(s): 482.12</p> <p>There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ...</p> <p>This CONDITION is not met as evidenced by: Based on records reviewed and interviews, the Condition Participation for Governing Body Condition was not met as evidenced by the failure to ensure the quality of patient care determination by Emergency Department (ED) Physicians were based on complete and accurate medical record information provided by a crisis agency completing emergency crisis evaluations for 4 of 6 sampled patient records (Patient Record #2A, 3A, 3B, and 3D). In addition, evidence that indicated the Governing Body failed to ensure a</p>	A 043		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 043	<p>Continued From page 1</p> <p>system was in place to verify services from crisis agencies were furnished by qualified individuals for two crisis agencies (Crisis Agency #1 and #2), that these agencies' performances were discussed and reported to the Quality Assurance and Performance Improvement Committee (QAPI), and the Governing Body approved the overall 2018 QAPI program.</p> <p>Findings:</p> <p>1. Standard: §482.12(a)(5) Medical Staff Accountability also known as A0049 - The Governing Body failed to ensure the quality of patient care determination by Emergency Department (ED) Physicians, were based on complete and accurate medical record information provided by a crisis agency completing emergency crisis evaluations for 4 of 6 sampled patient records whose records indicated crisis evaluations were conducted (Patient Record #2A, 3A, 3B, and 3D). See A0049 for details.</p> <p>2. Standard: §482.12(e) Contracted Services also known as A0083 - The Governing Body failed to ensure a system was in place to verify services from crisis agencies were furnished by qualified individuals for two crisis agencies (Crisis Agency #1 and #2) and that these agencies' performances were discussed and reported to the Quality Assurance and Performance Improvement Committee (QAPI). See A0083 for details.</p> <p>3. The Governing Body has an overall responsibility for the services furnished at the hospital which includes the review and approval of the hospital's Performance and Patient Safety</p>	A 043			

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A 043	Continued From page 2 Improvement Plans (QAPI program). Documentation provided to the surveyors indicated that the Board of Directors approved the 2017 St. Mary's Regional Medical Center Performance and Patient Safety Improvement Plan at a meeting on 3/29/17. On 5/22/18 at 10:25 AM, the Risk Manager provided documentation that hospital's 2018 Performance Improvement and Patient Safety Plan was scheduled to be reviewed in June 2018 by the System Quality Committed and was scheduled to be brought to the full board for approval in September 2018. Based on the fact that the 2018 Performance Improvement and Patient Safety Plan was not scheduled for full board review until September 2018, eight months after the plan would be in effect, the Governing Body has failed to provide oversight of the QAPI programs within the hospital. The cumulative effect of these deficient practices resulted in noncompliance with this Condition of Participation.	A 043			
A 049	MEDICAL STAFF - ACCOUNTABILITY CFR(s): 482.12(a)(5) [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. This STANDARD is not met as evidenced by: Based on record reviews and interview, it was determined that the Governing Body failed to	A 049			

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A 049	<p>Continued From page 3</p> <p>ensure the quality of patient care determination by Emergency Department (ED) Physicians were based on complete and accurate medical record information provided by a crisis agency completing emergency crisis evaluations for 4 of 6 sampled patient records that indicated a Crisis Agency evaluated the patient in the ED. (Patient Record #2A, 3A, 3B, and 3D).</p> <p>Findings:</p> <p>During record reviews, it was noted that four records (Patient Record #2A, 3A, 3B, and 3D) indicated the patient had been evaluated by Crisis Agency #1. However, the records failed to contain documentation of the referenced evaluation of the patient performed by Crisis Agency #1.</p> <p>On 5/16/18 between 1:48 PM and 2:09 PM and on 5/17/18 at 12:07 PM and 1:30 PM, interviews were conducted with the Vice President of Emergency Services/Physician A, the Director of Emergency Service, and the Risk Manager. The following information was obtained during these interviews: the crisis agencies provide further evaluation of the patients which may involve extensive interviews with the patients and community members if needed; the agencies would make recommendations of what they think should happen with the patient; and treatment decisions were made in conjunction with the crisis agencies.</p> <p>On 5/18/18 at 9:35 AM, the surveyors interviewed the Vice President of Emergency Services/Physician A and the Director of Emergency Services regarding Patient Record #2A. The Director of Emergency Services looked in their electronic medical record and confirmed</p>	A 049			

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A 049	Continued From page 4 that the crisis agency report had not been scanned and attached to Patient Record #2A. On 5/21/18 at 11:26 AM, surveyors discussed with the Director of Emergency Services that the evaluation by Crisis Agency #1 was not in Patient Records #3A, #3B, and #3D. On 5/21/18 at 11:19 AM, the Risk Manager verified that they did not have any crisis agency reports and she had reports faxed to her today. On 5/21/18 at 12:15 PM, the Vice President of Emergency Services/Physician A indicated that the crisis workers discuss with the ED staff and a consultation report should go into the medical record.	A 049			
A 083	CONTRACTED SERVICES CFR(s): 482.12(e) The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services. This STANDARD is not met as evidenced by: Based on record reviews and interviews, the Governing Body failed to ensure a system was in place to verify services from crisis agencies were furnished by qualified individuals for two crisis agencies (Crisis Agency #1 and #2) and that these agencies performances were discussed and reported to the Quality Assurance and	A 083			

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A 083	<p>Continued From page 5 Performance Improvement Committee (QAPI).</p> <p>Findings:</p> <p>The governing body's responsibilities in relation to the furnishing of services would include ensuring any individuals furnishing services through an agency are qualified and credentialed to provide a safe and effective care.</p> <p>The hospital has utilized Agency #1 through 3/31/18 and Agency #2 since 4/1/18, to furnish mental health crisis services to patients that present to the Emergency Department (ED).</p> <p>During an interview on 5/17/18 at 12:07 PM, conducted with the Vice President of Emergency Services, Director of Emergency Service and Risk Manager, it was stated that the purpose of Agency #1 and Agency #2 was for bed management, resources in the community, and evaluation. These evaluations may involve extensive interviews in the hospital and out in the community. The crisis workers would discuss with the medical providers their evaluations, would offer what they think may be appropriate for the patient, and would discuss plans for the patient.</p> <p>The involvement of the agencies with the patients in the ED indicates an integration of services furnished between the hospital and the two separate agencies.</p> <p>On 5/21/18 at 2:37 PM, the Risk Manager indicated to the surveyor that the hospital did not have a contract with the agencies that have been and continue to furnish crisis services to patients in their ED, but they did have a Memorandum of Understanding (MOU) with each agency. She</p>	A 083			

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A 083	<p>Continued From page 6</p> <p>also indicated that the hospital had not credentialed the individuals from Agency #1 and #2.</p> <p>A review of the MOU with Agency #1, dated February 20, 2015, and the MOU with Agency #2, dated April 2, 2018, did not include any language related to ensuring qualified and credentialed individuals would be provided by the agencies.</p> <p>On May 21, 2018 at 2:48 PM, the Director of the Emergency Department was asked how it was determined that staff from Agency #1 were qualified and he stated he "does not know the qualifications of crisis workers". He also indicated that there was no discussions or reporting to the QAPI Committee regarding these agencies.</p> <p>Record reviews determined that services were provided at the hospital or services were recommended upon discharge from Crisis Agency #1 or #2, for 13 ED patient records reviewed (Patient Record #1B, #1C, #1D, #2A, #2C, #3A, #3B, #3D, #4A, #4B, #8, #9, and #11).</p>	A 083			