



Paul R. LePage, Governor

Ricker Hamilton, Commissioner

Department of Health and Human Services  
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June 26, 2018

Peter Holden, Administrator  
St Mary's Health System  
PO Box 7291  
Lewiston, ME 04243

Dear Mr. Holden:

The Plan of Correction for the complaint survey, completed on May 22, 2018, for St Mary's Regional Medical Center has been received in our office.

Upon review, your Plan of Correction received on June 21, 2018 was found to be acceptable as submitted.

If you have any questions, please feel free to call me through Marcia Smith at (207) 287-9259 or by email at [Marcia.Smith@maine.gov](mailto:Marcia.Smith@maine.gov).

Sincerely,

Elizabeth Church, RN, BSN  
Manager of Acute Care and Long Term Care  
Division of Licensing and Certification

cc: Nancy Hannah CMS - Boston Regional Office

Complaint # 27958

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

PRINTED: 08/11/2018  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  700034	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  C 08/22/2018
NAME OF PROVIDER OR SUPPLIER  ST MARY'S REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 63 CAMPUS AVENUE - PO BOX 201 LEWISTON, ME 04240		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 000	INITIAL COMMENTS  Federal Complaint #27958  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:	A 000			
A 043	GOVERNING BODY CFR(s): 482.12  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 ...  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	A 043	Deficiency A 043  The governing body at St. Mary's has an overall responsibility for the services furnished by the hospital which includes the review and approval of the hospital's Performance and Patient Safety Improvement Plan.  Covenant Health develops, annually, a system-wide Quality Plan for the health system. St. Mary's utilizes the Covenant Quality Plan to develop system quality goals that are approved by the St. Mary's Board of Directors, our governing body.  The Covenant Quality Plan was approved by Covenant Board Quality Committee on February 22, 2018 and the Covenant Board of Directors on February 23, 2018. Prior to the approval of the quality plan, the St. Mary's System Quality Committee developed goals for 2018 during the November 15, 2017 meeting.		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Pete Hoffman TITLE SUP, Incom President (X6) DATE 6-21-18

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.

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

PRINTED: 08/17/2018  
FORM APPROVED  
OMB NO. 0930-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/UPPER/OLIA IDENTIFICATION NUMBER:  200034	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  C 08/22/2018
NAME OF PROVIDER OR SUPPLIER  ST MARY'S REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 81 CAMPUS AVENUE - PO BOX 201 LEWISTON, ME 04243		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 043	Continued From page 1 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.  Findings:  1. Standard: §482.12(a)(6) 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 8 sampled patient records whose records indicated crisis evaluations were conducted (Patient Record #2A, 3A, 3B, and 4B). See A0049 for details.  2. Standard: §482.12(a) 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.  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	A 043	(A 043 Continued)  These goals were added to the Covenant Quality Plan and developed into the St. Mary's Quality Management Plan. This plan was reviewed and approved by the St. Mary's System Quality Board on June 13, 2018 and approved by the St. Mary's Board of Directors on June 20 <sup>th</sup> , 2018.  The hospital's Performance and Patient Safety Improvement Plan was previously approved by the Board of Directors on March 29, 2017. Due to the review and approval timeline of the Covenant Health Quality Plan and the St. Mary's Quality Management Plan, the local plan was not approved within a 12-month period.  To ensure the St. Mary's Quality Management Plan is approved in a timely manner by the St. Mary's Board of Directors, the Director of Quality will work with Covenant Health to develop the system-wide quality plan by December 2018.  This will allow St. Mary's adequate time to update and/or develop their annual Quality Management Plan. The approval of the Quality Management Plan will be tracked by the Clinical Practice Committee to make certain this is meeting the required timeline.  (See page 3) Completed 6.20.18		

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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	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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 3/28/17.  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 Committee 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.	A 043	6/25/18 @ 305pm - Spoke to Erin Hayes. The following will be added to the POC for <del>A 043</del> A 043:  Please see A049 & A043 POC (pages 3-6) for corrections for finding #1 & #2 under A043  Marcia Smith RNBSN - 6/25/18	
A 049	<b>MEDICAL STAFF - ACCOUNTABILITY</b> 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	Deficiency A 049  The governing body at St. Mary's must ensure the medical staff is accountable to the governing body for the quality of care provided to patients.  St. Mary's utilizes an outside agency, to perform crisis evaluations on patients, when required, in the Emergency Department.	

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PRINTED: 09/11/2018  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(A1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  300024	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  C 05/23/2018
NAME OF PROVIDER OR SUPPLIER  ST MARY'S REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 55 CAMPUS AVENUE - PO BOX 201 NEWTON, ME 04249	
(04) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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 1:40 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	<p>(A 049 Continued)</p> <p>To ensure the quality of patient care by Emergency Department providers is based on complete and accurate medical records, crisis evaluation forms need to be available in the patient's medical record as soon as possible after the evaluation.</p> <p>A new process will ensure that crisis evaluations are available for provide use prior to the crisis worker leaving the facility.</p> <p>To hold the medical staff accountable for the quality of care provided to patients, St. Mary's will implement a monthly chart audit process of 20 to 25 patients who have received assessments from crisis staff to ensure the documentation is available in the chart. The monthly audit will continue until a 95% compliance rate has been obtained for 3 consecutive months.</p> <p>The audit will then be performed quarterly unless the compliance rate drops below 95% and then it will be performed monthly again. Audit results are part of the Emergency Department quality metrics.</p>	

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PRINTED: 06/11/2018  
FORM APPROVED  
OMB NO. 0938-0381

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  200004	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  C 06/22/2018
NAME OF PROVIDER OR SUPPLIER  ST MARY'S REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 93 CAMPUS AVENUE - PO BOX 201 LEWISTON, ME 04243	
(K4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(N5) COMPLETION DATE
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 11:28 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 003	<b>CONTRACTED SERVICES</b> 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	<b>Deficiency A 083</b>  The governing body must ensure a system in place to verify that services provided by a contracted agency are furnished by qualified individuals. St. Mary's did not have a process in place to obtain credentialing information about the employees who performed crisis evaluations on patients in the Emergency Department.  St. Mary's has created a process to ensure all who perform crisis evaluations are qualified. A list of all employees who will perform crisis evaluations on patients at St. Mary's is now available in the Emergency Department. In addition, this list will include information regarding credentials and education for the employees.	

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PRINTED: 05/11/2018  
FORM APPROVED  
OMB NO. 0938-0381

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NAME OF PROVIDER OR SUPPLIER  ST MARY'S REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 63 CAMPUS AVENUE - PO BOX 261 LEWISTON, ME 04243	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 083	Continued From page 8 Performance Improvement Committee (QAPI).  Findings:  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.  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).  During an interview on 6/17/18 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.  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.  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	A 083	(A 083 Continued)  When a new crisis employee is hired, the crisis provider will contact the Director of the Emergency Department to obtain security clearance and the information regarding the employee will be added to the list at St. Mary's.  St. Mary's will also initiate regular meetings with the crisis provider beginning June 28 <sup>th</sup> . These meetings will be held to review current and new crisis employees, documentation and communication concerns, competency reviews of the employees and quality metrics reported to the State of Maine.  This information will be communicated at the Emergency Department meetings and the Clinical Practice Committee.  Due 06.28.18	

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NAME OF PROVIDER OR SUPPLIER  ST MARY'S REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 65 CAMPUS AVENUE - PO BOX 261 LEWISTON, ME 04243	
(#4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(#5) COMPLETION DATE
A 083	<p>Continued From page 0</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, 2016, 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 2:45 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, #5B, #9, and #11).</p>	A 083		