Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2117769	01/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bon Secours Harbourview Outpatient Infusion Center	7185 Harbour Towne Parkway, Suite 107, Suffolk, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Bons Secours Maryview Medical Outpatient Infusion Center on January 17, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's 2017 and 2018 hematology proficiency testing (PT) documentation, and an interview, the laboratory failed to retain the attestation statement signed by the laboratory director (LD) for one (1) of six (6) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation, a total of 6 events, revealed no LD attestation statement for the 2018 Event 1. The inspector requested to review the attestation documentation. No documentation was available for review. 2. In an exit interview with the Point of Care Coordinators, Practice Manager, and Laboratory Administrator at approximately 2:00 PM , it was confirmed the findings as outlined above.

D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least eighty (80) percent (%) of acceptable responses for three (3) out of six (6) hematology analytes on the 2018 third (3rd) testing event. Findings include: 1. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) PT records (a total of 6 events reviewed) revealed scores of less than 80 % for the following hematology analytes in the 2018 3rd event: 60% Score -Red Blood Cell count (RBC): HSY -13 unacceptable, HSY-14 unacceptable; 60% Score-Hematocrit (HCT): HSY-13 unacceptable, HSY-14 unacceptable; 60% Score-Hemoglobin (HGB): HSY -13 unacceptable, HSY-14 unacceptable. 2. In an interview with the Point of Care Coordinators, Practice Manager, and Laboratory Administrator at approximately 2:00 PM , it was confirmed that the laboratory received unsatisfactory scores as outlined above.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing (PT) records, procedure manual, and an interview, the laboratory failed to document remedial action taken for the unsatisfactory third (3rd) Hematology testing event in calendar year 2018. Findings include: 1. Review of 2017 and 2018 American Proficiency Institute (API) hematology PT test result documentation (a total of six events) revealed no evidence of remedial action for the following unsatisfactory analyte scores on the 2018 3rd Event: 60% Red Blood Cell count (RBC): HSY -13 unacceptable, HSY-14 unacceptable; 60% Hematocrit (HCT): HSY-13 unacceptable, HSY-14 unacceptable; 60% Hemoglobin (HGB): HSY -13 unacceptable, HSY-14 unacceptable; with an overall unsatisfactory Hematology event score of 76%. 2. Review of the laboratory's procedure manual revealed a policy (Policy Number OPIC.0012 Version 1.3 Evaluating Proficiency Testing Results) which stated, "document the causes and corrective action taken to prevent failures from happening in the future, evaluating the test systems affected, retest the PT specimens, perform a scheduled quality assurance follow up review of all corrective actions taken, document the review as proficiency testing review is a well justified laboratory expense." The inspector requested documentation of the PT remedial action for the API 2018 3rd Event. No documentation was available for review. The Point of Care Coordinators stated, "the technical consultant that was responsible for following up on that event is no longer

	working with us". 3. In an interview with the Point of Care Coordinators, Practice Manager, and Laboratory Administrator at approximately 2:00 PM , it was confirmed that the laboratory failed to document remedial action taken, as outlined above, according to their policy. .
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the laboratory's Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), personnel files, procedure manual, and interviews, the laboratory director (LD) did not perform competency assessments for the technical consultant (TC) in calendar years 2017 and 2018. Findings: 1. Review of the laboratory's CMS 209 revealed that the LD performed the the duties of TC and that thirteen (13) testing personnel performed Complete Blood Count (CBC) patient testing during the twenty-four (24) months reviewed. 2. Review of the available testing personnel files revealed that TP C performed the Sysmex XP-300 Hematology competency assessments from calendar year 2017 to the end of calendar year 2018. Review of the laboratory's available personnel files revealed no competency assessment documentation for TP C in the role of TC in calendar years 2017 and up to the date of the inspection on 1/17/19. (See Personnel Code Sheet) 3. Review of the laboratory's procedure manual revealed a quality assurance (QA) policy (OPIC.0013 Version 1.3 Employee Competency Skill Assessment) that stated, "the laboratory director is responsible in ensuring that the evaluation of competency is available for all personnel for duties performed'. The inspector requested to review competency assessment documentation for TP C in the role of TC. The documentation was not available for review. The Point of Care Coordinators stated, in an interview at approximately 11:30 AM, "we have had a lot of turnover and we do not have the competency assessment for the consultant". 4. In an interview with the Point of Care Coordinators, Practice Manager, and Laboratory Administrator at approximately 2:00 PM , it was confirmed that the LD failed to document competency assessments for TP C in the TC duties performed during the timeframes outlined above.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each

	consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), personnel competency assessments, procedure manual, and interviews, the laboratory director (LD) did not delegate, in writing, the job duties and responsibilities of technical consultant (TC) to the personnel performing the duties of TC from January 2017 to the end of calendar year 2018. Findings include: 1. Review of the laboratory's CMS 209 form revealed that the LD also performed the the duties of TC and that thirteen (13) testing personnel performed Complete Blood Count (CBC) patient testing during the twenty-four (24) months reviewed. 2. Review of the available testing personnel files revealed that TP C performed the duties of TC by performing competency assessments from calendar year 2017 to the end of calendar year 2018. (See Personnel Code Sheet.) 3. Review of the procedure manual revealed no documentation of the delegation of duties to TP C as the TC, in writing, by the LD. The inspector requested to review the delegation of duties. The documentation was not available for review. 4. In an interview with the Point of Care Coordinators, Practice Manager, and Laboratory Administrator at approximately 2:00 PM , it was confirmed that the LD failed to delegate in writing, the job duties and responsibilities of the TC during the twenty-four (24) months reviewed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and interviews, the technical consultant (TC) failed to perform annual Hematology competency evaluations for two (2) of thirteen (13) testing personnel (TP) in calendar year 2017. Findings include: 1. Review of the laboratory's CMS 209 revealed that the LD performed the the duties of TC and that thirteen (13) testing personnel performed Complete Blood Count (CBC) patient testing during the twenty-four (24) months reviewed. 2. Review of the available testing personnel files revealed that TP C performed the Sysmex XP-300 Hematology Competency Check List assessments for those TP performing patient CBC testing from calendar year 2017 to the end of calendar year 2018. The inspector noted that the files contained no competency evaluations in calendar year 2017 for: TP A, TP B. (See Personnel Code Sheet.) The inspector requested to review the documentation. No records were available for review. The Point of Care Coordinators stated, in an interview at approximately 11:30 AM, "we have looked for, but we do not have the 2017 hematology competency assessments for these personnel and the consultant who would have performed them is no longer working for the laboratory". 3. In an interview with the Point of Care

	Coordinators, Practice Manager, and Laboratory Administrator at approximately 2:00 PM , it was confirmed that the TC failed to perform hematology competency evaluations for 2 of 13 TP, as outlined above, in calendar year 2017.