Form Submission for EOHHS Web Feedback at Sep 11, 2015 8:18 AM

Name:

Email:

Phone:

Subject: Complaints

Comments: Sept. 10, 2015

Division of Health Care Facility Licensure and Certification
Complaint Intake Unit
99 Chauncy Street
Boston, Massachusetts 02111

Dear Ambulatory Clinic Complaint Dept.,

This is a allegation pertaining to the license of the Four Women Health Services (FWHS) ambulatory care clinic.

Four Women has failed the CLIA laboratory re-testing. The failures listing sent to Four Women were:

"(1) The repeat history of proficiency testing failures in the specialty of Immunohematology, for the
analyte D(RhO), which constitutes a subsequent occurrence of unsuccessful participation in proficiency testing; and

(2) The laboratory director's failure to fulfill his responsibility for monitoring proficiency testing to
ensure that the laboratory is in compliance with the CLIA Condition of successful participation in
proficiency testing.

...that on January 20, 2015, the SA notified your laboratory of a first occurrence of unsuccessful participation in proficiency testing under the specialty of Immunohematology, for the
analyte ABO Group/Rh Typing, based on unsatisfactory results for the 2014 third event. On February 3, 2015, the SA received your allegation of compliance and evidence of correction which
was deemed to be acceptable. The subsequent occurrence of unsuccessful participation in PT, 2015
first event, indicates that the laboratory failed to either implement corrections as alleged or

monitor
for the effectiveness of its corrective actions.

Based on a review of proficiency testing performance, it was determined unsuccessful participation has been noted in the following area(s):

TESTING EVENTS
PROGRAM ANALYTE
SPECIALTY OR
SUBSPECIALTY
YOUR SCORE
2, 2014 AAB Immunohematology 0% Results Not Reported
3, 2014 AAB Immunohematology 60%
2, 2014 AAB ABO Group/Rh Typing (Non Tranfusion) 0% Reults Not Reported
3, 2014 AAB ABO Group/Rh Typing (Non Tranfusion) 60%

In addition, other standards were also found to be not met. Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program."

In the Aug. 2015 letter to the owner and physician there, , the CMS Dept of Health and Human Services wrote that Four Women will be sanctioned unless compliant.

If you would kindly docket my complaint and perform a survey/inspection there. Also please pull all grants and funding to them since they cannot seem to abide by the law/rules/regulations pertaining to Laboratory protocols/regulations.

Thank you very much.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2350
Boston, MA 02203

MA Dept. of Public Heal
99 Chauncy Street
Boston, MA 02111

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Northeast Division of Survey & Certification

IMPORTANT NOTICE - ACTION NECESSARY

Via certified mail.

August 25, 2015

Laboratory Director
Four Women Health Services, LLC
150 Emory Street
Attleboro, MA 02703

CLIA number: 22D0945040

RE: PROPOSED SANCTIONS DUE TO SUBSEQUENT OCCURRENCE OF UNSUCCESSFUL PARTICIPATION IN PROFICIENCY TESTING - IMPOSITION NOTICE TO FOLLOW IF PROPOSED SANCTIONS ARE IMPOSED

Dear

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. Part 493). Compliance with these regulations is a requirement for certification for the CLIA program.

Subpart H of 42 C.F.R Part 493 requires each laboratory certified to test specimens under the CLIA regulations to successfully participate in an approved proficiency testing program. The CLIA regulations at 42 C.F.R. § 493.2 define, as set out in Subpart H, unsuccessful proficiency testing performance as failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two out of three consecutive testing events.

Determination of Non-Compliance: Finding of Unsuccessful Participation in Proficiency Testing - Subsequent Occurrence

Evidence obtained by the Bureau of Health Care Safety & Quality, Massachusetts State Agency (SA) during a desk review conducted on May 21, 2015, of proficiency testing results submitted to CLIA from your laboratory's proficiency testing program shows your laboratory has a repeat history of unsatisfactory proficiency testing performance for the tests and events listed below

which constitutes a subsequent occurrence of unsuccessful participation in proficiency testing for these tests:

Testing Event PT Provider Test Score

TESTING EVENTS	PROGRAM	ANALYTE SPECIALTY OR SUBSPECIALTY	YOUR SCORE
2, 2014	AAB	D(RhO)	0%
3, 2014	AAB	D(RhO)	60%
1, 2015	AAB	D(RhO)	80%

Based on the repeat proficiency testing failures listed above, your laboratory is not in compliance with two CLIA Conditions. The enclosed Form CMS-2567, Statement of Deficiencies, specifically documents the laboratory's failure to meet the Condition-level requirements at:

- D2016 - 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]; and
- D6076 - 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing: laboratory director.

In addition, other standards were found to be not met.

Proposed Sanctions Based on Unsuccessful Participation in Proficiency Testing – Subsequent Occurrence

Pursuant to 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1806(a), and 493.1840(a)(3), we propose to take sanction actions against the laboratory's CLIA certificate based on Condition-level non-compliance as evidenced by:

(1) The repeat history of proficiency testing failures in the specialty of Immunohematology, for the analyte D(RhO), which constitutes a subsequent occurrence of unsuccessful participation in proficiency testing; and
(2) The laboratory director's failure to fulfill his responsibility for monitoring proficiency testing to ensure that the laboratory is in compliance with the CLIA Condition of successful participation in proficiency testing.

We propose to take the following sanction actions against the laboratory's CLIA certificate:

• 42 C.F.R. §§ 493.803(b), 493.1804(b)(1)(ii), 493.1806, and 493.1840(a)(3) – Principal Sanction: Limitation of the laboratory's CLIA certificate for the specialty of Immunohematology for not less than six months effective September 9, 2015. When a laboratory's CLIA certificate is limited in a specific specialty, the laboratory will not be permitted to perform any patient testing in that specialty.

NOTE: The laboratory may continue to perform parallel testing on patient specimens in the specialty of Immunohematology if needed to implement corrective actions, however, the laboratory may not report any patient test results in the specialty of Immunohematology during the period when its CLIA certificate is limited in the specialty of Immunohematology.

The laboratory has sixty (60) days in which to appeal the determination to limit its certificate in the specialty of Immunohematology. If the laboratory chooses not to file an appeal, limitation of its CLIA certificate in the specialty of Immunohematology will become effective September 9, 2015. If a timely hearing request is received, limitation of the laboratory's CLIA certificate in the specialty of Immunohematology will be effective with the date of the administrative hearing decision, if our determination of non-compliance is upheld.

As noted below, pursuant to 42 C.F.R. §§ 493.1840(a)(4) and 493.1844(d)(2)(ii)(B), limitation of the laboratory's CLIA certificate will not be delayed even if a hearing is filed if the laboratory fails to comply with the terms of the Directed Plan of Correction (see proposed sanction of a Directed Plan of Correction below).

• 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1806(c)(1), 493.1832, and 493.1844(h)(2) – Alternative Sanction: Directed Plan of Correction effective September 9, 2015. If this sanction is imposed, the laboratory is directed to

1) address any actual or potential negative patient outcome during the period of unsuccessful proficiency testing performance for the specialty of Immunohematology and submit acceptable evidence that this has been done within ten (10) calendar days from the date of the notice of imposition;

2) demonstrate that the laboratory has established an effective oversight mechanism to prevent recurrences of proficiency testing failure for all testing including testing in the specialty of Immunohematology and submit acceptable evidence that such a mechanism has been implemented within ten (10) calendar days from the date of the notice of imposition; and

3) demonstrate satisfactory performance in two consecutive proficiency testing events for the specialty of Immunohematology before the limitation of the laboratory's certificate in the specialty of Immunohematology can be lifted. The laboratory may obtain the two consecutive proficiency testing events from any proficiency testing program approved by CMS for the calendar year.

Acceptable evidence of correction to be submitted to meet the requirements of the Directed Plan of Correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken;
3) What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and,
4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please note that pursuant to 42 C.F.R. §§ 493.1840(a)(4) and 493.1844(d)(2)(ii)(B), if the laboratory fails to comply with the terms of the Directed Plan of Correction above, it will constitute failure to comply with a reasonable request from CMS for information and work on materials necessary to determine continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS, and will result in the limitation taking effect September 9, 2015, regardless of whether a hearing is filed. In addition, pursuant to 42 C.F.R. § 493.1840(a)(7), failure to comply with alternative sanctions is a basis for limitation, suspension, or revocation of any type of CLIA certificate.

* We note that on January 20, 2015, the SA notified your laboratory of a first occurrence of unsuccessful participation in proficiency testing under the specialty of Immunohematology, for the analyte ABO Group/Rh Typing, based on unsatisfactory results for the 2014 third event. On February 3, 2015, the SA received your allegation of compliance and evidence of correction which was deemed to be acceptable. The subsequent occurrence of unsuccessful participation in PT, 2015 first event, indicates that the laboratory failed to either implement corrections as alleged or monitor for the effectiveness of its corrective actions.

• 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1807(b), 493.1808(b), 493.1826, 493.1844(d)(1), and 493.1844(h)(2) – Medicare Alternative Sanction: Suspension of the laboratory's approval to receive Medicare payments for any services performed in the specialty of Immunohematology effective September 9, 2015.

The laboratory must agree in writing (in return for not having its Medicare approval cancelled immediately) to not charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended, i.e., in the specialty of Immunohematology. Failure to provide this written agreement will result in the cancellation of the laboratory's approval to receive Medicare payment for all laboratory services effective September 9, 2015.

As a consequence of the suspension of the approval to receive Medicare for services performed in specialty of, under section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will also no longer be available to the laboratory for all laboratory services performed in the specialty of

Immunohematology. *See* 42 C.F.R. § 440.2(b). Pursuant to 42 C.F.R. § 493.807, the suspension period for Medicare and Medicaid approval for these services is for a period of not less than six months.

Please be advised that the imposition of sanctions cannot be avoided by closure of your laboratory, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

Instructions for Sending in Your Response

The laboratory has ten (10) calendar days from the date of this notice, or until September 4, 2015, to submit in writing any evidence or information as to why the proposed sanctions for a subsequent occurrence of unsuccessful participation in proficiency testing for the specialty of Immunohematology and noncompliance with the Conditions of successful participation in proficiency testing and laboratory director should not be imposed. If we do not receive a timely submission or if we determine that the submission is unpersuasive, we will notify you in writing that we will proceed to impose the above-referenced sanctions. We will provide information regarding the laboratory's appeal rights at that time.

All responses, including written evidence as to why the proposed sanctions for a subsequent occurrence of unsuccessful participation in proficiency testing for the specialty of Immunohematology should not be imposed should be sent to:

Paul Miller
Acting, Branch Manager
Centers of Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room-2350
Boston, MA 02203

If you have any questions, please contact Charles Reynolds at (617) 565-9156 or Bethzaida Rodriguez at (617) 565-2146 of my staff.

Sincerely,

For Paul Miller
Acting, Branch Manager
Certification and Enforcement Branch

Enclosure: Form CMS-2567

cc: Paul DiNatale, Massachusetts SA

Via certified mail, return receipt # 91710821333939682432224