DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Western Division of Survey and Certification
San Francisco Regional Office
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

CENTERS FOR MEDICARE & MEDICAID SERVICES

Refer to: WDSC- GKY

**IMPORTANT NOTICE – PLEASE READ CAREFULLY**

March 18, 2016

Sunil Dhawan, M.D., Director
Elizabeth Holmes, Owner
Ramesh Balwani, Owner
Theranos, Inc.
7333 Gateway Boulevard
Newark, CA 94560

CLIA Number: 05D2025714

RE: PROPOSED SANCTIONS – CONDITIONS NOT MET IMMEDIATE JEOPARDY. **IMPOSITION NOTICE TO FOLLOW IF PROPOSED SANCTIONS ARE IMPOSED.**

Dear Dr. Dhawan[1], Ms. Holmes, and Mr. Balwani:

**This letter provides notice of sanctions the Centers for Medicare & Medicaid Services (CMS) is proposing to impose against the laboratory's Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate and of the laboratory's opportunity to submit in writing any evidence or information as to why the proposed sanctions should not be imposed. If the sanctions are imposed, we will provide the laboratory with a separate notice setting forth hearing rights and explaining the administrative appeals process.**

CMS conducted a CLIA recertification and complaint survey at Theranos, Inc. ("Theranos" or "laboratory"). The onsite portion of the survey was completed on November 20, 2015; however, the survey concluded with the receipt of critical information received from the laboratory on December 23, 2015. Based on this survey, Theranos was found to be out of compliance with the following five CLIA Condition-level requirements:

| | |
|---|---|
| D5024: 42 C.F.R. § 493.1215 | Condition: Hematology; |
| D5400: 42 C.F.R. § 493.1250 | Condition: Analytic systems; |
| D6076: 42 C.F.R. § 493.1441 | Condition: Laboratories performing high complexity testing; laboratory director; |
| D6108: 42 C.F.R. 493.1447 | Condition: Laboratories performing high complexity testing; technical supervisor; and, |

[1] Theranos, Inc.'s February 12, 2016 submission states: "The laboratory directors during the period covered by the survey no longer hold any position with the lab." However, because Dr. Dhawan was the laboratory director at the time of the CLIA recertification and complaint survey concluded on December 23, 2015, we will continue to hold Dr. Dhawan responsible for all CLIA deficiencies cited. We will continue to address all notices related to the December 23, 2015 CLIA survey to Dr. Dhawan and Theranos, Inc. (We note that the February 12 submission indicates that Kingshuk Das, M.D., had since been appointed the laboratory's director.)

D6168: 42 C.F.R. § 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

In addition, CMS determined that various CLIA Standard-level requirements were not met.

By letter dated January 25, 2016, CMS provided Theranos with a listing of all deficiencies identified during the survey on Form CMS-2567, Statement of Deficiencies. The January 25, 2016 letter also notified the laboratory that the seriousness of the deficiencies cited under 42 C.F.R. § 493.1215 resulted in the finding of immediate jeopardy to patient health and safety, and requested that the laboratory take immediate action to remove the jeopardy and bring any unmet Condition-level requirements into compliance. CMS gave the laboratory 10 calendar days from the date of receipt of the January 25, 2016 letter to submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies. On February 4, 2016, a Theranos representative requested an extension until February 12, 2016 to provide a submission, which CMS granted. CMS received a submission from the laboratory in response to the January 25, 2016 letter on February 12, 2016.

After careful review, we have determined that the laboratory's submission does not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 2016, and does not demonstrate that the laboratory has come into Condition-level compliance and abated immediate jeopardy. In general, we find that the statements made in the allegation of compliance and evidence of correction: 1) failed to adequately address the deficient practice cited; 2) are incomplete and failed to meet the criteria of acceptable evidence of correction; 3) do not ensure sustained compliance; and 4) show a lack of understanding of the CLIA requirements.

As the laboratory was advised in our January 25, 2016 letter, a credible allegation of compliance, as defined by regulation (42 C.F.R. § 493.2), is a statement or document that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problem.

It is important to note that for it to be credible, the allegation of compliance must be complete and address each of the deficiencies cited in the Statement of Deficiencies. For each deficiency, the allegation of compliance must include a corrective action date that is realistic in terms of the action being accomplished between the date of the survey and the planned date of completion.

As Theranos was also advised in our January 25, 2016 letter, the laboratory's allegation of compliance must be substantiated by acceptable evidence of correction which 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 the laboratory has made to ensure that the deficient practice does not recur; and

4) How the corrective action(s) is being monitored to ensure the deficient practice does not recur.

The following explanation details why the laboratory's February 12, 2016 submission does not constitute a credible allegation of compliance and acceptable evidence of correction:

D2094

**The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.**

Some documents pertaining to this deficiency referenced in the submission were not included. Specifically, the submission references "Ex. A, Tab 4, § 7.1.2.2.d.2." We found no such reference contained in the materials provided to CMS. In addition, Exhibit (Ex.) O, Tab 2 states: "The QC data are presented here: <Exhibit D Tab 7, Tab 8>." We found no "Tab 7" or "Tab 8" in Ex. D.

Although the laboratory's submitted protocol indicates that ungraded proficiency testing (PT) results will be evaluated, the submitted protocol does not explain how an investigation is performed and who must sign an investigation of ungraded PT samples.

In the submission, the laboratory concludes:

- "Not enough patient data available for meaningful analysis"
- "No evidence of systemic errors"
- "No patient impact is expected"

However, no information as to how the laboratory came to these conclusions related to patient outcomes was submitted. Documentation contained in Ex. O, Tab 2 also compares the "Range of Means" with no explanation as to what this refers to or how it correlates to the laboratory's ungraded PT results. The submission merely indicates that "the lab has investigated this ungraded PT event for ALP [alkaline phosphatase] and has documented its investigation and conclusion."

Furthermore, a Quality Monitoring and Process Improvement (QMPI) Program Meeting Agenda, CL FRM-00045-F1, was submitted as part of Ex A, Tab 13 and only includes PT for the Alternative Proficiency Assessment (APA). Based on information included in the submitted agenda, all PT issues were not addressed as required in CL QOP-00045, Revision A (Ex. A, Tab 12) in Sections 7.2.2.6 and 7.2.2.7.

**Proposed Sanctions**

Accordingly, pursuant to 42 C.F.R. §§ 493.1806, 493.1814, and 493.1840(a)(3), **based on the finding of immediate jeopardy and the laboratory's failure to meet all CLIA Condition-level requirements, and based on the failure by the owners and director of the laboratory to comply with certificate requirements and performance standards as evidenced by the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 2015**, CMS is proposing the following sanctions against the CLIA certificate of Theranos, Inc.:

- 42 U.S.C. § 263a(i), and 42 C.F.R. §§ 493.1806, 493.1840(a)(3), and 493.1840(e) – Principal Sanction: **Revocation** of the laboratory's CLIA certificate effective **60 calendar days from the notice of imposition**. If imposed the laboratory has 60 calendar days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.

- 42 C.F.R. §§ 493.1806, 493.1812, 493.1840(a)(3), and 493.1840(d)(2)(i) – Principal Sanction: **Limitation** of the laboratory's CLIA certificate for the specialty of hematology effective **eight calendar days from the notice of imposition** based on the finding of immediate jeopardy. The limitation will take effect regardless of whether a hearing request is filed and will remain in effect until the laboratory's CLIA certificate is revoked.

- 42 C.R.R. §§ 493.1806(c)(3), 493.1810(c)(2)(ii), 493.1810(d), and 493.1834 - Alternative Sanction: **Civil Money Penalty (CMP)** in the amount of $10,000 per day for each day of non-compliance effective **five calendar days from the notice of imposition**. If the laboratory requests a hearing, the CMP will not be collected until after the hearing decision is rendered. However, the $10,000/day will begin to accrue five (5) days from the notice of imposition and will continue to accrue until it can be verified that all the cited deficiencies have been corrected and the laboratory is in compliance with all Condition-level requirements or the laboratory's CLIA certificate is limited.

  In determining the amount of the penalty, CMS has taken into account the following factors: (1) the laboratory was found to be out of compliance with five CLIA Condition-level requirements as well as numerous Standard-level CLIA requirements during the survey completed on December 23, 2015; (2) the deficiencies cited during the survey, specifically related to the Condition-level requirement set forth 42 C.F.R. § 493.1215, Hematology, were so serious as to result in the determination of immediate jeopardy to patient health and safety; (3) the laboratory failed to remove the jeopardy after being provided an opportunity to do so; (4) the laboratory failed to come into Condition-level compliance after being provided ample opportunity to do so; (5) the laboratory failed to meet all hematology requirements specified in 42 C.F.R. §§ 493.1230 through 493.1256, § 493.1269, and §§ 493.1281 through 493.1299, as is required by 42 C.F.R. 493.1215 for a laboratory providing services in the specialty of hematology; (6) the laboratory failed to meet all analytic system requirements specified in 42 C.F.R. §§ 493.1251 through 493.1283; (7) the laboratory failed to meet all requirements for a

laboratory director of a laboratory performing high complexity testing, specified in 42 C.F.R. §§ 493.1443 and 493.1445; (8) the laboratory failed to meet all requirements for a technical supervisor overseeing high complexity testing specified in 42 C.F.R. §§ 493.1449 and 493.1451; (9) the laboratory failed to meet all requirements for testing personnel performing high complexity testing specified in 42 C.F.R. §§ 493.1489 and 493.1495; and (10) the laboratory has expressed no rational reasons for its failure to achieve compliance with all applicable Condition-level CLIA requirements.

- 42 C.F.R. §§ 493.1806(c)(1), 493.1832(b)(2), 493.1844(d)(1), and 493.1844(g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction** effective **five calendar days from the notice of imposition**. The laboratory will be directed to submit to this office within ten calendar days from the date of the notice of imposition of sanctions a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory's services from January 2014 to the present date. This list may be used to advise the laboratory's clients of the nature of its non-compliance and the nature and effective date of any sanctions imposed against the laboratory. The effective date of this sanction will not be delayed due to the filing of a hearing request.

- 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 Principal Sanction: **Suspension of the laboratory's approval to receive Medicare payments** for any services performed for the specialty of hematology on or after **eight calendar days from the notice of imposition**.

  As a consequence of the suspension of the approval to receive Medicare for services performed for the specialty of hematology, 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 no longer be available to the laboratory for all laboratory services performed for the specialty of hematology effective **eight calendar days from the notice of imposition.**

- 42 C.F.R. §§ 493.1807(a), 493.1808(a), 493.1842, and 493.1844(d)(3) – Principal Sanction: **Cancellation of the laboratory's approval to receive Medicare payments** for all laboratory services effective **60 calendar days from the notice of imposition**. This sanction will be effectuated even if the laboratory files a timely appeal.

  Moreover, in accordance with Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c) and 493.1809, payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for all laboratory services effective **60 calendar days from the notice of imposition**. See 42 C.F.R. § 440.2(b).

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

**When the laboratory's CLIA certificate is revoked, the laboratory will not be permitted to perform any testing, including waived testing and provider performed microscopy**

**procedures, regardless of whether or not the laboratory charges for the testing.[2] When the laboratory's CLIA certificate is limited for the specialty of hematology, the laboratory will not be permitted to perform any hematology testing, including waived testing and provider performed microscopy procedures, regardless of whether or not the laboratory charges for the testing[3].** Also, upon revocation of a laboratory's CLIA certificate 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owners or operator(s) (including the laboratory director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner, operator, and laboratory director at the time the deficiencies which led to the proposal of sanctions were identified by CMS.

When the sanctions become effective as referenced above, in accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), CMS will notify the general public by means of a notice published in a local newspaper when these actions become effective as referenced above.

**Instructions for Sending in Your Response**

**The laboratory has ten calendar days from the date of this notice, or until March 28, 2016 to submit in writing any evidence or information as to why the sanctions detailed above should not be imposed.** If a response is not made, is untimely, or does not successfully rebut the bases for the proposed sanctions, we will notify the laboratory in writing that we will proceed to impose the above-referenced sanctions. We will provide information regarding the laboratory's hearing rights and a description of the appeals process at that time.

All responses, including written evidence or information as to why the proposed sanctions should not be imposed, as well as any future correspondence pertaining to this sanction action should be sent to:

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification
Centers for Medicare & Medicaid Services
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

A copy of any response the laboratory makes to CMS' San Francisco Regional Office must also be sent to CMS' Central Office at the following address:

Division of Laboratory Services

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[2] The laboratory may continue to perform parallel testing on patient specimens if needed to implement corrective actions. However, the laboratory may not report any patient test results during the period when its CLIA certificate is revoked.

[3] The laboratory may continue to perform parallel testing on patient hematology specimens if needed to implement corrective actions. However, the laboratory may not report any patient hematology test results during the period when its CLIA certificate is limited for the specialty of hematology.