



Division of Clinical Improvement and Quality

IMPORTANT NOTICE – ACTION NECESSARY

SANCTIONS ARE BEING IMPOSED IN THIS NOTICE

Sent Via t via **email:** daisy.hearing@completecare.net
(Confirmation of successful transmission of email constitutes proof of receipt.)

August 6, 2024

Daisy Hearing, MD, CLS Director
Complete Integrative Care
3156 State Street
Medford, OR 97504

CLIA number: **38D2120851**

**RE: NOTICE OF IMPOSITION OF SANCTIONS – UNSUCCESSFUL PARTICIPATION
IN SODIUM PROFICIENCY TESTING – SUBSEQUENT OCCURRENCE**

Dear Director and Owner(s):

For a laboratory to be certified to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), it must comply with all applicable CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (codified at 42 U.S.C. § 263a) and Title 42 of the Code of Federal Regulations, Part 493.

We are writing to notify you of the determination by the Centers for Medicare & Medicaid Services (CMS) that Complete Integrative Care (the laboratory) located at the above address is not in compliance with the CLIA Condition-level requirements due to unsuccessful participation in proficiency testing for the analyte of Sodium. Therefore, CMS is imposing the following sanctions:

- Limitation of the laboratory’s CLIA certificate for any services performed in the analyte of Sodium
- A Directed Plan of Correction

By letter dated July 25, 2024, we proposed sanctions against the CLIA certificate of Complete Integrative Care as a result of unsuccessful participation in proficiency testing, as defined in 42 C.F.R. § 493.2, in the analyte of Sodium which resulted in the determination of noncompliance with the Condition-level requirements of successful participation in proficiency testing and laboratory director. We provided the laboratory ten (10) calendar days to submit in writing any evidence or information as to why these proposed sanctions should not be imposed.

As detailed on Form CMS-2567, Statement of Deficiencies, enclosed with our July 25, 2024 letter, under the Condition-level requirements at deficiency tags D2016, and D6000, the laboratory had a

history of unsuccessful proficiency testing performance, as defined in 42 C.F.R. § 493.2 in the analyte of Sodium as follows:

| <u>Proficiency Testing Event</u> | <u>PT Provider</u> | <u>Test</u> | <u>Score</u> |
|----------------------------------|--------------------|-------------|--------------|
| 2023, 3 | API | Sodium | 60% |
| 2024, 1 | API | Sodium | 40% |
| 2024, 2 | API | Sodium | 40% |

Your laboratory responded with a submission on July 31, 2024. Based on careful review of the submission, we find no evidence to refute that the laboratory had repeated unsatisfactory proficiency testing scores in the analyte of Sodium which resulted in the determination of noncompliance with the Condition-level requirements of successful participation in proficiency testing and laboratory director. The laboratory's July 31, 2024 submission provides no evidence to indicate that unsatisfactory proficiency testing performance for Sodium did not occur for the 2023 3rd Event, 2024 1st Event, and 2024 2nd Event..

Imposition of Sanctions

Accordingly, pursuant to 42 C.F.R. §§ 493.1806, 493.1814, 493.1838 and 493.1840(a)(3), **based on the laboratory's failure to meet all CLIA condition-level requirements, and based on the failure of the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the CLIA desk review completed on July 15, 2024**, we are taking action to impose sanctions against Complete Integrative Care's CLIA certificate as proposed in our July 25, 2024 letter, with effective dates as follows:

- 42 C.F.R. §§ 493.807, 493.1804, 493.1806, and 493.1840(a)(3) – Principal Sanction: **Limitation** of the laboratory's CLIA certificate for the analyte, specialty of Sodium effective August 21, 2024. When a laboratory's CLIA certificate is limited in a specific analyte, the laboratory is not permitted to perform any testing for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, in that analyte¹. See 42 U.S.C.A. § 263a.

Pursuant to 42 C.F.R. § 493.807, the laboratory must demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte, or test.

The laboratory has sixty (60) days from the date of this notice, or until October 5, 2024 in which to appeal the determination to limit its certificate in the analyte of Sodium. If the laboratory chooses not to file an appeal, limitation of its CLIA certificate in the analyte of Sodium will become effective October 5, 2024. If a timely hearing request is received, limitation of the laboratory's CLIA certificate in the analyte of Sodium will be effective with the date of the administrative hearing decision, if our determination of non-compliance is upheld.

¹ The laboratory may continue to perform parallel testing on specimens in the analyte of Sodium if needed to implement corrective actions, however, the laboratory may not report any test results in the analyte of Sodium during the period when its CLIA certificate is limited in the analyte of Sodium.

- 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 August 21, 2024. The laboratory is directed to: (1) address any actual or potential negative outcome during the period of unsuccessful proficiency testing performance for the analyte of Sodium and submit acceptable evidence that this has been done within fifteen (15) calendar days from the date of this notice, or by August 21, 2024; (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 analyte of Sodium and submit acceptable evidence that such a mechanism has been implemented within fifteen (15) calendar days from this notice, or by August 21, 2024; and (3) demonstrate satisfactory performance in two consecutive proficiency testing events for the analyte of Sodium before the limitation of the laboratory's certificate in the analyte of Sodium 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.

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. CMS will not change a laboratory's CLIA certificate type while an enforcement action is pending. In addition, a laboratory's CLIA certificate will remain active while an enforcement action is pending.

Appeal Rights

If Complete Integrative Care does not believe this determination to impose these actions against its CLIA certificate is correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board (DAB) in accordance with 42 C.F.R. §§ 493.1844(a)(1)-(2) and 42 C.F.R. §§ 498.40 through 498.78. A request for a hearing must be filed no later than **sixty (60) calendar days** after the date this letter is received (see 42 C.F.R. § 493.1844(f)). You should file your request for an appeal (accompanied by a copy of this letter) to the Department Appeals Board Electronic Filing System website (DAB E-file) at <https://dab.efile.hhs.gov>. Instructions for filing an appeal can be found on the DAB E-file website.

The Civil Remedies Division (CRD) recommends that parties with the capability to file documents electronically utilize DAB E-File. However, paper filing of documents in cases where electronic filing is allowed remains available for parties unable to file electronically. If a party is unable to use DAB E-File, it must send appeal-related documents to CRD using a postal or commercial delivery service at the following address:

Department of Health and Human Services
 Departmental Appeals Board, MS 6132
 Civil Remedies Division
 330 Independence Avenue, S.W.
 Cohen Building — Room G-644
 Washington, D.C. 20201

Please send a copy of your appeal to:

DCLIQEnforcement@cms.hhs.gov

A request for hearing should identify the specific issues, and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory may be assessed a fee to cover the government's cost related to the hearing.** See 42 C.F.R. § 493.643(d)(2).

How to File: When using DAB E-File for the first time, you will need to create an account by a) clicking Register on the DAB E-File home page; b) entering the requested information on the Register New Account form; and c) clicking Register Account at the bottom of the form. Each representative authorized to represent you must register separately to use the DAB E-File on your behalf.

The e-mail address and password given during registration must be entered on the login screen when accessing DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he/she is a party or an authorized representative. You can file a new appeal by a) clicking the File New Appeal link on the Manage Existing Appeals screen; then b) clicking Civil Remedies Division on the File New Appeal screen; and c) entering and uploading the requested information and documents on the File New Appeal-Civil Remedies Division form.

The Civil Remedies Division (CRD) requires all hearing requests to be signed and accompanied by the notice letter from CMS that addresses the action taken and your appeal rights. All submitted documents must be in Portable Document Format (PDF). Documents uploaded to DAB E-File on any day on or before 11:59p.m. ET will be considered to have been received on that day. You will be expected to accept electronic service of any appeal-related documents filed by CMS or that the CRD issues on behalf of the Administrative Law Judge (ALJ) via DAB E-File. Further instructions are located at: https://dab.efile.hhs.gov/appeals/to_cr_instructions. Please contact the Civil Remedies Division at 202-565-9462 if you have questions regarding the DAB E-Filing System. If you experience technical issues with the DAB E-Filing System, please contact E-File System Support at OSDABImmediateOffice@hhs.gov or call 202-565-0146 before 4:00p.m. EST.

If you do not have access to a computer or internet service, you may call the Civil Remedies Division at 202-565-9462 to request a waiver from e-filing and provide an explanation as to why you cannot file electronically, or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter via fax or by mailing to the address listed above.

If a timely request for a hearing is filed, i.e., by October 5, 2024, , the **limitation of the CLIA certificate** will not be effective until after an ALJ hearing that upholds CMS' determination of non-compliance and imposition of sanction(s). However, the Directed Plan of Correction is effective August 21, 2024 regardless of whether a hearing is requested. See 42 C.F.R. §§ 493.1844(d) and 493.1844(h).

If 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), we will notify the general public by posting the information on the Survey & Certification website at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Termination-Notices.html>.

Please be advised that the determination as to which alternative sanction or sanctions to impose, is not subject to appeal. *See* 42 C.F.R. §§ 493.1844(c)(4), (c)(7). Also, pursuant to 42 C.F.R. § 493.1840(a)(7), failure to comply with alternative sanctions is an additional basis to suspend and/or revoke the laboratory's CLIA certificate.

Please contact Jelani Sanaa by e-mail at DCLIQEnforcement@cms.hhs.gov with any questions concerning this letter.

Sincerely,

Latoya Laing, MS, MLS(ASCP)CM
Enforcement Branch Manager
Division of Clinical Laboratory Improvement and
Quality

Enclosure: Agreement

cc: Oregon Health Authority

AGREEMENT

I am the [owner/director] of Complete Integrative Care located at Complete Integrative Care 3156 State Street Medford, OR 97504 , CLIA number **38D2120851**.

By my signature below, Complete Integrative Care agrees in return for not having its Medicare approval suspended immediately or its Medicare approval suspended on October 5, 2024 not to charge Medicare beneficiaries or their private insurance carriers for laboratory services in the analyte of Sodium.

Complete Integrative Care also agrees to the limitation of its CLIA certification for the analyte of Sodium, due to unsuccessful participation in proficiency testing, in order that limitation is not imposed for the specialty of **GENERAL CHEMISTRY**. This means Complete Integrative Care agrees to not perform any testing for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, 42 U.S.C.A. § 263a, (for both Medicare and non-Medicare individuals) in the analyte of Sodium, Complete Integrative Care agrees to notify CMS to apply for reinstatement and be granted CMS approval prior to resuming testing in and receiving Medicare/Medicaid reimbursement for this analyte.

I understand that failure to provide this written agreement by August 21, 2024 will result in the automatic suspension of the laboratory’s approval to receive Medicare payment for all laboratory services effective October 5, 2024. I also understand that signing this agreement does not affect the laboratory’s appeal rights in connection with this sanction action.

Signature

Date

Print Name and Title

Contact address other than laboratory address

Contact telephone number

Contact FAX number

Contact email