DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Division of Clinical Laboratory Improvement and Quality

IMPORTANT NOTICE – ACTION NECESSARY

Sent via email: jdavis@atlantadiabetes.com
(Confirmation of successful transmission constitutes proof of receipt)

May 15, 2024

David Robertson, M.D., Director
Atlanta Diabetes Associates
1800 Howell Mill Road, Suite 450
Atlanta, GA 30318

CLIA: #11D0259599

RE: NOTICE OF IMPOSITION OF SANCTIONS – UNSUCCESSFUL PARTICIPATION IN TOTAL PROTEIN, CHLORIDE, AND BLOOD UREA NITROGEN PROFICIENCY TESTING – SUBSEQUENT OCCURRENCE

Dear Director and Owner(s):

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 Title 42 of the Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Laboratories are required to be in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

We are writing to notify you of the determination by the Centers for Medicare & Medicaid Services (CMS) that Atlanta Diabetes Associates (the laboratory) located at the above address is not in compliance with the CLIA Condition-level requirements due to unsuccessful participation in proficiency testing (PT) for the analytes Total Protein (TP), Chloride (CL), and Blood Urea Nitrogen (BUN) in the subspecialty of Routine Chemistry. Therefore, CMS is imposing the following sanctions:

- Limitation of the laboratory's CLIA certificate
- A Directed Plan of Correction

By letter dated April 9, 2024, we proposed sanctions against the CLIA certificate of Atlanta Diabetes Associates as a result of unsuccessful participation in proficiency testing, as defined in 42 C.F.R. § 493.2, for the analytes of TP, CL, and BUN in the subspecialty of Routine

Chemistry, 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) days to submit in writing any evidence or information as to why these proposed sanctions should not be imposed.

Your laboratory responded with submissions on April 19th and 23rd, 2024. The submissions included documents titled "2019_001 and attachment 1; ADA PT ltr 1st 011123; 11D259599 ADA PTD LTR 033023; 11D0259599 ADA PT ACCEPT AOC 021523; and 11D0259599 TP ASA PTD AOC 053123". We have carefully reviewed the entire April 19th and 23rd, 2024 submissions and determined your responses have no effect on our determination to impose sanctions.

As detailed on Form CMS-2567, Statement of Deficiencies, enclosed with our April 9, 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 for the analytes of TP, CL, and BUN in the subspecialty of Routine Chemistry as follows:

PT Event	PT Provider	Test	Score
2022, 3	API	Total Protein (TP)	0%
2023, 1	API	TP	40%
2023, 3	API	TP	0%
2022, 1	API	Chloride (CL)	40%
2022, 3	API	CL	0%
2023, 3	API	CL	0%
2024, 1	API	CL	20%
2023, 1	API	Blood Urea Nitrogen (BUN)	60%
2023, 3	API	BUN	0%
2024, 1	API	BUN	0%

Based on careful review of the laboratory's April 19th and 23rd, 2024 submissions, we find no evidence to refute that the laboratory had repeated unsatisfactory proficiency testing scores for the analytes of TP, CL, and BUN, which resulted in the determination of noncompliance with the Condition-level requirements of successful participation in proficiency testing and laboratory director. The laboratory's April 19th and 23rd, 2024 submissions provided no evidence to indicate that unsatisfactory proficiency testing performance for the analytes of TP, CL, and BUN did not occur for the PT events 1, and 3, 2022; events 1 and 3, 2023; and event 1, 2024.

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 survey completed on March 20, 2024, we are taking action to impose sanctions against Atlanta Diabetes Associates' CLIA certificate as proposed in our April 9, 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 analytes of TP, CL, and BUN in the subspecialty of Routine Chemistry effective May 30, 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 analyte. 1 *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 July 14, 2024, in which to appeal the determination to limit its certificate for the analytes of TP, CL, and BUN in the subspecialty of Routine Chemistry. If the laboratory chooses not to file an appeal, the limitation of its CLIA certificate for the analytes of TP, CL, and BUN in the subspecialty of Routine Chemistry will become effective on May 30, 2024. If a timely hearing request is received, the limitation of the laboratory's CLIA certificate for the analytes of TP, CL, and BUN in the subspecialty of Routine Chemistry will be effective with the date of the administrative hearing decision, if our determination of non-compliance is upheld.

- 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 May 30, 2024. The laboratory is directed to:

  (1) address any actual or potential negative outcome during the period of unsuccessful proficiency testing performance for the analytes TP, CL, and BUN in the subspecialty of Routine Chemistry and submit acceptable evidence that this has been done within fifteen (15) calendar days from the date of this notice, or by May 30, 2024;

  (2) demonstrate that the laboratory has established an effective oversight mechanism to prevent recurrences of proficiency testing failure for all testing including testing analytes TP, CL, and BUN in the subspecialty of Routine Chemistry and submit acceptable evidence that such a mechanism has been implemented within fifteen (15) calendar days from this notice, or by May 30, 2024; and

  (3) demonstrate satisfactory performance in two consecutive proficiency testing events for the analytes TP, CL, and BUN in the subspecialty of Routine Chemistry before the limitation of the laboratory's certificate analytes TP, CL, and BUN in the subspecialty of Routine Chemistry 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 individuals found to have been affected by the deficient practice;
2) How the laboratory has identified other individuals 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.

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 Atlanta Diabetes Associates 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 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 CRD 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 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 11:59 p.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 CRD 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 CRD 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 hearing is filed, i.e., by July 14, 2024, CMS does not impose limitation of the CLIA certificate, until after an ALJ hearing that upholds CMS's determination of non-compliance and imposition of sanction(s). However, the Directed Plan of Correction and the suspension of the laboratory's approval to receive all Medicare and Medicaid payment are effective May 30, 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 Registryhttps://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/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). 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 Janice Graves by e-mail at DCLIQEnforcement@cms.hhs.gov with any questions concerning this letter.

Sincerely,

Latoya Laing,
Enforcement Branch Manager
Division of Clinical Laboratory
Improvement and Quality

cc: Georgia Department of Community Health