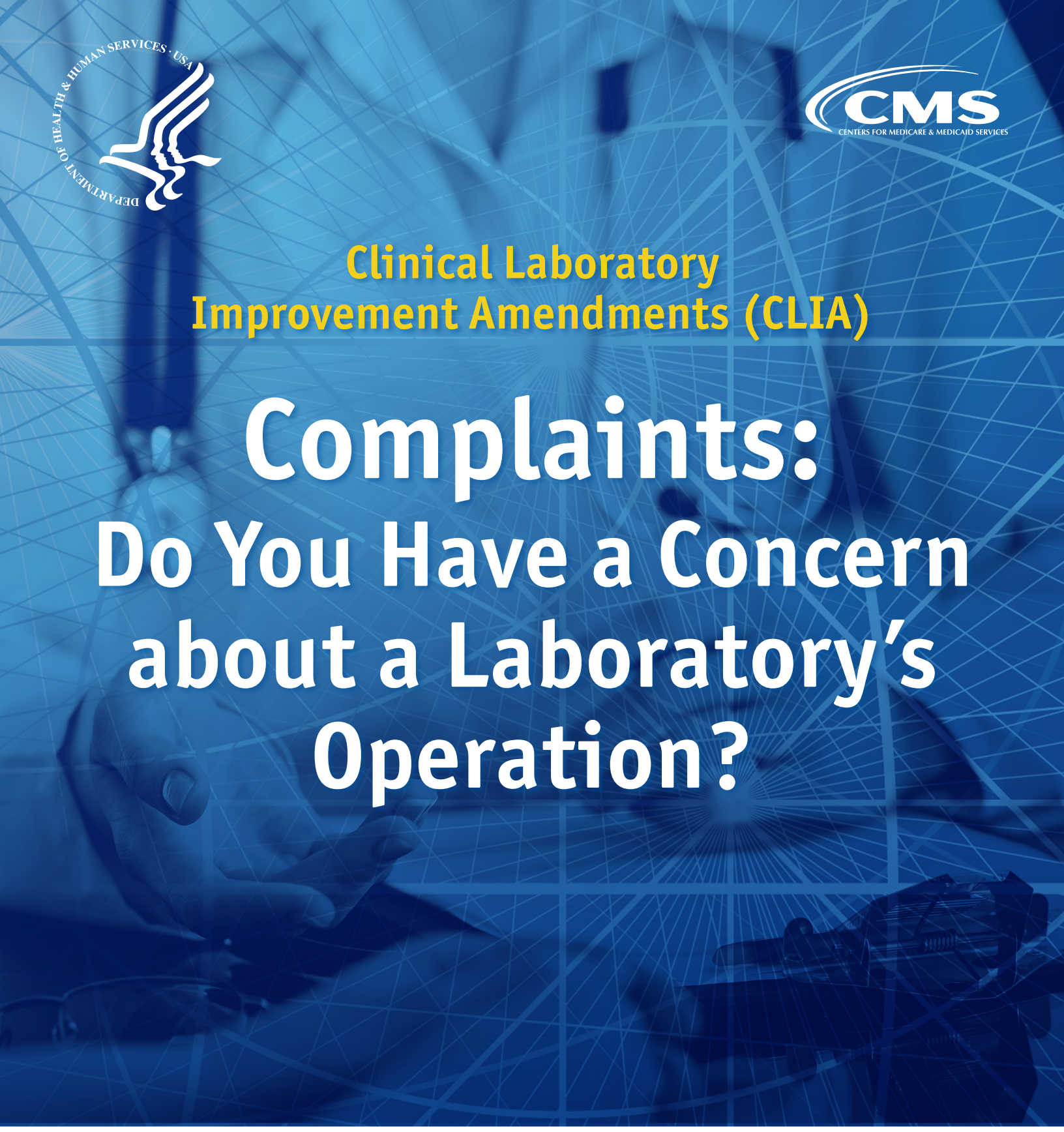

Clinical Laboratory Improvement Amendments (CLIA)

Complaints: Do You Have a Concern about a Laboratory's Operation?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed.

What is a complaint?

A complaint may be any concern that you may have about a laboratory's operation. Examples include the following:

- Quality of testing,
- Unlabeled specimens,
- Record falsification,
- Proficiency testing cheating,
- Confidentiality of patient information, and
- Laboratory personnel qualification or responsibility issues.

This is not a comprehensive list and only includes examples of some of the most common types of complaints.

Who can report a complaint?

Anyone can report a complaint. Complaints can be reported by, but not limited to, patients, patients' relatives, the public, physicians and personnel working in a laboratory.

Whom do I contact for reporting a complaint?

Contact the State Agency (SA) where the laboratory is located or the Accreditation Organization (AO), if known. You may also contact the Centers for Medicare and Medicaid Services (CMS) CLIA Lab Excellence Mailbox at LabExcellence@cms.hhs.gov.

If I have concerns or other questions about CLIA, whom should I contact?

- State Survey Agencies CLIA Contact List: CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf
- CMS CLIA Location Offices Contact List: CMS.gov/files/document/clia-operations-branch-contacts.pdf
- List of Approved Accreditation Organizations: CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf
- List of CLIA Exempt States: CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ExemptStatesList.pdf
- CMS CLIA Lab Excellence mailbox: LabExcellence@cms.hhs.gov

What information should I provide when reporting a complaint?

Please provide as much information as possible when reporting a complaint.

- Name and address of the laboratory and the CLIA certification number, if known
- Individual(s) involved or affected (e.g. patient's name, date of birth, sample identification number, etc.)
- A complete description of your concern (including patient/sample identification numbers, if applicable)
- Date(s) and time(s) of the incident(s)
- Your knowledge of the frequency and pervasiveness of the issue
- Names of any other agencies you have contacted
- Your contact information (name, address, email address and telephone number) Optionally, you can elect to remain anonymous
- Any other details or documentation that will verify the problem (e.g. copy of patient test report)

Am I required to provide my contact information?

You may choose not to provide your name and contact information (i.e., an anonymous complaint). However, we may not be able to contact you to gather any further necessary information or to inform you of the outcome of the investigation.

Will I remain anonymous if I provide my contact information?

If you provide your name and contact information, the investigating entity will make every attempt to maintain your anonymity as permitted by Federal or State laws. You can be assured that everything will be done to protect the privacy and anonymity of your complaint.

What happens after I report a complaint?

Every CLIA-related complaint is investigated and documented. If you provide contact information, you will receive acknowledgment that the complaint is being investigated. Once the investigation is complete, we will contact you regarding the outcome.

Some laboratories are accredited by a CMS-approved laboratory Accreditation Organization (AO). If your complaint is about an accredited laboratory, we may refer your complaint to the laboratory's AO. We will provide you with contact information for the AO. If you have further questions, please contact the AO.

Complaints that are not related to CLIA regulatory compliance will be referred to the appropriate entity whenever possible.

Where can I find additional information about CLIA?

For more information and resources regarding the CLIA program, please visit the CMS CLIA website at: CMS.gov/Regulations-and-Guidance/Legislation/CLIA/index

Additionally, you can email questions to the CMS Lab Excellence mailbox at: LabExcellence@cms.hhs.gov.

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