CLIA SANCTIONS AND PROCEDURES FOR APPEAL

What happens if your laboratory is found to be out of compliance with CLIA standards?

Your laboratory could be sanctioned, depending on the seriousness of the problem and your willingness to correct the deficiency as quickly as possible. In all cases, laboratories are first notified of deficiencies and given an opportunity to correct problems.

There are several types of sanctions which could be imposed on your laboratory by the Centers for Medicare and Medicaid Services (CMS). Your laboratory might be required to prepare a plan of correction, to obtain technical assistance, or to agree to participate in on-site monitoring.

More serious problems in the laboratory and/or unwillingness to comply with CLIA requirements may result in cease-testing orders, suspension of Medicare/Medicaid reimbursement, and revocation of your CLIA certificate. In rare circumstances, a laboratory may also be fined by CMS for failure to comply with CLIA standards.

There are three levels of deficiencies which may result in a sanction. The first category is "deficiencies which fall below" what CMS calls the "condition level" requirements. Condition level requirements are those which must be met before CMS will issue a certificate for you to continue to operate your laboratory. Failure to have a written procedure manual available to all laboratory staff would be an example of a deficiency below condition level.

The second category is condition level deficiencies without an immediate jeopardy; for example, failure to enroll and participate in an approved proficiency testing program.

The third and most serious category is "condition level deficiencies which pose an immediate jeopardy." An immediate jeopardy situation exists in the laboratory when immediate corrective action is necessary because the laboratory's noncompliance with one or more CLIA conditions has already caused, is causing, or is likely to cause serious injury, harm, or death to a patient, or that the health and safety of the public is at risk.

The severity of the deficiency and the overall compliance history of the laboratory are considered by the agency when imposing a sanction. Of course, of utmost importance is the laboratory's willingness to cooperate by making the necessary changes in laboratory practices required by CMS.

Those laboratories cited for deficiencies that do not pose immediate jeopardy will be notified at least 15 days prior to the effective date of a sanction. At least five days notification will be given for immediate jeopardy situations.

The sanctions will continue until the laboratory corrects all the deficiencies, so it is imperative the laboratory take appropriate corrective action as quickly as possible. In many cases, CMS can verify compliance with appropriate documentation without having to revisit the laboratory.

When deficiencies pose an immediate jeopardy, the laboratory will be required to take action to immediately remove the danger to public health.

If at the time of the revisit the laboratory has not corrected the problem, CMS will suspend or limit the laboratory's certificate and later revoke the certificate if necessary.

CMS may also seek a temporary restraining order against the laboratory activity should the agency believe that continuation of the harmful activity poses a significant hazard.

Appeal Rights

Hearings on CMS determinations that affect a laboratory's status under CLIA or in the Medicare Program are conducted by Administrative Law Judges (ALJ) assigned to the Departmental Appeals Board. An ALJ's decision is final unless one of the parties requests review by the Departmental Appeals Board within 60 days, and the Board reviews the case and issues a revised decision.

Prior to requesting a formal hearing, laboratories are encouraged to present credible documentation to the state survey agency staff or CMS regional office if the laboratory believes that it should not have been cited.

Informal opportunities to offer such evidence are available within the 5- or 15-day notification period prior to imposition of the sanction and during the exit conference of the on-site inspection.

Not all actions taken by CMS can be appealed by the laboratory. Examples of such actions include: the determination as to which sanction to impose, including the amount of a civil monetary penalty; a finding that a laboratory has below condition level deficiencies; the denial of Medicare payment for services for which the laboratory is not CLIA-certified; and the determination that a deficiency poses immediate jeopardy.

Laboratories can appeal the following actions (as initial determinations):

1. **The suspension, limitation, or revocation of a CLIA certificate by CMS because of noncompliance or by the Office of the Inspector General for fraud of abuse, or conviction of crimes related to CLIA certification;**
2. **The denial of a CLIA certificate;**
3. **The imposition of a sanction; or**
4. **The denial or cancellation of the laboratory's Medicare approval.**

CMS may impose a sanction prior to a hearing before an administrative law judge should the lab refuse to provide requested information or permission for CMS to inspect the lab. The only exception to this rule applies to civil monetary penalties and/or revocation, limitation, suspension, or revocation of a CLIA certificate for laboratories with condition level deficiencies which do not pose immediate jeopardy.

PRIOR TO REQUESTING A FORMAL HEARING, LABORATORIES ARE ENCOURAGED TO PRESENT CREDIBLE DOCUMENTATION TO THE STATE SURVEY AGENCY STAFF OR CMS REGIONAL OFFICE IF THE LABORATORY BELIEVES THAT IT SHOULD NOT HAVE BEEN CITED.