

Helpful Reference Guide to CLIA-Related Hearing Decision Index

The following lists cases/issues often cited in the CLIA-related Hearing Decision Index.

Case	Issue
DAB 1611, DAB 1663, CR 500 Hillman Rehabilitation Center v. HCFA	<i>Burden of Proof:</i> A petitioner must prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with relevant statutory and regulatory provisions.
DAB 1624 Ward General Practice v. HCFA	<i>Single Condition Out:</i> Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate.
DAB 1755 Oakland Medical Group, P.C. v. HCFA	<i>Improper PT Referral</i> <i>Physical Transport</i> The improper exchange of information between laboratories is an unlawful referral of proficiency testing samples. The mere fact that section 493.801(b)(3) prohibits inter-laboratory communications does not mean that the communications about results could not constitute intentional referral. A laboratory is responsible for the acts of its employees, even when it is unaware of the employees' actions.
DAB 1713 Edison Medical Laboratories, Inc. v. HCFA	<i>Burden of Proof</i> The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by CMS.
DAB 1756	<i>Standards/Overall Condition</i>

Stanley Boykansky, M.D. v. HCFA	If standard level deficiencies are sufficiently egregious, they will constitute a failure by a laboratory to comply with the overall condition of which the standards are subparts.
DAB 1731 US Bio-Chem Medical Laboratories, Inc. v. HCFA	<i>Standard of Review</i> The standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence on the record as a whole.
DAB 1763 Garden City Medical Clinic v. HCFA DAB 1628 Everett Rehabilitation and Medical Center v. HCFA	<i>Summary Judgment</i> A party opposing summary judgment must allege facts which, if true, would refute the facts relied upon by the moving party.
DAB 1762 Sentinel Medical Laboratories, Inc. v. HCFA	<i>Right to Appeal and Unconstitutionality</i> A laboratory owner or director has a right to a hearing to challenge revocation of a laboratory's CLIA certificate. Administrative forums do not have the authority to ignore unambiguous statutes or regulations on the basis that they are unconstitutional.
CR 438 Blanding Urgent Care Center Laboratory v. HCFA	<i>Improper PT Referral</i> <i>Physical Transfer</i> An unlawful referral of a testing sample to another laboratory may occur without an actual physical transport of the sample from one laboratory to another laboratory.
CR 935 Emil S. Sitto, M.D. and Associates, PLLC v. HCFA	<i>Improper PT Referral</i> <i>Physical Transfer</i> The intentional referral language of 41 C.F.R. § 493.801(b)(4) applies to constructive referral as well as physical transfer.
CR 690	<i>Amending an Initial Determination</i>

<p>Stanley Boykansky, M.D. v. HCFA</p>	<p>The regulations which govern CLIA enforcement by CMS and hearings involving an alleged failure by a clinical laboratory to comply with CLIA requirements do not prohibit CMS from amending or superseding a notice of an initial determination.</p>
<p>CR 667 Southfield Medical Clinic v. HCFA</p>	<p><i>Improper PT Referral Physical Transfer</i></p> <p>Collusion and referral of testing samples are not the same thing. The law distinguishes between the physical transport of proficiency testing samples from one laboratory to another for testing and collusion between two laboratories. See 42 C.F.R. §§ 493.801(b)(3) and (4).</p> <p><i>This argument was fully addressed and rejected by the Departmental Appeals Board in Oakland DAB1755 and Boykansky DAB1756. See also Sitto CR935.</i></p>
<p>CR 527 Eugene R. Pocock, M.D. v. HCFA</p>	<p><i>Proper Parties to Request a Hearing Director's Right to Appeal</i></p> <p>A laboratory director is an affected party who has a right to request a hearing, pursuant to 42 C.F.R. § 498.40, to contest HCFA's determination to revoke the CLIA certificate of the laboratory which he or she directs.</p>
<p>CR 334 Long Medical Laboratory v. HCFA</p>	<p><i>Importance of Proficiency Testing</i></p> <p>Proficiency testing should be the central element in determining a laboratory's competence, since it purports to measure actual test outcomes rather than merely gauging the potential for accurate outcomes.</p> <p><i>Intentional Referral</i></p> <p>The word "intentionally" should be given its common and ordinary meaning. "Intention" is a determination to act in a certain way. When one acts "intentionally," he or she</p>

	<p>acts deliberately, regardless of motivation.</p> <p>The Act and regulations do not distinguish between deliberate referrals that are motivated by good intentions and those which are motivated by some other purpose.</p>
<p>DAB 1526 Center Clinical Laboratory v. HCFA</p>	