

CLIA-RELATED HEARING DECISIONS

The following is a list of hearing decisions, in hearing decision date order, related to the CLIA program with informational guidance for each case. It is current through 12/31/2004. To view the actual text of the hearing decision click on the case name link under the “Decision Date and Case Name” column. To view a brief synopsis of each case, click on the highlighted area under the “Outcome” column. To view the regulatory authority for the primary issues involved in each case, click on the highlighted area under the “Regulatory References” column. The [Case Citation Reference Guide](#) lists cases and issues most often referenced in the decisions.

Decision Date and Case Name	Issues	Outcome	Regulatory References
9/23/1994 [CR334] Long Medical Laboratory v. HCFA	<ul style="list-style-type: none"> - Improper PT - Intentional PT referral - State laws vs. CLIA 	For HCFA	42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory. 42 CFR 493.1840(b) Adverse action based on improper referrals in proficiency testing.
9/28/1994 [CR335] Central Valley Medical Laboratory v. HCFA	<ul style="list-style-type: none"> - Client list - Directed Plan of Correction - Immediate Jeopardy --Pattern of deficiencies 	For HCFA	42 CFR 493.1832 Directed plan of correction and directed portion of a plan of correction. 42 CFR 493.1840(a)(7) Failed to comply with an alternative sanction imposed. 42 CFR 493.1804(d) Choice of sanction [relationship of deficiencies] 42 CFR 493.1844(c)(6) The determination that a laboratory’s deficiencies pose immediate jeopardy.
2/15/1995 [CR358] Center Clinical Laboratory v. HCFA	<ul style="list-style-type: none"> - Effective date - Immediate Jeopardy 	For Petitioner	42 CFR 493.1810(c)(2)(i) HCFA provides notice at least 5 days before the effective date of alternative sanctions. 42 CFR 493.1844(c)(6) The determination that a laboratory’s deficiencies pose immediate jeopardy.

<p>7/31/1995 [DAB1526] Center Clinical Laboratory v. HCFA</p>	<p>- Effective date</p>	<p>For HCFA</p>	<p>42 CFR 493.1844(h)(1) Effective date of adverse action (5 days after notice).</p>
<p>2/15/1996 [CR411] Center Clinical Laboratory v. HCFA</p>	<p>- Immediate Jeopardy (not subject to appeal)</p>	<p>For HCFA</p>	<p>42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.</p> <p>42 CFR 493 Subpart H (Participation in Proficiency Testing) 42 CFR 493 Subpart J (Patient Test Management) 42 CFR 493 Subpart K (Quality Control) 42 CFR 493 Subpart P (Quality Assurance) 42 CFR 493 Subpart M (Personnel)</p>
<p>9/30/1996 [CR438] Blanding Urgent Care Center Laboratory v. HCFA</p>	<p>- Improper PT - Intentional PT referral - Motive - Physical transport</p>	<p>For HCFA</p>	<p>42 CFR 493.2 Intentional violation.</p> <p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform.</p> <p>42 CFR 493.1840(b) Adverse action based on improper referrals in proficiency testing.</p>
<p>10/9/1996 [CR439] Primary Care Medical Group v. HCFA</p>	<p>- Improper PT - Intentional PT referral - Lab Director</p>	<p>For HCFA</p>	<p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform.</p> <p>42 CFR 493.1441 The laboratory director must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p>

<p>12/27/1996 [CR451] Ward General Practice Clinic v. HCFA</p>	<ul style="list-style-type: none"> - Acceptable Plan of Correction - Certificate change - Immediate jeopardy 	<p>For HCFA</p>	<p>42 CFR 493.1800 Basis and scope of enforcement procedures.</p> <p>42 CFR 493.1806(a) Applicability. HFCA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p> <p>42 CFR 493.1806(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions.</p>
<p>5/30/1997 [CR476] California Medical Associates Laboratory v. HCFA</p>	<ul style="list-style-type: none"> - Choice of sanctions - Lab closure - Voluntary cessation 	<p>For HCFA</p>	<p>42 CFR 493.1800 Basis and scope of enforcement procedures.</p> <p>42 CFR 493.1806(a) Applicability. HFCA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p> <p>42 CFR 493.1806(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions.</p> <p>42 CFR 493.1804(d) Choice of sanction: Factors considered.</p>
<p>7/24/1997 [DAB1624] Ward General Practice Clinic v. HCFA</p>	<ul style="list-style-type: none"> - Certificate change - History of non-compliance 	<p>For HCFA</p>	<p>42 CFR 493.1800 Basis and scope of enforcement procedures.</p> <p>42 CFR 493.1804 General considerations of enforcement.</p>

<p>8/5/1997 [CR487] Williams Bio Medical Laboratory v. HCFA</p>	<ul style="list-style-type: none"> - Burden of proof - Directed Plan of Correction - Standard deficiencies 	<p>For HCFA</p>	<p>42 CFR 493.1816(b) Action when deficiencies are not at the condition level. Failure to correct deficiencies.</p> <p>42 CFR 493.1820 Ensuring timely correction of deficiencies.</p> <p>42 CFR 493.1832(c) Duration of a directed plan of correction.</p> <p>42 CFR 493.1840(a)(7) Failed to comply with an alternative sanction imposed under this subpart.</p>
<p>10/21/1997 [CR501] Thyroid Specialty Laboratory v. HCFA</p>	<ul style="list-style-type: none"> - Intentional PT referral - Lab Director - Motive 	<p>For HCFA</p>	<p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform.</p> <p>42 CFR 493.1840(b) Adverse action based on improper referrals in proficiency testing.</p>
<p>3/31/1998 [CR527] Eugene R. Pocock, M.D. v. HCFA</p>	<ul style="list-style-type: none"> - Affected party (right to hearing) - Lab Director - Operator 	<p>For HCFA</p>	<p>42 CFR 493.2 Definitions. Operator.</p> <p>42 CFR 498.2 Definitions. [Affected party].</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p> <p>42 CFR 498.40 Request for Hearing. An affected party entitled to a hearing.</p>

<p>2/16/1999 [CR576] BAN Laboratories v. HCFA</p>	<ul style="list-style-type: none"> - Due process - Exit Conference - Immediate Jeopardy - Re-survey 	<p>For HCFA</p>	<p>42 CFR 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate.</p> <p>42 CFR 493.1806 Available sanctions.</p> <p>42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.</p>
<p>4/30/1999 [CR590] Melvin C. Murphy, M.D. v. HCFA</p>	<ul style="list-style-type: none"> - Director/Owner responsibilities - Intentional PT referral - State Law vs CLIA 	<p>For HCFA</p>	<p>42 CFR 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results.</p> <p>42 CFR 493.1840(b) Adverse action based on improper referrals in proficiency testing.</p>
<p>5/27/1999 [CR597] Eugene A. Shaneyfelt, M.D. v. HCFA</p>	<ul style="list-style-type: none"> - Certificate of Waiver - Director/Operator - Operator 	<p>For HCFA</p>	<p>42 CFR 493.2 Definitions: operator.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>

<p>6/7/1999 [CR599] Edison Medical Laboratories, Inc. v. HCFA</p>	<ul style="list-style-type: none"> - Accreditation - Immediate Jeopardy 	<p>For HCFA</p>	<p>42 CFR 493.1780(a) Validation inspection.</p> <p>42 CFR 493.1800 Basis and scope of enforcement procedures.</p> <p>42 CFR 493.1806 Available sanctions.</p> <p>42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.</p>
<p>6/9/1999 [CR600] Diagnostic and Educational Laboratory v. HCFA</p>	<ul style="list-style-type: none"> - Choice of sanctions - Lab Director - Standard deficiencies - Written documentation 	<p>For HCFA</p>	<p>42 CFR 493.1804(d) Choice of sanction: Factors considered.</p> <p>42 CFR 493.1816(b) Action when deficiencies are not at the condition level [i.e., standard level]. Failure to correct deficiencies.</p>
<p>10/6/1999 [C-99-309] Allstate Medical Laboratory, Inc. v. HCFA</p>	<ul style="list-style-type: none"> - Affected party 	<p>HCFA motion denied</p>	<p>42 CFR 498.2 Definitions. [Affected party]</p>
<p>12/7/1999 [CR632] US Bio-Chem Medical Laboratories v. HCFA</p>	<ul style="list-style-type: none"> - Certificate of Waiver Lab - Complainant disclosure - Duty to cooperate - Failure to permit inspection 	<p>For HCFA</p>	<p>42 CFR 493.1771 Condition: Inspection requirements applicable to all CLIA-certified laboratories.</p> <p>42 CFR 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate.</p>

<p>12/21/1999 [C-99-797] Carlos A. Cervera, M.D., Director, San Fernando Diagnostic Laboratory, Inc. v. HCFA</p>	<p>- Affected party</p>	<p>HCFA motion denied</p>	<p>42 CFR 498.2 Definitions. [Affected party]</p>
<p>12/23/1999 [DAB1713] Edison Medical Laboratories, Inc. v. HCFA</p>	<p>- Burden of proof - Due process - Immediate Jeopardy</p>	<p>For HCFA</p>	<p>42 CFR 493.1804(a) Purpose. The enforcement mechanisms.</p> <p>42 CFR 493.1806 Available sanctions.</p> <p>42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.</p>
<p>1/21/2000 [CR642] Kaulson Labs v. HCFA</p>	<p>- Clerical errors</p>	<p>For HCFA</p>	<p>42 CFR 493.1806(a) Applicability. HCFA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p> <p>42 CFR 493.1806(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions.</p>
<p>5/9/2000 [CR667] Southfield Medical Clinic v. HCFA</p>	<p>- Acts of employees - Improper PT - Unlawful collaboration</p>	<p>For HCFA</p>	<p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform.</p> <p>42 CFR 493.803 Condition: Successful participation.</p>

<p>6/21/2000 [DAB1731] US Bio-Chem Medical Laboratories v. HCFA</p>	<ul style="list-style-type: none"> - Complainant disclosure - Right to inspect 	<p>For HCFA</p>	<p>42 CFR 493.1 This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1998 (CLIA).</p> <p>42 CFR 493.3 Applicability.</p> <p>42 CFR 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate.</p>
<p>6/27/2000 [CR679] Sentinel Medical Laboratories, Inc. v. HCFA</p>	<ul style="list-style-type: none"> - Affected party - Due process - Effective date of prohibition - Exit Conference - Lab Director (2-year prohibition) - Lab Director responsibilities - Right to hearing - Voluntary cessation 	<p>For HCFA</p>	<p>42 CFR 498.2 Definitions. [Affected party].</p> <p>42 CFR 493.49(e) In the event of a noncompliance determination resulting in an HHS action.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p> <p>42 CFR 493.1884(d)(2) Suspension, limitation, or revocation of a laboratory's CLIA certificate.</p>

<p>7/18/2000 [CR688] Oakland Medical Group, P.C. v. HCFA</p>	<ul style="list-style-type: none"> - Accreditation - Independent contractor - Intentional PT referral - Owner/Operator - PT collaboration 	<p>For HCFA</p>	<p>42 CFR 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples.</p> <p>42 CFR 493.6(c)(3) A laboratory failing to meet the requirements of this section may be subject to suspension, revocation.</p> <p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform.</p> <p>42 CFR 493.1441 The laboratory director must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>42 CFR 493.1840(a) Adverse action based on actions of the laboratory's owner, operator or employees.</p> <p>42 CFR 493.1840(b) Adverse action based on improper referrals in proficiency testing.</p>
---	--	---------------------------------	--

<p>7/28/2000 [CR690] Stanley Boykansky, M.D. v. HCFA</p>	<ul style="list-style-type: none"> - Acceptable Plan of Correction - CMS modifying state agency findings - Intentional PT referral 	<p>For HCFA</p>	<p>42 CFR 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload.</p> <p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results.</p> <p>42 CFR 493.1806(a) Applicability. HCFA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p>
<p>9/11/2000 [CR698] Garden City Medical Clinic v. HCFA</p>	<ul style="list-style-type: none"> - Employee termination - Intentional PT referral - PT collaboration - Statistics 	<p>For HCFA</p>	<p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.1840(a) Adverse action based on actions of the laboratory's owner, operator or employees.</p>
<p>9/20/2000 [DAB1747] Kaulson Labs v. HCFA</p>	<ul style="list-style-type: none"> - Remand 	<p>For Petitioner</p>	<p>42 CFR 493.1844 Appeals procedures.</p>

<p>12/5/2000 [DAB1755] Oakland Medical Group, P.C. v. HCFA</p>	<ul style="list-style-type: none"> - Accreditation - Improper PT - Physical transfer - Standard/Condition level Deficiencies 	<p>For HCFA</p>	<p>42 CFR 493.61 Requirements for a certificate of accreditation.</p> <p>[See 7/18/2000 Oakland Medical Group, P.C. v. HCFA]</p>
<p>12/21/2000 [DAB1756] Stanley Boykansky, M.D. v. HCFA</p>	<ul style="list-style-type: none"> - Intentional PT referral - Physical transfer - Single condition out 	<p>For HCFA</p>	<p>42 CFR 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload.</p> <p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform.</p> <p>42 CFR 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results.</p> <p>42 CFR 493.1806(a) Applicability. HCFA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p>
<p>1/24/2001 [CV 00-12209 SVW (CWx)] Physicians Independent Laboratory Inc. v. Donna Shalala, DHHS, [et.al.]</p>	<ul style="list-style-type: none"> - Administrative remedies - Suspension before hearing - TRO 	<p>For DHHS</p>	<p>42 CFR 493.1840(d) Procedures for suspension or limitation.</p>

<p>1/26/2001 [DAB1762] Sentinel Medical Laboratories, Inc. v. HCFA</p>	<ul style="list-style-type: none"> - Administrative remedies - Constitutionality - Director responsibilities - 2-year prohibition 	<p>For HCFA</p>	<p>42 CFR 493.49(e) In the event of a noncompliance determination resulting in an HHS action.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p> <p>42 CFR 493.1844(d)(2) Suspension, limitation, or revocation of a laboratory's CLIA certificate.</p>
<p>1/30/2001 [DAB1763] Garden City Medical Clinic v. HCFA</p>	<ul style="list-style-type: none"> - Accreditation - Remand - Summary Judgment - Witness cross-examination 	<p>For Petitioner</p>	<p>42 CFR 493.1844(a) Appeals procedures. General rules.</p> <p>42 CFR 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples.</p>
<p>2/15/2001 [No. 00-3138] Edison Medical Lab. Inc. v. HCFA</p>	<ul style="list-style-type: none"> - Accreditation 	<p>For HCFA</p>	
<p>3/6/2001 [CR749] Union City Diagnostic Laboratory v. HCFA</p>	<ul style="list-style-type: none"> - Immediate Jeopardy - Quality Control - Single condition out 	<p>For HCFA</p>	<p>42 CFR 493.1701 Condition: Quality assurance. The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures.</p> <p>42 CFR 493.1806(a) Applicability. HCFA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p> <p>42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.</p>

<p>5/10/2001 [CV 00-12209 SVW (CWx)] Physicians Independent Laboratory Inc. v. Donna Shalala, DHHS, [et. al.]</p>	<ul style="list-style-type: none"> - Administrative remedies - District Court jurisdiction 	<p>For DHHS</p>	<p>42 CFR 493.1840(d) Procedures for suspension or limitation.</p>
<p>5/14/2001 [CR773] American Women's Center v. HCFA</p>	<ul style="list-style-type: none"> - Cease and desist - Due process (notice receipt) - Good cause for late filing - Remand 	<p>For HCFA [Partial remand]</p>	<p>42 CFR 493.1810 Imposition and lifting of alternative sanctions. Notice of noncompliance and of proposed sanction.</p> <p>42 CFR 493.1812(b) Opportunity to respond.</p> <p>42 CFR 493.1844 Appeals procedures.</p>
<p>6/12/2001 [CR779] Evette Elsenety, M.D. v. HCFA</p>	<ul style="list-style-type: none"> - Accreditation - Person (definition) - Summary Disposition - 2-year prohibition 	<p>For HCFA</p>	<p>42 CFR 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
<p>6/18/2001 [No. 01-2872 (KSH)] U.S.A v. Edison Medical Laboratory Service Corporation</p>	<ul style="list-style-type: none"> - TRO 	<p>For USA</p>	<p>42 CFR 493.1846 Civil action.</p>
<p>7/31/2001 [Case No. 01-72447] Preferred Family Medicine, P.C. [et al.] v. CMS</p>	<ul style="list-style-type: none"> - Accreditation - TRO 	<p>For CMS</p>	<p>42 CFR 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples.</p>

<p>8/3/2001 [CR805] Mark Gary Hertzberg, M.D., P.C. v. CMS</p>	<ul style="list-style-type: none"> - Accreditation - Due process - Physical transfer - PT collaboration - Single condition out 	<p>For CMS</p>	<p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>42 CFR 493.1806(a) Applicability. HFCA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p>
<p>8/28/2001 [Case No. 01-72447] Preferred Family Medicine, P.C., [et. al.] v. Tommy G. Thompson, DHHS, [et. al]</p>	<ul style="list-style-type: none"> - District Court jurisdiction 	<p>For DHHS</p>	
<p>10/10/2001 [DAB1790] Premium Diagnostic Laboratory Inc. v. CMS</p>	<ul style="list-style-type: none"> - Appeal of ALJ dismissal 	<p>For CMS</p>	<p>42 CFR 493.1773 Dismissal for cause. (No right to hearing)</p> <p>42 CFR 493.1844(b) Actions that are initial determinations.</p>

<p>10/23/2001 [CR829] RNA Laboratories, Inc. and Ter-Zerharian Medical Clinic v. CMS</p>	<ul style="list-style-type: none"> - Affected parties - Director/Owner - Improper PT referral - PT collaboration - PT records -Statistics 	<p>For CMS</p>	<p>42 CFR 498.2 Definitions. [Affected party.]</p> <p>42 CFR 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results.</p> <p>42 CFR 493.1407 Laboratory director responsibilities.</p>
<p>11/08/2001 [DAB1796] Evette Elsenety, M.D., et. al v. HCFA</p>	<ul style="list-style-type: none"> - Person (definition) - 2-year prohibition 	<p>For CMS</p>	<p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
<p>12/14/2001 [DAB1805] Mark Gary Herzberg, M.D., P.C. v. CMS</p>	<ul style="list-style-type: none"> - Improper PT referral 	<p>For CMS</p>	<p>42 CFR 493.801 Enrollment and testing of samples</p>
<p>12/17/2001 [CR848] Edward Ming-Che Lai, M.D. v. CMS</p>	<ul style="list-style-type: none"> - Lab Director 	<p>For Petitioner</p>	<p>42 CFR 493.51 Notification requirements for laboratories issued a certificate of compliance.</p> <p>42 CFR 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate.</p>

<p>01/28/2002 [CR863] Sol Teitelbaum, M.D. v. CMS</p>	<ul style="list-style-type: none"> - Effective date of prohibition - Lab Director - Operator - Right to hearing - 2-year prohibition 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.2 Definitions. (Operator).</p> <p>42 CFR 493.1407 Laboratory Director responsibilities.</p> <p>42 CFR 493.1806 Available sanctions.</p> <p>57 Fed. Reg. 7226 (1992) (Lab director is an operator; legislative purpose of CLIA.)</p>
<p>02/25/2002 [CR875] Millenium Medical Group v. CMS</p>	<ul style="list-style-type: none"> - Affected party - Ownership - 2-year prohibition 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 498.40(c)(1) Affected party.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
<p>03/12/2002 [CR879] Caroline D. Zohoury, D.O. v. CMS</p>	<ul style="list-style-type: none"> - Denial CLIA application - Owner/Operator - 2-year prohibition 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.2 Definitions (owner/operator)</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
<p>03/18/2002 [DAB1820] RNA Laboratories, Inc., and Ter-Zakarin Medical Clinic v. CMS</p>	<ul style="list-style-type: none"> - Improper PT referral - Lab Director 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801(a) Enrollment and testing of samples.</p> <p>42 CFR 493.1403 Laboratory Director condition of participation.</p>

<p>04/15/2002 [CR889] Gen Sys Incorporated v. CMS</p>	<ul style="list-style-type: none"> - Immediate Jeopardy - Lab Director qualifications - Summary Judgment - Technical Supervisor qualifications 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.2 Definitions (Immediate Jeopardy).</p> <p>42 CFR 493.1441 Laboratory Director.</p> <p>42 CFR 493.1447 Technical Supervisor.</p>
<p>06/19/2002 [CR919] Dearborn Family Clinic v. CMS</p>	<ul style="list-style-type: none"> - Improper PT referral - Lab Director responsibilities - Technical Supervisor qualifications 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801 Enrollment and testing of samples.</p> <p>42 CFR 493.1441 Laboratory Director.</p> <p>42 CFR 493.1447 Technical Supervisor.</p> <p>42 CFR 493.1806(a) Available sanctions (Applicability).</p>
<p>07/29/2002 [CR935] Emil S. Sitto, M.D., & Associates, PLLC v. CMS</p>	<ul style="list-style-type: none"> - Improper PT referral - Lab Director responsibilities - Technical Supervisor qualifications 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.61 Requirements for a certificate of accreditation.</p> <p>42 CFR 493.801 Enrollment and testing of samples.</p> <p>42 CFR 493.1441 Laboratory Director.</p> <p>42 CFR 493.1447 Technical Supervisor.</p>

<p>07/30/2002 [CR936] Medical Service Laboratories v. CMS</p>	<ul style="list-style-type: none"> - Immediate Jeopardy - PT enrollment 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801 Enrollment and testing of samples.</p> <p>42 CFR 493.1844(c)(6) Appeals procedures (Immediate jeopardy not subject to appeal).</p> <p>42 CFR 493.1844(d)(4)(ii) If an ALJ decision upholds the suspension imposed because of immediate jeopardy, that suspension becomes a revocation.</p>
<p>08/01/2002 [CR939] Carlos A. Cervera, M.D. v. CMS</p>	<ul style="list-style-type: none"> - Constitutional issue - Lab Director - Misrepresentation on CLIA application - 2-year prohibition 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.2 Definitions (owner/operator).</p> <p>42 CFR 493.643 Fee for determination of program compliance.</p> <p>42 CFR 493.1840(a)(1) Misrepresentation in obtaining certificate.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
<p>08/30/2002 [CR946] Alaa Ahmed, M.Sc., Ph.D., (Global Esoteric Reference Labs, Inc.) v. CMS</p>	<ul style="list-style-type: none"> - Improper proficiency testing - Laboratory Director - 2-year prohibition 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801 Enrollment and testing of samples.</p> <p>42 CFR 493.1205(e)(1) Supplies exceeding expiration date.</p> <p>42 CFR 493.1441 Laboratory Director.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>

<p>09/27/2002 [CR957] Lackawanna Medical Group Laboratory v. CMS</p>	<ul style="list-style-type: none"> - Improper proficiency testing - 2-year prohibition 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801(b)(4) Intentional referral of proficiency testing samples.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
<p>10/04/2002 [DAB1849] Sol Teitelbaum, M.D. v. CMS</p>	<ul style="list-style-type: none"> - Deficiencies during a Lab Director's tenure - Lab Director - Summary Judgment - 2-year prohibition 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.2 Definitions (owner/operator).</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
<p>11/18/2002 [CR975] Preferred Family Clinic v. CMS</p>	<ul style="list-style-type: none"> - Improper PT - Lab Director 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801(b) Testing of proficiency testing samples.</p> <p>42 CFR 493.1441 Laboratory Director.</p> <p>42 CFR 493.1806(a),(b) Available sanctions (applicability, principal sanctions).</p>
<p>11/27/2002 [CR981] St. Charles Health Care v. CMS</p>	<ul style="list-style-type: none"> - Standard-level deficiencies not corrected in 12 months - Unacceptable AOC - Unsuccessful PT 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.2 Definitions (credible allegation of compliance; unsuccessful proficiency testing performance).</p> <p>42 CFR 493.1816(b) Failure to correct standard-level deficiencies within 12 months.</p> <p>42 CFR 493.1840(a)(4) Failure to comply with reasonable request by HCFA for any information necessary to determine compliance.</p>

<p>02/03/2003 [CR999] Preferred Family Medicine v. CMS</p>	<ul style="list-style-type: none"> - Improper PT - Physical transport - PT collaboration 	<p>For CMS</p>	<p>42 CFR 493.563 Validation inspections - basis and focus.</p> <p>42 CFR 493.569(a) Validation inspection of an accredited laboratory out of compliance with Condition-level requirements.</p> <p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.801(b)(4) Intentional referral of proficiency testing samples.</p> <p>42 CFR 493.1804(d) Choice of sanction: Factors considered.</p>
<p>03/21/2003 [DAB1870] Lackawanna Medcial Group Laboratory v. CMS</p>	<ul style="list-style-type: none"> - Improper PT - Relationship of 42 CFR 493.801(b)(1) and 42 CFR 493.801(b)(4) - Summary Judgment 	<p>For CMS</p>	<p>42 CFR 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload.</p> <p>42 CFR 493.801(b)(4) Intentional referral of proficiency testing samples.</p>
<p>04/14/2003 [CR1025] Medimex Clinical Laboratory v. CMS</p>	<ul style="list-style-type: none"> - Doctrine of Laches - Immediate Jeopardy - Lab Director responsibilities 	<p>For CMS</p>	<p>42 CFR 493.1403 and 493.1441 Laboratory Director provides overall management and direction.</p>

<p>05/01/2003 [DAB1878] Alaa Ahmed, M.Sc., Ph.D. (Global Esoteric Reference Labs, Inc.) v. CMS</p>	<ul style="list-style-type: none"> - Improper PT - Lab Director responsibilities - State licensure issue (lab name) 	<p>For CMS</p>	<p>42 CFR 493.801 Enrollment and testing of samples.</p> <p>42 CFR 493.1441 Lab Director.</p>
<p>06/12/2003 [CR1055] Roy Hollins/Western Reference Laboratory v. CMS</p>	<ul style="list-style-type: none"> - Due process - Owner - Untimely filing of request for hearing - 2-year prohibition 	<p>For CMS</p>	<p>42 CFR 498.70(c) Dismissal of a late filed request.</p> <p>42 CFR 493.1844(b) Hearings are conducted in accordance with procedures set forth at 42 CFR Part 498.</p> <p>42 CFR 493.1844(d)(4) Effect of ALJ decision.</p>
<p>06/16/2003 [Docket No. C-03-203] Alani Medical Management Corp., d.b.a. Advanced Diagnostic Services Laboratory v. CMS</p>	<ul style="list-style-type: none"> - Affected party (right to hearing) - Alternative sanction (civil money penalties) 	<p>Denial of CMS' motion to dismiss and Petitioner's motion for summary judgment</p>	<p>42 CFR 493.1806 Available sanctions.</p>

<p>08/26/2003 [CR1079] Bolsa Medical Group Laboratory, Sheldon Barasch, M.D. v. CMS</p>	<ul style="list-style-type: none"> - Delegation of responsibilities - Intentional PT referral - Physical transport of PT sample - Relationship of 42 CFR 493.801(b)(3) and 42 CFR 493.801(b)(4) 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>42 CFR 493.1840(a)(8) Adverse action.</p>
<p>08/28/2003 [CR1080] James Bryant, M.D. v. CMS</p>	<ul style="list-style-type: none"> - Affected party (right to hearing) - Owner/operator - 2-year prohibition 	<p style="text-align: center;">Dismissal</p>	<p>42 CFR 493.1844 Appeals procedures.</p> <p>42 CFR 493.2 Definitions (owner/operator)</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>

<p>09/17/2003 [CR1083] Immuno Biogene, Inc., Charles T. Black, M.D. v. CMS</p>	<ul style="list-style-type: none"> - Improper PT - Immediate Jeopardy - Failure to notify CMS of receipt of PT samples from another laboratory - Lab Director responsibilities 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801(b) Testing of proficiency testing samples.</p> <p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.</p> <p>42 CFR 493.1407 Laboratory director responsibilities.</p>
<p>11/14/2003 [CR1109] White Lake Family Medicine, P.C. v. CMS</p>	<ul style="list-style-type: none"> - Intentional PT referral - Physical transport 	<p style="text-align: center;">For CMS</p>	<p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p>
<p>11/18/2003 [CR1111] William Komaiko, M.D. v. CMS</p>	<ul style="list-style-type: none"> - Affected party (right to hearing) - Owner/operator - 2-year prohibition 	<p style="text-align: center;">Dismissal</p>	<p>42 CFR 493.1844 Appeals procedures.</p> <p>42 CFR 493.2 Definitions (owner/operator)</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>

<p>02/03/2004 [Docket No. C-03-566]] Bethesda Pathology Clinic, Inc. v. CMS</p>	<ul style="list-style-type: none"> - Affected party (right to hearing) - Owner/Operator - Transfer of ownership - 2-year prohibition 	<p>Dismissal</p>	<p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p> <p>42 CFR 493.1844 Appeals procedures.</p> <p>42 CFR 498.70(b) The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.</p>
<p>04/19/2004 [CR1167] Vijay Sakhuja, M.D. v. CMS</p>	<ul style="list-style-type: none"> - CMS access to laboratory records - Condition Level Non-compliance - Immediate Jeopardy - Plan of Correction 	<p>For CMS</p>	<p>42 CFR 493.1771 & 1773 Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.</p> <p>42 CFR 493.1844(c)(6) Actions that are not initial determinations -- The determination that a laboratory's deficiencies pose immediate jeopardy.</p>
<p>06/09/2004 [CR1189] American Diagnostic Labs (by Ayazar Rahman, Owner, & Charles Panchari, M.D., Director), v. CMS</p>	<ul style="list-style-type: none"> - Condition Level Non-compliance - Immediate Jeopardy - "Remedial Purpose" of imposition of Civil Money Penalty 	<p>For CMS</p>	<p>42 CFR 493.1804(b)(2) CMS may impose principal or alternative sanctions when it finds that a laboratory has a "condition-level" deficiency.</p> <p>42 CFR 493.1844(b)(3) The imposition of an alternative sanction is subject to ALJ review as an initial determination.</p>

	<ul style="list-style-type: none"> - State Licensure Requirements - Temporary Restraining Order - 2-year prohibition 		<p>42 CFR 493.1804(a) Civil Money Penalty.</p> <p>42 CFR 493.1423(a) Testing personnel. State license.</p> <p>42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
<p>09/13/2004 [CR1212] Millennium Clinical Laboratories, Inc., v. CMS</p>	<ul style="list-style-type: none"> - Condition Level Non-compliance - Civil Money Penalty - Immediate Jeopardy (when declared) - State Operations Manual (guidance) 	<p>For CMS</p>	<p>42 CFR 493.1804(b)(2) CMS may impose principal or alternative sanctions when it find that a laboratory has a "condition-level" deficiency</p> <p>42 CFR 493.1834 Civil Money Penalty.</p> <p>42 CFR 493.2 Definition of Immediate Jeopardy.</p> <p>SOM Appendix C, Section 6100 (non-regulatory)</p>
<p>10/06/2004 [DAB1946] Immuno Biogene, Inc., v. CMS</p>	<ul style="list-style-type: none"> - Appeal of ALJ decision [CR1083] - Civil Money Penalty - Condition Level Non-compliance with Immediate Jeopardy - Improper PT (inter-laboratory communications) - Failure to notify CMS of receipt of PT samples from 	<p>For CMS</p>	<p>42 CFR 493.801(b) Testing of proficiency testing samples.</p> <p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.</p>

	<p>another laboratory</p> <ul style="list-style-type: none"> - Lab Director responsibilities 		<p>42 CFR 493.1407 Laboratory director responsibilities.</p>
<p>11/09/2004 [DAB1951] White Family Medicine, P.C., v. CMS</p>	<ul style="list-style-type: none"> - Appeal of ALJ decision [CR1109] - Improper PT - Summary judgment 	<p>For CMS</p>	<p>42 CFR 493.801(b) Testing of proficiency testing samples.</p> <p>42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p>