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 12/31/2009. 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 "Regulatory References" link on page one. The Case Citation Reference Guide lists cases and issues most often referenced in the decisions.

[Quick jump to 1994 cases, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009.]

Decision Date and Case Name	Issues	Outcome	Regulatory References
9/23/1994 [CR334] Long Medical Laboratory v. HCFA	- 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	- 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	- 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.
7/31/1995 [DAB1526] Center Clinical Laboratory v. HCFA	- Effective date	For HCFA	42 CFR 493.1844(h)(1) Effective date of adverse action (5 days after notice).

2/15/1996 [CR411] Center Clinical Laboratory v. HCFA	- Immediate Jeopardy (not subject to appeal)	For HCFA	42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy. 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)
9/30/1996 [CR438] Blanding Urgent Care Center Laboratory v. HCFA	- Improper PT - Intentional PT referral - Motive - Physical transport	For HCFA	42 CFR 493.2 Intentional violation. 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. 42 CFR 493.1840(b) Adverse action based on improper referrals in proficiency testing.
10/9/1996 [CR439] Primary Care Medical Group v. HCFA	- Improper PT - Intentional PT referral - Lab Director	For HCFA	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. 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.
12/27/1996 [CR451] Ward General Practice Clinic v. HCFA	- Acceptable Plan of Correction - Certificate change - Immediate jeopardy	For HCFA	42 CFR 493.1800 Basis and scope of enforcement procedures. 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. 42 CFrR 493.1806(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions.

5/30/1997 [CR476] California Medical Associates Laboratory v. HCFA	- Choice of sanctions - Lab closure - Voluntary cessation	For HCFA	42 CFR 493.1800 Basis and scope of enforcement procedures. 42 CFrR 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. 42 CFR 493.1806(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions. 42 CFR 493.1804(d) Choice of sanction: Factors considered.
7/24/1997 [DAB1624] Ward General Practice Clinic v. HCFA	- Certificate change - History of non-compliance	For HCFA	42 CFR 493.1800 Basis and scope of enforcement procedures. 42 CFR 493.1804 General considerations of enforcement.
8/5/1997 [CR487] Williams Bio Medical Laboratory v. HCFA	- Burden of proof - Directed Plan of Correction - Standard deficiencies	For HCFA	42 CFR 493.1816(b) Action when deficiencies are not at the condition level. Failure to correct deficiencies. 42 CFR 493.1820 Ensuring timely correction of deficiencies. 42 CFR 493.1832(c) Duration of a directed plan of correction. 42 CFR 493.1840(a)(7) Failed to comply with an alternative sanction imposed under this subpart.

10/21/1997 [CR501] Thyroid Specialty Laboratory v. HCFA	- Intentional PT referral - Lab Director - Motive	For HCFA	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. 42 CFR 493.1840(b) Adverse action based on improper referrals in proficiency testing.
3/31/1998 [CR527] **Eugene R. Pocock, M.D. v. HCFA**	- Affected party (right to hearing) - Lab Director - Operator	For HCFA	42 CFR 493.2 Definitions. Operator. 42 CFR 498.2 Definitions. [Affected party]. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. 42 CFR 498.40 Request for Hearing. An affected party entitled to a hearing.
2/16/1999 [CR576] BAN Laboratories v. HCFA	- Due process - Exit Conference - Immediate Jeopardy - Re-survey	For HCFA	42 CFR 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate. 42 CFR 493.1806 Available sanctions. 42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.

4/30/1999 [CR590] Melvin C. Murphy, M.D. v. HCFA	- Director/Owner responsibilities - Intentional PT referral - State Law vs CLIA	For HCFA	42 CFR 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results. 42 CFrR 493.1840(b) Adverse action based on improper referrals in proficiency testing.
5/27/1999 [CR597] Eugene A. Shaneyfelt, M.D. v. HCFA	- Certificate of Waiver - Director/Operator - Operator	For HCFA	42 CFR 493.2 Definitions: operator. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.
6/7/1999 [CR599] Edison Medical Laboratories, Inc. v. HCFA	- Accreditation - Immediate Jeopardy	For HCFA	42 CFR 493.1780(a) Validation inspection. 42 CFR 493.1800 Basis and scope of enforcement procedures. 42 CFR 493.1806 Available sanctions. 42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.
6/9/1999 [CR600] Diagnostic and Educational Laboratory v. HCFA	- Choice of sanctions - Lab Director - Standard deficiencies - Written documentation	For HCFA	42 CFR 493.1804(d) Choice of sanction: Factors considered. 42 CFR 493.1816(b) Action when deficiencies are not at the condition level [i.e., standard level]. Failure to correct deficiencies.

10/6/1999 [C-99-309] Allstate Medical Laboratory, Inc. v. HCFA	- Affected party	HCFA motion denied	42 CFR 498.2 Definitions. [Affected party]
12/7/1999 [CR632] US Bio-Chem Medical Laboratories v. HCFA	- Certificate of Waiver Lab - Complainant disclosure - Duty to cooperate - Failure to permit inspection	For HCFA	42 CFR 493.1771 Condition: Inspection requirements applicable to all CLIA-certified laboratories. 42 CFR 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate.
12/21/1999 [C-99-797] Carlos A. Cervera, M.D., Director, San Fernando Diagnostic Laboratory, Inc. v. HCFA	- Affected party	HCFA motion denied	42 CFR 498.2 Definitions. [Affected party]
12/23/1999 [DAB1713] Edison Medical Laboratories, Inc. v. HCFA	- Burden of proof - Due process - Immediate Jeopardy	For HCFA	42 CFR 493.1804(a) Purpose. The enforcement mechanisms. 42 CFR 493.1806 Available sanctions. 42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.
1/21/2000 [CR642] Kaulson Labs v. HCFA	- Clerical errors	For HCFA	42 CFR 4931806(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. 42 CFR 493.1806(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions.

5/9/2000 [CR667] Southfield Medical Clinic v. HCFA	- Acts of employees - Improper PT - Unlawful collaboration	For HCFA	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. 42 CFR 493.803 Condition: Successful participation.
6/21/2000 [DAB1731] US Bio-Chem Medical Laboratories v. HCFA	- Complainant disclosure - Right to inspect	For HCFA	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). 42 CFR 493.3 Applicability. 42 CFR 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate.
6/27/2000 [CR679] Sentinel Medical Laboratories, Inc. v. HCFA	- Affected party - Due process - Effective date of prohibition - Exit Conference - Lab Director (2-year prohibition) - Lab Director responsibilities - Right to hearing - Voluntary cessation	For HCFA	42 CFR 498.2 Definitions. [Affected party]. 42 CFR 493.49(e) In the event of a noncompliance determination resulting in an HHS action. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. 42 CFR 493.1884(d)(2) Suspension, limitation, or revocation of a laboratory's CLIA certificate.

7/18/2000 [CR688] Oakland Medical Group, P.C. v. HCFA	- Accreditation - Independent contractor - Intentional PT referral - Owner/Operator - PT collaboration	For HCFA	42 CFR 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples. 42 CFR 493.6(c)(3) A laboratory failing to meet the requirements of this section may be subject to suspension, revocation. 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. 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. 42 CFR 493.1840(a) Adverse action based on actions of the laboratory's owner, operator or employees. 42 CFR 493.1840(b) Adverse action based on improper referrals in proficiency testing.
7/28/2000 [CR690] Stanley Boykansky, M.D. v. HCFA	- Acceptable Plan of Correction - CMS modifying state agency findings - Intentional PT referral	For HCFA	42 CFR 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload. 42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 CFR 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results. 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.

9/11/2000 [CR698] Garden City Medical Clinic v. HCFA	- Employee termination - Intentional PT referral - PT collaboration - Statistics	For HCFA	42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 CFR 493.1840(a) Adverse action based on actions of the laboratory's owner, operator or employees.
9/20/2000 [DAB1747] Kaulson Labs v. HCFA	- Remand	For Petitioner	42 CFR 493.1844 Appeals procedures.
12/5/2000 [DAB1755] Oakland Medical Group, P.C. v. HCFA	- Accreditation - Improper PT - Physical transfer - Standard/Condition level Deficiencies	For HCFA	42 CFR 493.61 Requirements for a certificate of accreditation. [See 7/18/2000 Oakland Medical Group, P.C. v. HCFA]
12/21/2000 [DAB1756] Stanley Boykansky, M.D. v. HCFA	- Intentional PT referral - Physical transfer - Single condition out	For HCFA	42 CFR 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload. 42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 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. 42 CFR 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results. 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.

1/24/2001 [CV 00-12209 SVW (CWx)] Physicians Independent Laboratory Inc. v. Donna Shalala, DHHS, [et.al.]	- Administrative remedies - Suspension before hearing - TRO	For DHHS	42 CFR 493.1840(d) Procedures for suspension or limitation.
1/26/2001 [DAB1762] Sentinel Medical Laboratories, Inc. v. HCFA	- Administrative remedies - Constitutionality - Director responsibilities - 2-year prohibition	For HCFA	42 CFR 493.49(e) In the event of a noncompliance determination resulting in an HHS action. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. 42 CFR 493.1844(d)(2) Suspension, limitation, or revocation of a laboratory's CLIA certificate.
1/30/2001 [DAB1763] Garden City Medical Clinic v. HCFA	- Accreditation - Remand - Summary Judgment - Witness cross-examination	For Petitioner	42 CFR 493.1844(a) Appeals procedures. General rules. 42 CFR 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples.
2/15/2001 [No. 00-3138] Edison Medical Lab. Inc. v. HCFA	- Accreditation	For HCFA	

3/6/2001 [CR749] Union City Diagnostic Laboratory v. HCFA	- Immediate Jeopardy - Quality Control - Single condition out	For HCFA	42 CFR 493.1701 Condition: Quality assurance. The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures. 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. 42 CFR 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.
5/10/2001 [CV 00-12209 SVW (CWx)] Physicians Independent Laboratory Inc. v. Donna Shalala, DHHS, [et. al.]	- Administrative remedies - District Court jurisdiction	For DHHS	42 CFR 493.1840(d) Procedures for suspension or limitation.
5/14/2001 [CR773] American Women's Center v. HCFA	- Cease and desist - Due process (notice receipt) - Good cause for late filing - Remand	For HCFA [Partial remand]	42 CFR 493.1810 Imposition and lifting of alternative sanctions. Notice of noncompliance and of proposed sanction. 42 CFR 493.1812(b) Opportunity to respond. 42 CFR 493.1844 Appeals procedures.
6/12/2001 [CR779] Evette Elsenety, M.D. v. HCFA	- Accreditation - Person (definition) - Summary Disposition - 2-year prohibition	For HCFA	42 CFR 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

6/18/2001 [No. 01-2872 (KSH)] U.S.A v. Edison Medical Laboratory Service Corporation	- TRO	For USA	42 CFR 493.1846 Civil action.
7/31/2001 [Case No. 01-72447] Preferred Family Medicine, P.C. [et al.] v. CMS	- Accreditation - TRO	For CMS	42 CFR 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples.
8/3/2001 [CR805] Mark Gary Hertzberg, M.D., P.C. v. CMS	- Accreditation - Due process - Physical transfer - PT collaboration - Single condition out	For CMS	42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory. 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.
8/28/2001 [Case No. 01-72447] Preferred Family Medicine, P.C., [et. al.] v. Tommy G. Thompson, DHHS, [et. al]	- District Court jurisdiction	For DHHS	
10/10/2001 [DAB1790] Premium Diagnostic Laboratory Inc. v. CMS	- Appeal of ALJ dismissal	For CMS	42 CFR 493.1773 Dismissal for cause. (No right to hearing) 42 CFR 493.1844(b) Actions that are initial determinations.
10/23/2001 [CR829] RNA Laboratories, Inc. and Ter-Zerharian Medical Clinic v. CMS	- Affected parties - Director/Owner - Improper PT referral - PT collaboration - PT records - Statistics	For CMS	42 CFR 498.2 Definitions. [Affected party.] 42 CFR 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results. 42 CFR 493.1407 Laboratory director responsibilities.
11/08/2001 [DAB1796] Evette Elsenety, M.D., et. al v. HCFA	- Person (definition) - 2-year prohibition	For CMS	42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

12/14/2001 [DAB1805] Mark Gary Herzberg, M.D., P.C. v. CMS	- Improper PT referral	For CMS	42 CFR 493.801 Enrollment and testing of samples
12/17/2001 [CR848] Edward Ming-Che Lai, M.D. v. CMS	- Lab Director	For Petitioner	42 CFR 493.51 Notification requirements for laboratories issued a certificate of compliance. 42 CFR 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate.
01/28/2002 [CR863] Sol Teitelbaum, M.D. v. CMS	- Effective date of prohibition - Lab Director - Operator - Right to hearing - 2-year prohibition	For CMS	42 CFR 493.2 Definitions. (Operator). 42 CRF 493.1407 Laboratory Director responsibilities. 42 CFR 493.1806 Available sanctions. 57 Fed. Reg. 7226 (1992) (Lab director is an operator; legislative purpose of CLIA.)
02/25/2002 [CR875] Millenium Medical Group v. CMS	- Affected party - Ownership - 2-year prohibition	For CMS	42 CFR498.40(c)(1) Affected party. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.
03/12/2002 [CR879] Caroline D. Zohoury, D.O. v. CMS	- Denial CLIA application - Owner/Operator - 2-year prohibition	For CMS	42 CFR 493.2 Definitions (owner/operator) 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

03/18/2002 [DAB1820] RNA Laboratories, Inc., and Ter-Zakarin Medical Clinic v. CMS	- Improper PT referral - Lab Director	For CMS	42 CFR 493.801(a) Enrollment and testing of samples. 42 CFR 493.1403 Laboratory Director condition of participation.
04/15/2002 [CR889] Gen Sys Incorporated v. CMS	- Immediate Jeopardy - Lab Director qualifications - Summary Judgment - Technical Supervisor qualifications	For CMS	42 CFR 493.2 Definitions (Immediate Jeopardy). 42 CFR 493.1441 Laboratory Director. 42 CFR 493.1447 Technical Supervisor.
06/19/2002 [CR919] Dearborn Family Clinic v. CMS	- Improper PT referral - Lab Director responsibilities - Technical Supervisor qualifications	For CMS	42 CFR 493.801 Enrollment and testing of samples. 42 CFR 493.1441 Laboratory Director. 42 CFR 493.1447 Technical Supervisor. 42 CFR 493.1806(a) Available sanctions (Applicability).

07/29/2002 [CR935] Emil S. Sitto, M.D., & Associates, PLLC v. CMS	- Improper PT referral - Lab Director responsibilities - Technical Supervisor qualifications	For CMS	42 CFR 493.61 Requirements for a certificate of accreditation. 42 CFR 493.801 Enrollment and testing of samples. 42 CFR 493.1441 Laboratory Director. 42 CFR 493.1447 Technical Supervisor.
07/30/2002 [CR936] Medical Service Laboratories v. CMS	- Immediate Jeopardy - PT enrollment	For CMS	42 CFR 493.801 Enrollment and testing of samples. 42 CFR 493.1844(c)(6) Appeals procedures (Immediate jeopardy not subject to appeal). 42 CFR 493.1844(d)(4)(ii) If an ALJ decision upholds the suspension imposed because of immediate jeopardy, that suspension becomes a revocation.

08/01/2002 [CR939] Carlos A. Cervera, M.D. v. CMS	- Constitutional issue - Lab Director - Misrepresentation on CLIA application - 2-year prohibition	For CMS	42 CFR 493.2 Definitions (owner/operator). 42 CFR 493.643 Fee for determination of program compliance. 42 CFR 493.1840(a)(1) Misrepresentation in obtaining certificate. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.
08/30/2002 [CR946] Alaa Ahmed, M.Sc., Ph.D., (Global Esoteric Reference Labs, Inc.) v. CMS	- Improper proficiency testing - Laboratory Director - 2-year prohibition	For CMS	42 CFR 493.801 Enrollment and testing of samples. 42 CFR 493.1205(e)(1) Supplies exceeding expiration date. 42 CFR 493.1441 Laboratory Director. 42 CFR 493.1840(a)(8) Within preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.
09/27/2002 [CR957] Lackawanna Medical Group Laboratory v. CMS	- Improper proficiency testing - 2-year prohibition	For CMS	42 CFR 493.801(b)(4) Intentional referral of proficiency testing samples. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

10/04/2002 [DAB1849} Sol Teitelbaum, M.D. v. CMS	- Deficiencies during a Lab Director's tenure - Lab Director - Summary Judgment - 2-year prohibition	For CMS	42 CFR 493.2 Definitions (owner/operator). 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.
11/18/2002 [CR975] Preferred Family Clinic v. CMS	- Improper PT - Lab Director	For CMS	42 CFR 493.801(b) Testing of proficiency testing samples. 42 CFR 493.1441 Laboratory Director. 42 CFR 493.1806(a),(b) Available sanctions (applicability, principal sanctions).
11/27/2002 [CR981] St. Charles Health Care v. CMS	- Standard-level deficiencies not corrected in 12 months - Unacceptable AOC - Unsuccessful PT	For CMS	42 CFR 493.2 Definitions (credible allegation of compliance; unsuccessful proficiency testing performance). 42 CFR 493.1816(b) Failure to correct standard-level deficiencies within 12 months. 42 CFR 493.1840(a)(4) Failure to comply with reasonable request by HCFA for any information necessary to determine compliance.
02/03/2003 [CR999] Preferred Family Medicine v. CMS	- Improper PT - Physical transport - PT collaboration	For CMS	42 CFR 493.563 Validation inspections - basis and focus. 42 CFR 493.569(a) Validation inspection of an accredited laboratory out of compliance with Condition-level requirements. 42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 CFR 493.801(b)(4) Intentional referral of proficiency testing samples. 42 CFR 493.1804(d) Choice of sanction: Factors considered.

03/21/2003 [DAB1870] Lackawanna Medcial Group Laboratory v. CMS	- Improper PT - Relationship of 42 CFR 493.801(b)(1) and 42 CFR 493.801(b)(4) - Summary Judgment	For CMS	42 CFR 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload. 42 CFR 493.801(b)(4) Intentional referral of proficiency testing samples.
04/14/2003 [CR1025] Medimex Clinical Laboratory v. CMS	- Doctrine of Laches - Immediate Jeopardy - Lab Director responsibilities	For CMS	42 CFR 493.1403 and 493.1441 Laboratory Director provides overall management and direction.
05/01/2003 [DAB1878] Alaa Ahmed, M.Sc., Ph.D. (Global Esoteric Reference Labs, Inc.) v. CMS	- Improper PT - Lab Director responsibilities - State licensure issue (lab name)	For CMS	42 CFR 493.801 Enrollment and testing of samples. 42 CFR 493.1441 Lab Director.
06/12/2003 [CR1055] Roy Hollins/Western Reference Laboratory v. CMS	- Due process - Owner - Untimely filing of request for hearing - 2-year prohibition	For CMS	42 CFR 498.70(c) Dismissal of a late filed request. 42 CFR 493.1844(b) Hearings are conducted in accordance with procedures set forth at 42 CFR Part 498. 42 CFR 493.1844(d)(4) Effect of ALJ decision.

06/16/2003 [Docket No. C-03-203] Alani Medical Management Corp., d.b.a. Advanced Diagnostic Services Laboratory v. CMS	- Affected party (right to hearing) - Alternative sanction (civil money penalties)	Denial of CMS' motion to dismiss and Petitioner's motion for summary judgment	42 CFR 493.1806 Available sanctions.
08/26/2003 [CR1079] Bolsa Medical Group Laboratory, Sheldon Barasch, M.D. v. CMS	- 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)	For CMS	42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory. 42 CRF 493.1840(a)(8) Adverse action.
08/28/2003 [CR1080] James Bryant, M.D. v. CMS	- Affected party (right to hearing) - Owner/operator - 2-year prohibition	Dismissal	42 CFR 493.1844 Appeals procedures. 42 CFR 493.2 Definitions (owner/operator) 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.
09/17/2003 [CR1083] Immuno Biogene, Inc., Charles T. Black, M.D. v. CMS	- Improper PT - Immediate Jeopardy - Failure to notify CMS of receipt of PT samples from another laboratory - Lab Director responsibilities	For CMS	42 CFR 493.801(b) Testing of proficiency testing samples. 42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples. 42 CFR 493.1407 Laboratory director responsibilities.

11/14/2003 [CR1109] White Lake Family Medicine, P.C. v. CMS	- Intentional PT referral - Physical transport	For CMS	42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.
11/18/2003 [CR1111] William Komaiko, M.D. v. CMS	- Affected party (right to hearing) - Owner/operator - 2-year prohibition	Dismissal	42 CFR 493.1844 Appeals procedures. 42 CFR 493.2 Definitions (owner/operator) 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.
02/03/2004 [Docket No. C-03-566]] Bethesda Pathology Clinic, Inc. v. CMS	- Affected party (right to hearing) - Owner/Operator - Transfer of ownership - 2-year prohibition	Dismissal	42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. 42 CFR 493.1844 Appeals procedures. 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.

04/19/2004 [CR1167] Vijay Sakhuja, M.D. v. CMS	- CMS access to laboratory records - Condition Level Non-compliance - Immediate Jeopardy - Plan of Correction	For CMS	42 CFR 493.1771 & 1773 Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories. 42 CFR 493.1844(c)(6) Actions that are not initial determinations -- The determination that a laboratory's deficiencies pose immediate jeopardy.
06/09/2004 [CR1189] American Diagnostic Labs (by Ayazar Rahman, Owner, & Charles Panchari, M.D., Director), v. CMS	- Condition Level Non-compliance - Immediate Jeopardy - "Remedial Purpose" of imposition of Civil Money Penalty - State Licensure Requirements - Temporary Restraining Order - 2-year prohibition	For CMS	42 CFR 493.1804(b)(2) CMS may impose principal or alternative sanctions when it finds that a laboratory has a "condition-level" deficiency. 42 CFR 493.1844(b)(3) The imposition of an alternative sanction is subject to ALJ review as an initial determination. 42 CFR 493.1804(a) Civil Money Penalty. 42 CFR 493.1423(a) Testing personnel. State license. 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

09/13/2004 [CR1212] Millennium Clinical Laboratories, Inc., v. CMS	- Condition Level Non-compliance - Civil Money Penalty - Immediate Jeopardy (when declared) - State Operations Manual (guidance)	For CMS	42 CFR 493.1804(b)(2) CMS may impose principal or alternative sanctions when it find that a laboratory has a "condition-level" deficiency 42 CFR 493.1834 Civil Money Penalty. 42 CFR 493.2 Definition of Immediate Jeopardy. SOM Appendix C, Section 6100 (non-regulatory)
10/06/2004 [DAB1946] Immuno Biogene, Inc., v. CMS	- 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 another laboratory - Lab Director responsibilities	For CMS	42 CFR 493.801(b) Testing of proficiency testing samples. 42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples. 42 CFR 493.1407 Laboratory director responsibilities.

11/09/2004 [DAB1951] White Family Medicine, P.C., v. CMS	- Appeal of ALJ decision [CR1109] - Improper PT - Summary judgment	For CMS	42 CFR 493.801(b) Testing of proficiency testing samples. 42 CFR 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.
1/11/05 [DAB 1958] Vijay Sakhuja, M.D., v. CMS	- Acceptable Plan of Correction - Appeal of ALJ decision [CR 1167] - Condition Level Non-compliance - State Agency Procedures	For CMS	42 CFR 493.1806 Available sanctions.

1/13/05 [CR1267] Sonali Diagnostic Laboratory v. CMS	- Condition Level Non-compliance with Immediate Jeopardy - Due Process (Exit Conference) - Extension of CLIA certificate - Remedial Purpose of Civil Money Penalty - State Operations Manual (guidance) - Technical Supervisor Qualifications	For CMS	42 CFR 493.49 Requirements for a certificate of compliance. 42 CFR 493.1101 Facility administration for nonwaived testing. 42 CFR 493.1449(c)(5) Technical supervisor qualifications. 42 CFR 493.1804(b) Basis for decision to impose sanctions.
2/18/05 [CR1280] Rustom Ali, Ph.D., Operator of Scottsdale Medical Laboratory v. CMS	- Condition Level Non-compliance - Misrepresentation - Remedial Purpose of Civil Money Penalty - Responsibility for Compliance Rests with Laboratory - 2-year Prohibition	For CMS	42 U.S.C. Section 263a(i)(1) 42 CFR 493.1804(a)(3) Purpose [of sanctions].
3/18/05 [CR1283] Clinical Immuno Diagnostic Lab, Inc., v. CMS	- ALJ Jurisdiction to Review Imposition of Civil Money Penalty - Misrepresentation	For CMS	42 U.S.C. Section 263a(i)(1) 42 CFR 493.1840(a)(1) Guilty of misrepresentation in obtaining a CLIA certificate.

4/21/05 [CR1295] Open Faith Medical Laboratory, v. CMS	- Condition Level Non-compliance with Immediate Jeopardy - Certificate of Registration - Denial of Accreditation - Laboratory Director Qualifications - Summary Judgment	For CMS	42 CFR 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. 42 CFR 493.1804(b) Basis for decision to impose sanctions. [Just one condition level deficiency is sufficient.]
09/09/05 [CR1366] Comprehensive Care Center of Plantation Key; Hartsville Convalescent Center; Key West Convalescent Center, Inc.; and Marathon Manor v. CMS	- Definition of owner - Owner/operator - Ownership of laboratory - 2-year prohibition	For CMS	42 CFR 493.2 Definitions (owner/operator) 42 CFR 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.
12/2/05 [CR1374] Canal Medical Laboratory, v. CMS	- ALJ Jurisdiction to Review Imposition of Civil Money Penalty - Condition Level Non-compliance with Immediate Jeopardy - Laboratory director responsibilities - Plan of Correction - Remedial Purpose of Civil Money Penalty - Reviewing Ungraded Proficiency Testing Scores - Successful Participation in Proficiency Testing	For CMS	42 CFR 493.1236(b)(2) Evaluation of proficiency testing performance. 42 CFR 493.803(a) Successful Participation [in proficiency testing]. 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 42 CFR 493.1407(e)(4)(iii) Laboratory director responsibilities.

1/13/2006 [CR1390] Dimensions Medical Laboratory, Inc. v. CMS	- Administrative finality - Plan of correction - Res judicata	For CMS	42 CFR 493.1844(b) Initial determinations.
1/17/06 [CR1267] [DAB 2008] Rustom Ali, Ph.D., Sonali Diagnostic Laboratory v. CMS	- Appeal of ALJ Decision CR1267	For CMS	42 CFR 493.45, 42 CFR 493.1806(a) Condition level non-compliance.
1/30/06 [CR1402] James G. Morgan, D.O., Laboratory Director v. CMS	- Dismissal - Good cause	For CMS	42 CFR 498.40(a)(2) Requests for hearing.
2/28/06 [CR1280] [DAB 2016] Rustom Ali, Jahan Ferdous, and Scottsdale Medical Laboratory v. CMS	- Appeal of ALJ Decision CR 1280 - Imposition of Principal and Alternative Sanctions - Owner/operator	For CMS	42 CFR 493.2 Definitions (owner/operator) 42 CFR 493.1701 Quality assurance. 42 CFR 493.1806(c) Impose one or more intermediate sanctions in lieu of or in addition to principal sanctions.
5/22/06 [CR1451] Delmarva Professional Services, v. CMS	- Owner/operator - Summary disposition - 2-year prohibition	For CMS	42 CFR 493.2 Definitions (owner/operator). 42 CFR 493.1840 2-year prohibition.
8/31/06 [CR1496] Lyle Griffith, M.D., v. CMS	- Plan of correction - Motion to dismiss - Summary judgment	For CMS	42 CFR 493.1804(b) Imposition of sanctions. 42 CFR 493.1844(c)(4) Initial determinations.
8/31/06 [CR1497] HRT Laboratory, Inc., v. CMS	- Content requirements for a hearing request - Plan of correction - Motion to dismiss	For CMS	42 CFR 498.40(b) Basis for appeal. 42 CFR 493.1804(b) Imposition of sanctions.

6/13/07 [CR1607] Physician Laboratory Technology, Inc., v. CMS	- Condition-level noncompliance - CMP - 2-year prohibition	For CMS	42 CFR 493.2 Definition of owner/operator. 42 CFR 493.1804(b) Imposition of sanctions. 42 CFR 493.1840(a)(8) 2-year prohibition.
8/01/07 [CR1630] Wade Pediatrics v. CMS	- Estoppel - Improper PT referral ("intentional") - Summary judgment	For CMS	42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.
8/13/07 [Memorandum HHS No. A-0575] Rustom Ali; et.al., v. US DHHS 8/13/07 [Memorandum HHS No. 2008 Rustom Ali d/b/a Sonali Diagnostic Laboratory, v. US DHHS	- Appeal of DAB - Simultaneous imposition of intermediate and principal sanctions - Stop testing prior to hearing due to immediate jeopardy	For DHHS	42 CFR 493.1806(c) Impose one or more intermediate sanctions in lieu of or in addition to principal sanctions.
10/03/07 [DAB2118] [CR1497] HRT Laboratory, Inc., v. CMS	- Appeal of DAB - Lab closure in face of sanctions - Initial determinations subject to appeal - Unacceptable Plan of Correction not appealable	For CMS	42 CFR 498.40(b) Basis for appeal. 42 CFR 493.1804(b) Imposition of sanctions. 42 CFR 493.1844(ff.) Initial determinations.

11/08/07 [CR1688] Wade Borg, M.D., v. CMS	- Condition-level noncompliance - State requirements - Summary judgment	For CMS	42 CFR 493.1355 Condition: Laboratories performing PPM procedures; laboratory director. 42 CFR 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.
01/09/08 [CR1723] Daniel M. Stewart, v. CMS	- Intentional PT referral - Laboratory director requirments - Proficiency testing - Summary judgment	For CMS	42 CFR 493.801 Condition: Enrollment and testing of samples. 42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory. 42 CRF 493.803 Condition: Successful participation. 42 CFR 403.1403 Condition: Laboratory Director.
02/11/08 [CR1630] [Decision No. 2153] Wade Pediatrics, v. CMS	- Appeal of ALJ Decision - Intentional PT referral	For CMS	42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.

02/27/08 [CR1743] Stat Lab I, Inc., v. CMS	- Condition-level noncompliance: analytical systems - Immediate jeopardy - Laboratory director requirements - Technical consultant requirements - Summary judgment - 2 year prohibition	For CMS	42 CFR 493.1250 Condition: Analytic systems. 42 CFR 493.1403 Condition: Laboratory director. 42 CFR 493.1409 Condition: Technical Consultant.
03/18/08 [CR1754-1758] Hematology & Oncology Services, LLC, v. CMS	- Administrative finality - Hearing requests - Summary judgment - 2 year prohibition	For CMS	42 CFR 493.1840(a)(8) 2 year prohibition. 42 CFR 493.1844(a)(2) Appeals procedures. 42 CFR 498.40 Request for hearing.
06/23/08 [CR1807] Mahmoud H. Aly, M.D., v. CMS	- Abandonment - Dismissal - Proficiency testing requirements	For CMS	42 CFR 493.69(a)(b) Dismissal for Abandonment
07/16/08 [CR1819] Family Practice Medical Center, v. CMS	- Dismissal - Condition-level noncompliance with immediate jeopardy	For CMS	42 C.F.R. 493.1844 Appeal Procedures 42 C.F.R. 498.40(a)(2) Request for Hearing 42 C.F.R. 498.70(c) Dismissal for Cause
06/02/2009 [U.S. Court of Appeals, 10th Circuit] Wade Pediatrics v. CMS	- Appeal of ALJ Decision - Intentional PT referral	For CMS	42 CFR 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.
09/16/2009 [CR2005] Associated Internists, P.C., v CMS	- Dismissal - Plan of correction / Allegation of Compliance	For CMS	42 CRF 493.40(b) Request for hearing. Content of request for hearing.

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	***Burden of Proof:*** 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	***Single Condition Out:*** 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	***Improper PT Referral*** ***Physical Transport*** 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	***Burden of Proof*** 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 Stanley Boykansky, M.D. v. HCFA	***Standards/Overall Condition*** 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	***Standard of Review*** 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	***Summary Judgment*** 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	***Right to Appeal and Unconstitutionality*** 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	***Improper PT Referral*** ***Physical Transfer*** 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	***Improper PT Referral*** ***Physical Transfer*** The intentional referral language of 41 C.F.R. § 493.801(b)(4) applies to constructive referral as well as physical transfer.

CR 690 Stanley Boykansky, M.D. v. HCFA	***Amending an Initial Determination*** 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.
CR 667 Southfield Medical Clinic v. HCFA	***Improper PT Referral*** ***Physical Transfer*** 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). This argument was fully addressed and rejected by the Departmental Appeals Board in Oakland DAB1755 and Boykansky DAB1756. See also Sitto CR935.
CR 527 Eugene R. Pocock, M.D. v. HCFA	***Proper Parties to Request a Hearing*** ***Director's Right to Appeal*** 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.

CR 334 Long Medical Laboratory v. HCFA	***Im***portan***ce of Proficiency Testing*** 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. ***Intentional Referral*** 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 acts deliberately, regardless of motivation. 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.
DAB 1526 Center Clinical Laboratory v. HCFA	***Sanctions*** The statute and regulations provide wide discretion to HCFA in selecting appropriate sanctions to respond to a laboratory's non-compliance with CLIA requirements.

Hearing Digest

Long Medical Center v. HCFA [CR334] Docket No. C-94-294

CLIA #: 10D0272768
State: Florida
Type of Certificate: Registration
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner intentionally submitted proficiency testing samples to a reference laboratory in violation of applicable law and regulations

Arguments:

Petitioner alleges that:

- it referred proficiency tests to another laboratory to check on the quality of that laboratory's services;

- it did not report to AAB (American Association of Bioanalysts) as its own test results the results of the proficiency tests it referred to another laboratory;

- inasmuch as it is licensed by the State of Florida, it should enjoy "automatic certification" under CLIA**.**

Ruling excerpts:

A laboratory refers proficiency tests "intentionally" if it does so deliberately, and not inadvertently.

If a laboratory has intentionally referred a proficiency testing sample to another laboratory, that laboratory's motive for referring the sample is irrelevant as a defense against HCFA's revocation of its CLIA certificate or its approval to receive Medicare reimbursement.

Congress intended CLIA to supersede State licensing laws, to the extent that any conflict might exist between CLIA and State laws.

The Act mandates revocation of a CLIA certificate for improper referral of proficiency testing samples by a laboratory.

Central Valley Medical Laboratory v. HCFA [CR335] Docket No. C-94-062

CLIA #: 05D610725
State: California
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner's director and owner failed to comply with a directed plan of correction.

Petitioner's pattern of failure to comply with conditions for certification under CLIA caused immediate jeopardy to individuals whose tests were performed by Petitioner.

The cytology testing performed by Petitioner manifested serious deficiencies, which resulted in a failure by Petitioner to assure accurate and reliable testing.

Arguments:

Petitioner asserts that:

- the deficiencies identified by the surveyors do not establish a pattern of deficiencies in Petitioner's operations;

- the deficiencies identified by the surveyors did not pose immediate jeopardy to patients;

- because it was ceasing its operations it did not need to provide HCFA with a client list.

Ruling excerpts:

The repeated deficiencies establish a pattern of deficiencies, both in the performance of tests by Petitioner and in the management of Petitioner's operations.

The pattern of deficiencies placed individuals whose tests were performed by Petitioner at a risk of serious harm, thus, in immediate jeopardy.

Petitioner did not send a list of physicians and clients to HCFA in compliance with the directed plan of correction.

Center Clinical Laboratory v. HCFA [CR358] Docket No. C-93-096

CLIA #: 31D0107410
State: New Jersey
Type of Certificate: Compliance
ALJ: Mimi Hwang Leahy

Basis for Sanction(s):

Fictitious patient test results and fabricated control data created a situation of immediate jeopardy.

Arguments:

HCFA failed to adhere to the time requirements specified in the Secretary's regulations.

Ruling excerpts:

HCFA's imposition of the principal sanction of suspension of Petitioner's CLIA certificate was unauthorized and premature.

Further disposition: Decision reversed. See DAB1526, July 31, 1995.

Center Clinical Laboratory v. HCFA [DAB1526] Docket No. C-93-096

CLIA #: 31D0107410
State: New Jersey
Type of Certificate: Compliance
DAB: Judith A. Ballard, M. Terry Johnson, Donald F. Garrett

Basis for Sanction(s):

Appeal of ALJ decision in CR358.

Arguments:

HCFA asserted that it had complied with all of the procedures prescribed under the CLIA statute and regulations for imposing the sanctions in question.

Ruling excerpts:

HCFA acted properly in imposing all of the sanctions in question.

The regulations provide that where a laboratory's deficiencies pose immediate jeopardy, the effective date of a suspension need only be five days after the date of the notice.

The statute and regulations provide wide discretion to HCFA in selecting appropriate sanctions to respond to a laboratory's non-compliance with CLIA requirements.

The DAB reverses the ALJ decision and remands this case to the ALJ to consider the substantive grounds for the sanctions. See CR411, Docket No. C-95-160, July 15, 1996.

Center Clinical Laboratory v. HCFA [CR411] Docket No. C-93-096

CLIA #: 31D0107410
State: New Jersey
Type of Certificate: Compliance
ALJ: Mimi Hwang Leahy

Basis for Sanction(s):

[The procedural history of this case is contained in the decision CR358, and in the decision of the appellate panel of the Departmental Appeals Board, DAB1526, which reversed decision and remanded the case for further proceedings.]

Petitioner failed to meet the condition-level requirements for quality assurance, proficiency testing, management of patient tests, quality control, laboratory director and supervisor as specified by the regulations.

Arguments:

Petitioner argues that its practice does not violate the regulation.

Ruling excerpts:

HCFA's determination of "immediate jeopardy" is not reviewable.

HCFA proved that Petitioner had condition-level deficiencies under 42 C.F.R.Part 493, Subpart H, J, K, P and M.

HCFA properly imposed principal sanctions against Petitioner.

Other cases referenced:

Center Clinical Laboratory v. HCFA [CR358] [DAB1526]

Blanding Urgent Care Center Laboratory v. HCFA [CR438] Docket No. C-95-171

CLIA #: 46D0525318
State: Utah
Type of Certificate: Compliance
ALJ: Jill S. Clifton

Basis for Sanction(s):

Petitioner intentionally referred its proficiency testing samples.

Arguments:

Petitioner argues that:

- "intentionally" [as in "intentionally referred its proficiency testing samples to another laboratory for analysis"] means that a lab intended to report another lab's PT results as its own;

- the referral was made to the laboratory for internal quality control measures;

- HCFA is without authority to revoke Petitioner's CLIA certificate because Petitioner did not manifest the requisite intent;

- it did not physically send PT samples to another laboratory for analysis;

- HCFA must establish that Petitioner's violation was knowing and willful before HCFA can revoke Petitioner's CLIA certificate.

Ruling excerpts:

"Intentionally referred" requires not specific intent, but general intent, that is, an intent to act. Motive is irrelevant. It is necessary merely that a person act deliberately, that is, not inadvertently.

If proficiency testing samples are referred to another laboratory for analysis, with the knowledge that they were proficiency testing samples, the referral can be expected to be intentional, that is, deliberate, not inadvertent.

Where intentional referral of a laboratory's proficiency testing samples to another laboratory for analysis has occurred, there is no possibility of a less severe sanction than a one-year minimum mandatory revocation.

For a laboratory to have referred proficiency testing samples to another laboratory for analysis, it need not physically take or transfer its proficiency testing samples to another laboratory.

A laboratory that obtains analysis of its proficiency testing samples from another laboratory violates 42 U.S.C. 263a(i)(4) regardless of whether the laboratory reports to the PT agency its own results or the results obtained from the other laboratory.

Other cases referenced:

Long Medical Laboratory v. HCFA [CR334]

Primary Care Medical Group vs. HCFA [CR439] Docket No. C-95-161

CLIA #: 05D0588599
State: California
Type of Certificate: Compliance
ALJ: Jill S. Clifton

Basis for Sanction(s):

Petitioner intentionally referred its proficiency testing samples to another laboratory for analysis and was otherwise deficient in meeting CLIA requirements.

Arguments:

Petitioner argues that:

- revocation of a Petitioner's CLIA certificate is improper unless Petitioner or its employees knowingly and willfully violated a CLIA condition;

- 42 C.F.R. 493.2 makes it clear that no intentional violation can occur without the putative offender's knowing and willful noncompliance with a legal duty imposed by the CLIA regulations;

- the referral was made for internal quality control measures;

- neither Petitioner nor any of its employees had a specific intent to violate a CLIA condition;

- the laboratory owner/director was unaware of testing personnel referral of proficiency testing samples until the survey and thus could not have intended to violate the CLIA regulation.

Ruling excerpts:

HCFA need only establish a general intent to act, and not, as Petitioner suggests, specific intent, as would be required in a criminal case.

The CLIA statute and applicable regulations require HCFA to revoke a laboratory's CLIA certificate for at least one year if the laboratory "intentionally refers" its proficiency testing samples to another laboratory for analysis.

"Intentionally referred" [as in "intentionally referred" its proficiency testing samples to another laboratory for analysis] requires not specific intent, but general intent, that is, an intent to act. Motive is irrelevant.

Where "intentionally" is not specifically defined in the context of CLIA civil sanctions, one can infer that it should be given its common and ordinary meaning. This conclusion is in accordance with that of Administrative Law Judge Steven Kessel in the case of Long Medical Laboratory v. HCFA, CR334 (1994).

The laboratory director was responsible for the actions of testing personnel in intentionally referring proficiency testing samples to another laboratory for analysis, and the fact that the director had no knowledge of intentional referral is irrelevant.

The director had a duty to keep apprised of the day-to-day operation of his laboratory and to exercise proper supervision over his employees. He was obligated also to familiarize himself with the applicable CLIA regulations.

Ward General Practice Clinic vs. HCFA [CR451] Docket No. C-96-443

CLIA #: 19D0897371
State: Louisiana
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner manifested deficiencies that represented an immediate jeopardy.

The plan of correction did not correct the deficiencies.

Arguments:

Petitioner asserts that it did correct the deficiencies identified by ceasing to perform those tests and procedures in the performance of which Petitioner was found to be deficient.

Ruling excerpts:

The ALJ did not find that Petitioner corrected its deficiencies simply by ceasing to perform certain tests and procedures.

It is a matter of HCFA's discretion whether to permit a laboratory to convert its operations to procedures and tests other than those in the performance of which it has been found to be deficient, in lieu of imposing sanctions against that laboratory.

The deficiencies identified in Petitioner's operations raise serious questions as to whether Petitioner would be capable of converting its operations to waived tests and, in particular, PPM procedures, without continuing to pose health and safety threats to patients.

The regulations confer broad enforcement authority on HCFA, in order to assure that laboratories comply with CLIA.

Further disposition:

Decision affirmed on appeal. See DAB1624.

California Medical Associates Laboratory v. HCFA [CR476] Docket No. C-96-261

CLIA #: 05D0711870
State: California
Type of Certificate: Compliance
ALJ: Stephen J. Ahlgren

Basis for Sanction(s):

Petitioner did not correct its failure to comply with CLIA conditions.

Arguments:

Petitioner contends that because it acknowledged the deficiencies, had ceased much of its laboratory testing and was willing voluntarily to cease the remainder of its laboratory testing, it is unfair to sanction Petitioner with suspension.

Ruling excerpts:

Nothing in the Act nor the regulations prohibits HCFA from imposing sanctions even if a laboratory ceases operations voluntarily.

The ALJ finds that HCFA's determination to impose sanctions against Petitioner is in no way constrained or limited by Petitioner's admission of wrongdoing or his offer to voluntarily cease laboratory testing.

If laboratories were allowed to circumvent the imposition of sanctions by closing down for a period of time, and then reopening when they saw fit, without correcting the deficiencies cited by the state agency, the government’s enforcement powers could be seriously eroded.

Ward General Practice Clinic vs. HCFA [DAB1624] Docket No. C-96-443

CLIA #: 19D0897371
State: Louisiana
Type of Certificate: Compliance
For the DAB: Judith A. Ballard, M. Terry Johnson, Donald F. Garrett

Basis for Sanction(s):

Laboratory appeal of ALJ decision in CR451.

Arguments:

Petitioner asserted that:

- its proposal to discontinue the procedures cited as deficient in the survey comprised a more than adequate plan of correction;

- HCFA had erred by not allowing it to perform lower level testing;

- ALJ mistakenly relied upon Petitioner's purported history of noncompliance in reaching his decision;

- it should be afforded an opportunity "to undergo a second examination, or present a new plan of correction."

Ruling excerpts:

Petitioner had a history of noncompliance in terms of its operation of the laboratory in question here, which was directly relevant to HCFA's decision to deny approval for converting the laboratory's operation to a lower level of testing.

Petitioner's assertions that the applicable legal provisions may be constitutionally void are beyond the scope of this Board's review.

The regulation does not suggest that by withdrawing its certification as to some tests, a laboratory may avoid sanctions for deficiencies which affect the overall safety of its testing program.

There is neither a statutory nor regulatory basis for Petitioner's suggestion that it be given another examination or chance to submit a new plan of correction.

A laboratory's failure to comply with even a single condition represents a serious breakdown in one of the major health care delivery or safety systems of the laboratory, all of which are critical to ensuring the provision of acceptable health care services and essential for purposes of the laboratory's operations.

Other cases referenced:

Center Clinical Laboratory vs. HCFA [DAB1526]
Ward General Practice Clinic vs. HCFA [CR451]

Williams Bio Medical Laboratory v. HCFA [CR487] Docket No. C-96-101

CLIA #: 05D0642670
State: California
Type of Certificate: Compliance
ALJ: Edward D. Steinman

Basis for Sanction(s):

Petitioner failed to correct deficiencies within 12 months of the initial survey.

Petitioner failed to comply with the terms of the Directed Plan of Correction requiring that all deficiencies (whether condition-level or standard-level) be corrected.

Arguments:

Petitioner contends that it was in compliance with deficiencies.

Ruling excerpts:

Petitioner has submitted no acceptable documentation to refute the evidence introduced by HCFA.

HCFA may impose principal sanctions where a laboratory fails to correct deficiencies within 12 months of the day of the inspection or where it fails to comply with an alternative sanction, such as a Directed Plan of
Correction.

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. The petitioner, not HCFA, bears the ultimate burden of persuasion. This case is governed by the burden of proof set forth in Hillman.

Other cases referenced:

Hillman Rehabilitation Center [DAB1663]

Thyroid Specialty Laboratory v. HCFA [CR501] Docket No. C-96-336

CLIA #: 26D0710182
State: Missouri
Type of Certificate: Compliance
ALJ/Decision Maker: Mimi Hwang Leahy

Basis for Sanction(s)

Petitioner's conducted unlawful referral of certain proficiency testing samples.

Arguments

Petitioner argues that:

- the testing personnel inadvertently referred the proficiency test samples under a random quality control procedure in place for patient samples;

- its laboratory director was not aware of the referrals until the surveyor brought the matter to his attention.

Ruling excerpts

A violation under 42 U.S.C. § 263a(i)(4) may be established on proof that a proficiency test sample has been referred for analysis by one laboratory to another laboratory, and the referring laboratory had knowledge that the sample it was referring was a proficiency test sample instead of a patient specimen.

Petitioner's evidence and arguments on good motives and lack of specific intent to violate 42 U.S.C. § 263a(i)(4) are not material.

Other cases referenced:

Primary Care Medical Group [CR439]
Long Medical Laboratory [CR334]

Eugene R. Pocock, M.D. v. HCFA [CR527] Docket No. C-97-024

CLIA #: 05D0575026
State: California
Type of Certificate: Accreditation
ALJ: Edward D. Steinman

Basis for Sanction(s):

Petitioner prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the revocation of the laboratory he directed.

Arguments:

Petitioner's asserts that:

- although he did assume the role of laboratory director for State purposes, he was never at any time the laboratory director for CLIA purposes;

- as the director, he was only responsible for the anatomical testing section of the laboratory;

- owner did not permit Petitioner to perform his duties as CLIA director.

Ruling excerpts:

Petitioner is an affected party and has a right to a hearing under 42 C.F.R. § 498.40, which flows from the sanctions imposed by HCFA against the laboratory.

The evidence establishes that Petitioner was the CLIA laboratory director.

CLIA regulations are clear that there can be only one laboratory director who is responsible for all operations, both clinical and anatomical, if such testing is conducted at the laboratory.

Petitioner fell within the definition of "operator" as that term is defined in 42 C.F.R. § 493.2. Congress by statute and HCFA through the CLIA regulations ensure the health and safety of recipients of laboratory testing by imposing obligations on the laboratory operator [director] to make sure that such testing meets all federal regulatory standards.

Congress imposed duties on the laboratory director by regulation. Failure to realize the regulatory ramifications of being designated as a laboratory director does not alter the legal obligations imposed.

HCFA's determination to prohibit Petitioner from owning or operating a laboratory for two years in accordance with 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), is affirmed.

Other cases referenced:

Hillman Rehabilitation Center [CR500] [DAB1663]

BAN Laboratories v. HCFA [CR576] Docket No. C-97-418

CLIA #: 45D0683772
State: Texas
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner was not complying with conditions of certification. The deficiencies were so severe as to pose immediate jeopardy

Arguments:

Petitioner argues that:

- the laboratory had corrected its deficiencies and wished to be resurveyed for compliance with CLIA conditions;

- it was denied due process by HCFA in that representatives of the State agency did not hold a proper and complete exit conference with Petitioner at the close of the survey;

- it was denied due process by HCFA in that it should have been resurveyed prior to the sanction imposition date, inasmuch as it had submitted allegedly credible allegations of compliance to HCFA.

Ruling excerpts:

There is no provision in the regulations governing laboratories which compels HCFA or its designee to conduct an exit conference with a laboratory at the completion of a survey.

Petitioner's submission to HCFA of allegations of compliance did not trigger a duty on HCFA's part to assure that Petitioner was resurveyed.

Under the applicable regulations, the presence of even one condition-level deficiency is sufficient to authorize HCFA to impose principal and alternative remedies.

Melvin C. Murphy, M.D., P.C. v. HCFA [CR590] Docket No. C-98-497

CLIA #: 23D0694149
State: Michigan
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s)

Petitioner referred proficiency testing samples or portions of samples to another laboratory for analysis, and failed in other respects to comply with CLIA requirements.

Arguments

Petitioner argues that:

- the proficiency tests were performed as required;

- the presence of proficiency testing results at another laboratory can be explained by the fact that the director served as laboratory director for both laboratories;

- under principles of State law governing agency, it may not be held liable for the unauthorized acts of the director;

- it may not be held responsible because there is nothing in the facts or the applicable law which would permit holding Petitioner (as opposed to the director) responsible for the intentional and unlawful acts of the director.

Ruling excerpts

Petitioner had a statutory duty to assure that proficiency tests were being performed onsite and not elsewhere.

Petitioner may not evade its responsibility to comply with the requirements of CLIA on the grounds that the Petitioner [owner] delegated responsibility to operate the laboratory to [the director] and assert that he was unaware of [the director] actions.

The issue of Petitioner's responsibility under CLIA is not resolved by principles of State agency law.

If the laboratory director fails to execute properly Petitioner’s [owner] obligation to comply with CLIA requirements then it is Petitioner's duty to assure that the requirements are met.

Eugene A. Shaneyfelt, M.D. v. HCFA [CR597] Docket No. C-98-351

CLIA #: 04D0468059
State: Arkansas
Type of Certificate: Waiver
ALJ: Andrew D. Steinman

Basis for Sanction(s):

Revocation of the certificate of waiver for Petitioner's office laboratory.

Arguments:

Petitioner argues that he should not be subject to the two-year ban on owning or operating a lab because he was not an "operator" of a laboratory that had its certificate revoked.

Ruling excerpts:

HCFA was authorized to revoke the CLIA certificate of waiver for Petitioner's in-office lab because Petitioner was an "operator" of a laboratory whose CLIA certificate was revoked.

Other cases referenced:

Eugene R. Pocock, M.D. [CR527]

Edison Medical Laboratories, Inc. v. HCFA [CR599] Docket No. C-99-095

CLIA #: 31D0857248
State: New Jersey
Type of Certificate: Accreditation
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner had been found to be deficient in meeting conditions under CLIA and the extent and nature of these deficiencies were such as to pose immediate jeopardy to Petitioner's clients.

Arguments:

Petitioner:

- concedes that there may have been minor problems in its operations, but asserts that these problems all were easily correctable and were, in fact, corrected by Petitioner;

- makes a general argument in opposition to HCFA's assertions of noncompliance with condition level CLIA requirements since it has been certified as a clinical laboratory by an accreditation organization.

Ruling excerpts:

The ALJ has no authority to consider whether a condition level deficiency poses immediate jeopardy.

The CLIA certification process is not subordinate to, nor does it defer to, whatever accreditation or certifications may be made by private organizations.

Other cases referenced:

Center Clinical Laboratory [DAB1526]
Center Clinical Laboratory [CR411]
Ward General Practice Clinic [DAB1624]
Hillman Rehabilitation Center [DAB1663]

Decision affirmed on appeal. See DAB1713 **and** 3rd Circuit Court of Appeals No. 00-3138**.**

Diagnostic and Educational Laboratory v. HCFA [CR600] Docket No. C-98-218

CLIA #: 03D0886075
State: Arizona
Type of Certificate: Compliance
ALJ: Edward D. Steinman

Basis for Sanction(s):

Petitioner failed to correct deficiencies at the standard level within 12 months of the initial survey.

Arguments:

Petitioner argues:

- HCFA should not have imposed the sanction of revocation against its CLIA certificate since HCFA accepted its Plan of Correction and, subsequently, issued a Certificate of Compliance;

- HCFA's decision to revoke the laboratory's certificate was arbitrary and capricious and that a lesser sanction would be appropriate;

- because 42 C.F.R. § 493.1816 gives a laboratory twelve months to correct deficiencies that are not at the Condition level, standard-level deficiencies "could never warrant a sanction as harsh and serious as suspension or revocation";

- HCFA wrongly based its decision to seek revocation in part upon "complaints" received by it, without giving Petitioner any notice and an opportunity to respond.

Ruling excerpts:

It was [Petitioner's] responsibility to correct the three standard-level deficiencies that were identified in the survey, and this responsibility did not end when HCFA issued the certificate of Compliance.

HCFA's decision to revoke, rather than limit or suspend, Petitioner's CLIA certificate, does not seem arbitrary or an abuse of discretion.

It is within HCFA's discretion to chose to revoke a laboratory's CLIA license when it has failed to correct its Standard-level deficiencies within twelve months after a survey.

HCFA had a lawful basis for its determination of the choice of remedy in accordance with 42 C.F.R. § 493.1816.

The ALJ ruled that documentation of compliance with the CLIA regulations after the survey and evidence of that compliance is not relevant.

Other cases referenced:

Hillman Rehabilitation Center [CR500] [DAB1663]

Allstate Medical Laboratory, Inc. v. HCFA Docket No. C-99-309

CLIA #: 05D0932859
State: California
Type of Certificate: Compliance
ALJ: Edward D. Steinman

Basis for Action(s):

Ruling denying HCFA's motion to dismiss Petitioner's hearing request.

Arguments:

HCFA argues that only the laboratory is a proper party to challenge the sanctions.

Petitioner argues that he is an "affected party" under 42 C.F.R. 498.2 and has a right to a hearing.

Ruling excerpts:

The ALJ finds that HCFA's assertion that only laboratories are the proper parties to request a hearing to challenge HCFA's sanction is without merit.

The ALJ concludes that a laboratory, its owner, and its operator, all have equal standing and all possess a right to be heard on sanctions imposed by HCFA against the laboratory.

Other cases referenced:

Eugene R. Pocock, M.D. [CR527]

US Bio-Chem Medical Laboratories v. HCFA [CR632] Docket No. C-99-601

CLIA #: 19D898093
State: Louisiana
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner refused to produce documents requested by inspectors during a complaint inspection of a laboratory with a certificate of waiver, resulting in non-compliance with the CLIA condition of inspection.

Arguments:

Petitioner argues it was justified in refusing to produce evidence by the surveyors' refusal to inform Petitioner of the source of the complaint which triggered the complaint investigation.

Ruling excerpts:

Petitioner's refusal to cooperate with the inspectors constituted a failure by Petitioner to comply with the condition which requires a laboratory to cooperate with inspectors and does not permit a laboratory to withhold information from inspectors under any circumstance. The duty to cooperate is unconditional.

Other cases referenced:

Hillman Rehabilitation Center [CR500] [DAB1663]

See also, US Bio-Chem Medical Laboratories [DAB1731] **(DAB affirmation)**

Carlos A. Cervera, M.D., Director, San Fernando Diagnostic Laboratory, Inc. v. HCFA

Docket No. C-99-797

CLIA #: 05D0959931
State: California
Type of Certificate: Compliance
ALJ: Marc R. Hillson

Basis for Action(s):

Ruling denying HCFA's motion to dismiss and granting extension of time for submission of readiness report.

Arguments:

HCFA contends Petitioner as laboratory director does not have the right to an appeal in a matter involving sanction taken by HCFA against Petitioner's laboratory.

Ruling excerpts:

The Petitioner is an "affected party" within the meaning of 42 C.F.R. 498.2 and that to cite Petitioner as laboratory director and prohibit him from owning or operating a laboratory for two years, while at the same time denying him the same right to a hearing that the laboratory has raises significant issues of fairness and due process.

Other cases referenced:

Allstate Medical Laboratory, Inc. [Docket No. C-99-309]

Edison Medical Laboratories, Inc. v. HCFA [DAB1713] Docket No. A-99-96

CLIA #: 31D0857248
State: New Jersey
Type of Certificate: Accreditation
DAB: Cecilia Sparks Ford, Donald F. Garrett, M. Terry Johnson

Basis for Sanction(s):
Appeal of ALJ decision in CR599.

Arguments:

Petitioner argues:

- it had not received a due process hearing because the ALJ wrongly concluded he could not reach the question of whether the deficiencies charged constituted immediate jeopardy;

- it had not received a due process hearing because the ALJ employed the wrong burden of proof;

- it had not received a due process hearing because neither HCFA nor the ALJ provided a neutral and objective review of the State inspection results;

- the findings of the inspectors were erroneous and unfair because the State agency was seeking to close down minority-owned laboratories.

Ruling excerpts:

The ALJ properly reviewed the underlying deficiencies and properly declined to review finding of whether the deficiencies constituted immediate jeopardy.

The ALJ correctly assigned the burden of proof.

The ALJ determined that the Petitioner's remaining due process claims are meritless.

Petitioner provided no support for its allegations of bias against it on the part of the [State agency] inspectors or the ALJ.

The DAB sustains the ALJ decision in its entirety and upholds the revocation.

Petitioner failed to demonstrate any prejudice from the extra time which it had after the close of the survey before [the State agency] determined that its deficiencies posed an immediate jeopardy and initiated enforcement action.

Other cases referenced:

Ward General Practice Clinic [DAB1624]
Hillman Rehabilitation Center [DAB1663]
Cross Creek Health Care Center [DAB1665]
Warren N. Barr Pavilion of Illinois Masonic Medical Center [DAB1705]
Richmond Community Action Program, Inc. [DAB1571].
Rural Day Care Ass'n of N.E. North Carolina [DAB1489]

See also, Edison Medical Lab, Inc v HCFA, Circuit Court Decision [No.00-3138] (affirmation)

Kaulson Laboratories, Inc. v. HCFA [CR642] Docket No. C-98-178

CLIA #: 31D0690640
State: New Jersey
Type of Certificate: Compliance
ALJ: Jill S. Clifton

Basis for Sanction(s):

Petitioner failed to comply with one or more laboratory conditions under CLIA.

Arguments:

Petitioner suggests errors are inevitable and should be acted upon if they appear deliberate or due to carelessness.

Ruling excerpts:

Petitioner errors (clerical and reporting) are not trivial and go to the integrity of the laboratory's testing process.

Other cases referenced:

Hillman Rehabilitation Center [DAB1663] [CR500].

See also, Garden City Medical Laboratory v. HCFA [DAB1747] (DAB affirmation)

Southfield Medical Clinic vs. HCFA [CR667] Docket No. C-00-071

CLIA#: 23D0365332
State: Michigan
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner had failed to comply with the condition governing proficiency testing stated in 42 C.F.R. § 493.803.

Arguments:

Petitioner argues:

- there was no intentional referral of [proficiency test] samples to another laboratory for analysis, no improper referral within the meaning of the Statute, no improper collaboration within the meaning of the Statute and no other deficient test practices regarding [proficiency test] samples;

- the statute, regulations and case law do not support a finding that a laboratory technician acting alone can create the intent element of the statute;

- it should not be held legally responsible for the unauthorized acts of its employee.

Ruling excerpts:

The undisputed material facts establish that Petitioner failed to comply with the requirements of the condition that is stated in 42 C.F.R. § 493.803.

Under CLIA, a laboratory is liable for the acts of its employees whether or not those acts are authorized or even known about by the laboratory's management.

Other cases referenced:

Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1663]
Family Home Health Services [CR615 aff'd, DAB1716].
Blanding Urgent Care Center Laboratory [CR438]
Melvin C. Murphy, M.D., P.C. [CR590]

US Bio-Chem Medical Laboratories v. HCFA [DAB 1731] Docket No. A-2000-37

CLIA #: 19D898093
State: Louisiana
Type of Certificate: Compliance
DAB: Donald F. Garrett, Marc R. Hillson, Judith A. Ballard

Basis for Sanction(s):

Appeal of ALJ decision in CR632.

Arguments:

Petitioner:

- challenged HCFA's authority to act against Petitioner, asserting that Petitioner has never participated in the Medicare program.

- argued its right under the United States Constitution to know who complained against it.

Ruling excerpts:

While HCFA has jurisdiction over the Medicare program, it has numerous other responsibilities, including the implementation of CLIA. The CLIA regulations at Part 493 clearly apply to a broader set of laboratories than those participating in Medicare.

The right to inspect is unconditional.

Sentinel Medical Laboratories, Inc. v. HCFA [CR679] Docket No. C-98-277

CLIA #: 05D0910312
State: California
Type of Certificate: Compliance
ALJ: Edward D. Steinman

Basis for Sanction(s):

Petitioner prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the revocation of the laboratory he directed.

Arguments:

Petitioner argues:

- as a mere employee, it would have been impossible to carry out the duties of a laboratory director and any attempt to enforce [CLIA] regulations would violate his constitutional right to due process;

- the regulations are invalid because they do not apply equally to laboratory directors and other laboratory employees;

- the regulations are void for vagueness, because they do not specify how an employee-laboratory director is to gain the cooperation of a laboratory's owners if the director uncovers improper or fraudulent practices;

- if a laboratory director discovers wrongdoing at his or her laboratory and is unable to correct it, he or she could not be required to report the wrongdoing to HCFA or the State agency, because to do so would violate the laboratory director's constitutional right against self-incrimination;

- [the ALJ] should reject the extensive findings of deficiencies by the state surveyors because, the surveyors failed to follow the appropriate survey procedures;

- the sanction HCFA proposes to enforce against him, namely the two-year ban on owning or operating a CLIA laboratory, should be stayed pending his exhaustion of his administrative remedies, and throughout the period of judicial review.

Ruling excerpts:

The Petitioner's status as an employee-laboratory director, as opposed to an owner-laboratory director, is irrelevant to determining what the CLIA statute and regulations require of him, therefore, Petitioner's constitutional arguments are without merit

The Fifth Amendment right against self-incrimination is inapplicable.

The laboratory director, not other employees, is responsible for the overall operation of the laboratory.

Cessation of the laboratory's operations while subject to a CLIA survey, or after receipt of the survey findings in the [survey report], does not excuse the laboratory operators or owners from the two-year sanction against owning or operating a CLIA laboratory once a CLIA certificate is revoked.

To permit a non-complying laboratory to continue to operate until all appeals were exhausted would be dangerous to the health and safety of the individuals served by the laboratory.

There is no provision in the regulations governing laboratories which compels HCFA or its designee to conduct an exit conference with a laboratory at the completion of a survey of that laboratory.

The laboratory director has standing to request a hearing independent of the laboratory.

Other cases referenced:

Eugene R. Pocock, M.D. [CR527]
Helvering v. Mitchell [303 U.S. 391, 402]
BAN Laboratories [CR576]
Hillman Rehabilitation Center [CR500] [DAB1663]
Indiana Department of Public Welfare [DAB781].
Golden State Manor Rehabilitation Center [DAB1597]
California Medical Associates Laboratory [CR476]

See also, Sentinel Medical Laboratories, Inc. v. HCFA [DAB1762] **(DAB affirmation)**

Oakland Medical Group, P.C. v. HCFA [CR688] Docket No. C-99-731

CLIA #: 23D0365805
State: Michigan
Type of Certificate: Accreditation
ALJ: Jose A. Anglada

Basis for Sanction(s):

Petitioner performed improper referral of PT samples to another laboratory for analysis and failed to treat PT samples in the same manner as patient samples.

Arguments:

Petitioner argues:

- laboratory technician performing PT was not an employee;

- sanctions imposed and proposed are not appropriate according to the enforcement procedures section of CLIA regulations, and a plan of correction is the most appropriate sanction given the severity of the alleged standard deficiency;

- the declarations of [AAB representative and state agency representative] do not support HCFA's allegations;

- an intentional referral of PT samples has not been shown by HCFA;

- results received by the AAB represent small standard deviations, there is a high probability that multiple laboratories produced the same figures and that occasional human error in rounding a few numbers does not warrant revocation of a laboratory's CLIA certificate;

- the [accrediting organization], as HCFA's agent, reported no deficiencies.

Ruling excerpts:

Whether testing personnel are an independent contractor or not is irrelevant, inasmuch as Petitioner is responsible for the actions of all individuals it authorizes to perform testing at its facility on its behalf.

The revocation of Petitioner's CLIA certificate for a period of one year is not unreasonable in light of the failure to satisfy the condition level requirements.

The declarations of [AAB representative and state agency representative] constitute appropriate evidence in support of HCFA's allegations.

Petitioner intentionally referred proficiency tests to another laboratory and/or engaged in inter-laboratory communications (collaboration) and then reported the results obtained as Petitioner's own results.

Petitioner did not arrive at PT results identical to that of eight other laboratories through human error or coincidence, but by intentional referral, collaboration, and manipulation of those results.

The absence of reported deficiencies by [an accrediting organization] does not bar HCFA from finding Petitioner out of compliance with CLIA requirements.

Other cases referenced:

Long Laboratory v. HCFA [CR344]
Blanding Urgent Care Center v. HCFA [CR438]
Southfield Medical Clinic v. HCFA [CR667]
Falls Riverway Realty, Inc. v. Niagara Falls [754 F.2d 49(2d. Cir. 1985)]
Anderson v. Liberty Lobby, Inc. [477 U.S. 242, 248, 249 (1986)]
Pollock v. American Tel. & Tel. Long Lines [794 F.2d. 860, 864, (3rd Cir., 1986)]
Stanley Boykansky, M.D. v. HCFA [CR690]

See also, Oakland Medical Group, P.C. v HCFA [DAB1755] **(DAB affirmation)**

Stanley Boykansky, M.D. v. HCFA [CR690] Docket No. C-99-715

CLIA #: 23D0372207
State: Michigan
Type of Certificate: Accreditation
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner referred proficiency test samples to another laboratory for testing or had collaborated with another laboratory.

Arguments:

Petitioner asserts:

- HCFA failed to give it adequate notice of the basis for its determination to impose remedies;

- HCFA lacks the authority to make findings which differ from those which its agents make in conducting CLIA compliance surveys;

- some deficiencies may have existed in its operation, but it filed a plan of correction which addressed these deficiencies;

- HCFA lacks authority to impose principal sanctions against it inasmuch as there exists no outstanding failures by Petitioner to comply with CLIA participation requirements.

Ruling excerpts:

HCFA did not fail to give Petitioner adequate notice of its determinations.

The regulations which establish enforcement procedures under CLIA vest in HCFA the authority to determine independently whether noncompliance exists and the extent of that noncompliance. HCFA is free to accept or reject a State survey agency's and to modify them as it determines to be appropriate.

HCFA is under no obligation to accept a plan of correction from a laboratory where that laboratory has failed to comply with CLIA conditions of participation.

[The ALJ] disagrees with the *Blanding* decision to the extent that it supports the proposition that 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. (Ruling reversed by DAB1756.)

Petitioner and the other eight laboratories colluded to produce nearly identical proficiency testing results.

Other cases referenced:

Blanding Urgent Care Center Laboratory [CR438]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1663]
Southfield Medical Clinic [CR667]

See also, Stanley Boykansky, M.D. v HCFA [DAB1756] (DAB affirmation)

Garden City Medical Laboratory v. HCFA [CR698] Docket No. C-99-831

CLIA #: 23D0367601
State: Michigan
Type of Certificate: Accreditation
ALJ: Jose A. Anglada

Basis for Sanction(s):

Petitioner deficient in meeting conditions under CLIA because of the improper referral of laboratory and PT samples to another laboratory.

Arguments:

Petitioner argues:

- there was no intentional referral of proficiency testing samples;

- the laboratory acted in good faith by terminating the employee who created the problem;

- the Government has not shown that the proficiency testing was not performed in the ordinary course of business;

- the statistical analysis offered by HCFA is not statistically significant.

Ruling excerpts:

Although there is no evidence of referral of PT samples, based on the scores reported to [the proficiency testing agency] the unequivocal conclusion is that Petitioner engaged in collaboration.

The defense of correcting the deficient practice by terminating an employee is unacceptable.

Petitioner failed to examine PT samples with its regular patient workload using the laboratory's routine methods.

Given the imprecision on manual testing methodology and the range of acceptable results, the chances of nine laboratories independently arriving at the same values by happenstance for all five specimens for even two different tests are close to nil.

Petitioner failed to comply with more than one laboratory condition under CLIA.

Other cases referenced:

Anderson v. Liberty Lobby, Inc. [477 U.S. 242, 248, 249]
Pollock v. American Telephone & Telegraph Long Lines
Melvin C. Murphy, M.D., P.C. [CR590]
Southfield Medical Clinic [CR667]

See also, Garden City Medical Laboratories [DAB1763] **(DAB affirmation)**

Kaulson Laboratories, Inc. v. HCFA [DAB1747] Docket No. A-2000-55

CLIA #: 31D0690640
State: New Jersey
Type of Certificate: Compliance
DAB: Judith A. Ballard, Cecilia Sparks Ford, Donald F. Garrett

Basis for Sanction(s):

Appeal of ALJ decision in CR642.

Arguments:

Petitioner:

- challenged the ALJ's findings on the CLIA conditions and argued that it had not been properly informed of the issues addressed by the ALJ, and was not afforded an opportunity to brief and to present evidence on those issues;

- argued it had agreed to forego presenting testimony at an in-person hearing based on the issue as identified in a prehearing conference;

-argued it was never clearly informed that issues beyond the issue identified in the prehearing conference and the ALJ's order confirming the prehearing conference would be considered by the ALJ.

Ruling excerpts:

HCFA and the ALJ resulted in substantial prejudice to Petitioner, which waived its right to an in-person hearing and submitted its briefs and documentary evidence without adequate notice that issues beyond those stated by HCFA in the prehearing conference would be considered by the ALJ.

The Board has the authority to modify, reverse or remand the ALJ Decision when there has been a prejudicial error of procedure. Here, we remand the case to the ALJ for further proceedings.

Other cases referenced:

Ward General Practice Clinic [DAB1624]
US Bio-Chem Medical Laboratories, Inc. [DAB1731]

Oakland Medical Group, P.C. v. HCFA [DAB1755] Docket No. A-2000-107

CLIA #: 23D0365805
State: Michigan
Type of Certificate: Accreditation
DAB: Judith A. Ballard, Donald F. Garrett, M. Terry Johnson

Basis for Sanction(s)

Appeal of ALJ decision in CR688.

Arguments

Petitioner took exception to 15 of the ALJ's 23 FFCLs [Findings of Fact and Conclusions of Law].

Ruling excerpts

DAB concluded that the challenged FFCLs are n

ot erroneous and are supported by substantial evidence on the record as a whole.

Limiting the concept of a referral to a physical transfer is inconsistent with the underlying purposes of the condition for certification.

The DAB rejected Petitioner's general contention that HCFA's citation to Petitioner's deficiencies in meeting standards rather than overall conditions limited HCFA to alternative sanctions.

The ALJ clearly did not err in rejecting Petitioner's contention that HCFA could not find noncompliance with CLIA requirements because Petitioner had passed a routine [accrediting organization] survey.

It is indisputable that a laboratory can be so pervasively noncompliant with standards as to have failed to comply with the overall condition.

Stanley Boykansky, M.D. v. HCFA [DAB1756] Docket No. A-2000-108

CLIA #: 23D0372207
State: Michigan
Type of Certificate: Accreditation
DAB: Judith A. Ballard, Donald F. Garrett, M. Terry Johnson

Basis for Sanction(s):

Appeal of ALJ decision in CR690.

Arguments:

On appeal to the Board, Petitioner excepted to all seven of the ALJ's findings of fact and conclusions of law (FFCLs).

Ruling excerpts:

The DAB disagrees with the ALJ that the regulation at section 493.801(b)(4) prohibiting intentional referral of PT samples is limited to cases where physical transfer is established.

The DAB reviewed Petitioner's exceptions and concluded that the ALJ Decision should be affirmed.

Other cases referenced:

Stanley Boykansky, M.D. [CR690]
US Bio-Chem Medical Laboratories, Inc. [DAB1731]
Ward General Practice Clinic [DAB1624]
Southfield Medical Clinic [CR667]
Blanding Urgent Care Center Laboratory [CR438]
Edison Medical Laboratories, Inc. [DAB1713]
Oakland Medical Group, P.C. [DAB1755]

Physicians Independent Laboratory, Inc. v. Donna Shalala, Secretary U.S. DHHS, [et.al.]
CV 00-12209 SVW (CWx) [01/24/2001]

CLIA #: 05D0642499
State: California
Type of Certificate: Compliance
Ruling by: Stephen V. Wilson, United States District Judge

Basis for Action(s):

Plaintiffs' motion for preliminary injunctive relief.

Arguments:

Plaintiffs made the motion for the District Court to issue a mandatory injunction to retroactively restore Plaintiffs' CLIA certification and reinstatement of its medicare reimbursements until such time as Plaintiffs receive a hearing before an ALJ.

Ruling excerpts:

Plaintiffs' claim that it is suffering irreparable harm is placed into question by the actions of the Plaintiffs to delay their ALJ hearing.

Plaintiffs' motion is denied.

See also, Physicians Independent Laboratory, Inc. v Donna Shalala, Secretary U.S. DHHS, [et. al]
[CV-00-12209 5/10/2001]

Sentinel Medical Laboratories, Inc. v. HCFA [DAB1762] Docket No. A-2000-92

CLIA #: 05D0910312
State: California
Type of Certificate: Compliance
DAB: Judith A. Ballard, M. Terry Johnson, Marc R. Hillson

Basis for Sanction(s):

Appeal of ALJ decision in CR679.

Arguments:

Petitioner argued the constitutionality of the CLIA provisions, and that the effectiveness of the two-year ban on his owning or operating another laboratory should be stayed until his appeal has been heard in federal court.

Ruling excerpts:

Petitioner was required to exhaust his administrative remedies. The ALJ is not required to terminate proceedings so that Petitioner could take his appeal to federal court for review of his constitutional arguments.

The DAB is not empowered to declare the CLIA statute or regulations unconstitutional.

The Fifth Amendment right against self-incrimination is inapplicable.

The DAB affirms and adopts each of the ALJ's findings of fact and conclusions of law.

Other cases referenced:

US Bio-Chem Medical Laboratories, Inc. [DAB1731]
Sentinel Medical Laboratories, Inc. [CR679]
U.S. v. Nixon
Gibas v. Saginaw Mining Co.
Howard v. FAA
Stieberger v. Heckler
Gilbert v. National Transportation Safety Board
Parisi v. Davidson
Sol Teitelbaum, M.D. v. U.S. Dept. of Health and Human Services
Garfield v. U.S. ex. rel. Goldsby
Burger Chef Systems, Inc. v. Govro
Price v. Westmoreland
United States v. A & P Trucking Co.

Garden City Medical Laboratory v. HCFA [DAB1763] Docket No. A-2000-14

CLIA #: 23D0367601
State: Michigan
Type of Certificate: Accreditation
DAB: Judith A. Ballard, Donald F. Garrett, M. Terry Johnson

Basis for Sanction(s):

Appeal of ALJ decision in CR698.

Arguments:

Petitioner filed seven general exceptions to the ALJ decision, including an argument that summary judgment was inappropriate.

Ruling excerpts:

The DAB reverses the ALJ decision and remands this case to the ALJ for further proceedings. Given the heavy reliance placed by the ALJ on the testimony of HCFA's affiants, the ALJ should address Petitioner's request for an opportunity to cross-examine those witnesses.

Further disposition:

Petitioner withdrew appeal.

Other cases referenced:

Garden City Medical Clinic [CR698]
Ward General Practice Clinic [DAB1624]
US Bio-Chem Medical Laboratories, Inc. [DAB1731]
Everett Rehabilitation and Medical Center [DAB1628]
Richardson v. Perales

Edison Medical Lab, Inc. v. HCFA [No. 00-3138]

CLIA #: 31D0857248
State: New Jersey
Type of Certificate: Accreditation
Before: Nygaard, Alito, and Rendell, Circuit Judges, 3rd Circuit

Basis for Sanction(s):

Appeal of DAB App. Div. No. A-99-96 [CR599] [DAB1713]

Arguments:

Petitioner appealed decision of DAB affirming revocation.

Ruling excerpts:

The Circuit Judges affirm the action of the Department of Health and Human Services in revoking Petitioner's certificate of accreditation.

Union City Diagnostic Laboratory v. HCFA [CR749] Docket No. C-99-831

CLIA #: 31D0894808
State: New Jersey
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioner failed to comply with one or more CLIA conditions and caused immediate jeopardy to its patients.

Arguments:

Petitioner:

- contested HCFA's findings and remedy determinations;

- asserted that it had quality control policies and manuals which the surveyors had failed to obtain or review.

Ruling excerpts:

HCFA is authorized to impose principal remedies against a laboratory where that laboratory fails to comply with one or more CLIA conditions.

[The ALJ] reiterates that the issue is not whether Petitioner had quality control policies, but whether it implemented them.

Other cases referenced:

Hillman Rehabilitation Center [DAB1663]

Physicians Independent Laboratory, Inc. v. Donna Shalala, Secretary U.S. DHHS, [et.al.]

CV 00-12209 SVW (CWx) [5/10/2001]

CLIA #: 05D0642499
State: California
Type of Certificate: Compliance
Ruling by: Stephen V. Wilson, United States District Judge

Basis for Action(s):

Defendants' motion to dismiss

Arguments:

Plaintiffs seek money damage against Federal employees acting in their official capacities.Defendants bring a motion to dismiss all causes of action arguing that the District Court is without jurisdiction to grant the relief sought by the Plaintiffs, that a Bivens action is not available to Plaintiffs, and that Plaintiffs must exhaust administrative remedies.

Ruling excerpts:

Defendants argue that because Plaintiffs have declined to participate in any ALJ hearing and seek monetary rather than preliminary injunctive relief pending an ALJ hearing, that the District Court no longer has jurisdiction over this matter. Defendants are correct.

Defendant motion to dismiss is granted.

See also, Physicians Independent Laboratory, Inc. v. Donna Shalala, DHHS [et.al.]
[CV00-12209 1/24/2001]

American Women's Center v. HCFA [CR773] Docket No. C-99-830

CLIA #: 31D0914104, 31D0914105, 31D0914106
State: New Jersey
Type of Certificate: Compliance
ALJ: Jose A. Anglada

Basis for Sanction(s):

Petitioner has three facilities, each with its own CLIA number, which were revoked due to failure to enroll in proficiency testing. The Petitioner continued to perform testing at each location. HCFA sent them a notice that they must cease and desist laboratory testing. Petitioner filed a request for hearing in response to the notices to cease and desist.

Arguments:

Petitioner asserts that:

- HCFA has failed to produce evidence to show that [two] facilities received the notices of suspension and revocation;

- the third facility received the notice of suspension, but alleges that HCFA ignored the facility response.

Ruling excerpts:

There is no legal requirement that HCFA show that the laboratory actually received the sanction letter.

The only specific requirement of the regulation as to the notice is that it be in writing.

The ALJ concludes that Petitioner's hearing request as to [two] facilities was untimely filed and good cause does not exist to extend the time for filing.

The ALJ denied HCFA's motion to dismiss the hearing request as to the [third] facility and remanded it to HCFA for further proceedings.

Other cases referenced:

Julio M. Soto, M.D. [CR418]
Ronald J. Crisp**,** M.D. [CR724]

Evette Elsenety, M.D., Et. Al. v. HCFA [CR779] Docket No. C-01-218 through C-01-233

CLIA #: 23D0365805
State: Michigan
Type of Certificate: Accreditation
ALJ: Steven T. Kessel

Basis for Sanction(s):

CLIA prohibits an entity whose CLIA certificate has been revoked from owning or operating another laboratory during the two-year period from the date of revocation.

Arguments:

The 16 Petitioners assert that to revoke their CLIA certificates would frustrate the intent of legislation, which requires that they be organized as part of a group practice.

Petitioners argue that their CLIA certificates not be revoked, inasmuch as they had nothing to do with the activities that resulted in the revocation of a certificate of a laboratory owned by the group.

Petitioners opposed HCFA's motion for summary disposition.

Ruling excerpts:

The ALJ considered the question of whether the group owned laboratory is a "person" within the meaning of CLIA.

Nothing in CLIA suggests that Congress intended the word "person" to mean only individuals and not corporations or companies.

Petitioners' certificates must be revoked as a matter of law based on the undisputed material facts.

There are no disputed issues of material fact in these cases. Consequently, summary dispositions are appropriate here.

Other cases referenced:

Oakland Medical Group, P.C. [CR688]

United States of America v. Edison Medical Laboratory Service Corporation

[Civil Action No. 01-2872 (KSH)]

CLIA #: 31D0857248
State: New Jersey
Type of Certificate: Accreditation
Ruling by: Katherine S. Hayden, United States District Judge

Basis for Action(s):

Order to show cause and temporary restraining order.

Arguments:

Plaintiff seeks to restrain defendants from operating a clinical laboratory, or soliciting or accepting materials derived from the human body for laboratory examination or other procedure without certification pursuant to the requirements of CLIA.

Ruling excerpts:

Plaintiff's application for an Order to Show Cause and a Temporary Restraining Order is granted.

Further Disposition:

Consent Decree filed July 6, 2001.

Preferred Family Medicine, P.C. v. Tommy G. Thompson, Secretary HHS, and Thomas Scully, Administrator CMS [Case No. 01-72447] [7/31/2001]

CLIA #: 23D0364632
State: Michigan
Type of Certificate: Accreditation
Ruling by: Victoria A. Roberts, United States District Judge

Basis for Action(s):

Plaintiffs' motion for preliminary injunctive relief.

Accreditation organization notified Plaintiff in September 1999 of pending denial of accreditation due to "complicity in proficiency test averaging." In October 1999, the Plaintiff was denied accreditation. The accreditation organization held a hearing in February 2000 and voted to reverse its initial decision to deny accreditation. More than a year after the accreditation organization reversed its denial decision, a complaint investigation survey was conducted by the State agency. CMS took action to revoke the Plaintiff's Certificate of Accreditation after finding Plaintiff not in compliance with CLIA as a result of "improper referral, collaboration, and non-integration" which occurred in testing events in 1998 and 1999.

Arguments:

Plaintiff:

- contends that canceling approval to receive Medicare payments for their laboratory services and revocation of their CLIA Certificate of Accreditation would effectively force the closure of Plaintiff's laboratory and cause irreparable harm to Plaintiffs and numerous Medicare and other patients;

- acknowledges that revocation will not take effect until a decision is rendered by the ALJ, however the effective date of the cancellation of the approval to receive Medicare payment for its laboratory services was prior to any opportunity for an ALJ decision;

- seeks declaratory relief and relief in the form of a writ of mandamus.

Ruling excerpts:

The District Court agreed with CMS that under CLIA, the actions of the laboratory's accreditation organization did not bind CMS in the performance of its CLIA enforcement responsibilities.

Accreditation organizations are obligated to provide HCFA with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited or revoked within 30 days of the action taken.

Plaintiff's Motion for Injunctive Relief is denied, Plaintiff's request for declaratory judgment and mandamus is denied; and Defendants' Motion to Dismiss is granted.

See also, Preferred Family Medicine, P.C. [et. al.] v. Tommy G. Thompson, DHHS [et. al.]
[8/28/2001]

Mark Gary Hertzberg, M.D., P.C. v. CMS [CR805] Docket No. C-99-763

CLIA #: 23D0671668
State: Michigan
Type of Certificate: Accreditation
ALJ: Alfonso J. Montano

Basis for Sanction(s):

Petitioner had intentionally referred its proficiency testing samples to another laboratory for analysis.

Arguments:

Petitioner argues that:

- CMS did not give it proper notice of condition-level deficiencies, and is therefore without authority to impose principal sanctions against Petitioner;

- the surveyors found no condition level deficiencies, and condition level deficiencies cannot simply be created by CMS as a result of the standard level violations alleged.

- CMS cannot impose principal sanctions pursuant to a finding of only standard-level deficiencies;

- the second notice from CMS cited a condition-level deficiency but argues that the second notice is deficient because it was received after the sanctions were imposed and provided no opportunity to respond or appeal previously undisclosed deficiencies;

- results received by [the proficiency testing organization] represent small standard deviations and thus a high probability that multiple laboratories produced the same figures.

Ruling excerpts:

CLIA requirements do not prohibit CMS from amending or superseding a notice of an initial determination.

Appellate panels of the Departmental Appeals Board have repeatedly ruled that a laboratory can be so pervasively noncompliant with standards as to have failed to have complied with the overall condition, therefore, the violation of a standard may constitute violation of a condition.

CMS is authorized to make independent determinations about the nature and severity of a laboratory's noncompliance with CLIA requirements

The ALJ rejected Petitioner's argument that section 493.801(b)(4) is limited to cases where physical transfer of the testing sample is established.

The ALJ concluded that the Petitioner engaged in collusion with other laboratories in testing proficiency testing samples. Petitioner has offered no persuasive arguments or evidence which rebut CMS's showing of collusion.

Other cases referenced:

Stanley Boykansky, M.D. [CR690] [DAB1756]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1663]

Blanding Urgent Care Center Laboratory [CR438]
Oakland Medical Group [DAB1755]

Preferred Family Medicine, P.C. v. Tommy G. Thompson, Secretary HHS, and Thomas Scully, Administrator CMS [Case No. 01-72447] [8/28/2001]

CLIA #: 23D0364632
State: Michigan
Type of Certificate: Accreditation
Ruling by: Victoria A. Roberts, United States District Judge

Basis for Action(s):

Supplemental Opinion & Order Denying Plaintiffs' Motion for Injunctive Relief and Request for Declaratory Judgment and Mandamus, and Granting Defendants' Motion to Dismiss

(To clarify whether the factual circumstances of this case come within the exception to the general rule that district courts do not have original subject matter jurisdiction over claims arising under the Medicare Act.)

Arguments:

Plaintiff argues that the District Court has subject matter jurisdiction of this matter, even though Plaintiff has not exhausted administrative remedies prior to judicial review as required by 42 U.S.C. 405(h).

Defendants respond that the District Court does not have subject matter jurisdiction to hear this matter, thereby requiring the dismissal of Plaintiff's claim without reaching the merits.

Ruling excerpts:

The District Court found that this matter did not fall within the exception, thus precluding it from having subject matter jurisdiction rule upon the issues presented by Plaintiff.

See also, Preferred Family Medicine, P.C. [et. al.] v. Tommy G. Thompson, DHHS [et. al.] [7/31/2001]

RNA Laboratories, Inc. and Ter-Zakarian Medical Clinic v. HCFA [CR829] Docket No. C-01-336 and C-01-337

CLIA #: 05D0879683
State: California
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Petitioners failed to test proficiency testing samples in the same manner as patients' specimens.

Arguments:

Petitioners argue:

- [one of the labs] tested proficiency testing samples in the same manner as it tested patients' specimens because it used the same equipment and testing techniques for both types of tests;

- CMS did not establish an unlawful referral of proficiency testing samples from one Petitioner to the other;

- with respect to the laboratory director condition, that it was the fault of the owner and not the laboratory director if Petitioner failed to produce proficiency testing documentation.

Ruling excerpts:

It is not necessary to establish a statistical probability of two laboratories producing identical results in any given test in order to find that it is highly unlikely that they would produce those identical results independently.

The regulation requires a laboratory to produce all of its records and to document each step in the testing and reporting of proficiency testing results.

The issue is whether Petitioner invalidated proficiency testing by testing proficiency testing samples more times than it tested patients' specimens. It is not whether Petitioner used different types of equipment or techniques to perform proficiency tests than it used to test patients' specimens.

The improper exchange of information between Petitioners would be an unlawful referral of proficiency testing samples.

The failures by Petitioners to comply with the proficiency testing condition also are failures to comply with the laboratory director condition.

A laboratory owner or director has a right to a hearing to challenge revocation of a laboratory's CLIA certificate.

Other cases referenced:

Stanley Boykansky, M.D. [CR690] [DAB1756]
Oakland Medical Group [DAB1755]
Carlos A. Cervera, M.D. [Docket No. C-99-797 Ruling Denying HCFA's Motion to Dismiss]
Allstate Medical Laboratory, Inc. [Docket No. C-99-309]
Sentinel Medical Laboratories, Inc. [DAB1762]

Evette Elsenety, M.D., et. al. v. HCFA [DAB1796] Docket No. A-2001-103

CLIA#: 23D0365805
State: Michigan
Type of Certificate: Accreditation

ALJ: Judith A. Ballard, Donald F. Garrett, M. Terry Johnson

Basis for Sanction(s):

Appeal of ALJ decision in CR779

[On November 7, 2000, HCFA advised each Petitioner that Oakland Medical Group's CLIA certificate had been revoked and that, since Oakland owned or operated each Petitioner, HCFA was also required to revoke each Petitioner's CLIA certificate. Each Petitioner requested a hearing before an ALJ and their appeals were consolidated into a single proceeding.]

Arguments:

Petitioners argue that:

- ALJ erred when he relied on HCFA Exhibit 3 as a basis for his finding. Oakland provided letter demonstrating ownership of 16 Petitioners.

- ALJ erred by expanding the plain meaning of the word "person" in 42 U.S.C. 263a(I)(3) to include corporations and companies.

Ruling Excerpts:

Summary disposition is appropriate where there are no disputed issues of material fact.

The general rules of construction applied to the United States Code are that, unless otherwise indicated, the word "person" includes company or corporation.

If "person" referred only to an individual, a group with a revoked certificate, such as Oakland here, could simply restart its operation in another laboratory.

The Board affirms and adopts each of the FFCL's underlying the ALJ Decision and sustain that decision in its entirety.

Other cases referenced:

Oakland Medical Group [CR688] [DAB1755]
US Bio-Chem Medical Laboratories [DAB1731]

Edward Ming-Che Lai, M.D. v. CMS [CR848] Docket No. C-01-288

CLIA #: 05D0956182
State: California
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Prohibition on lab director owning/operating another lab for 2 years as a result of the certificate revocation of Polymedic Clinical Laboratory, Inc.

Arguments:

Petitioner alleges:

- he was not serving as laboratory director of Polymedic Clinical Laboratory, Inc. in May 2000 when Polymedic failed to comply with a condition for certification under CLIA;

- his verbal agreement to be the laboratory's director was never finalized in writing and his directorship was never established officially;

- he had not entered into a final agreement to direct Polymedic, had not received any payment from Polymedic, and had not had any follow-up communications with the laboratory's owner until December 1999, when the owner told him the laboratory would not continue operation.

CMS argues that:

- Petitioner is not entitled to a hearing in that regulations which confer hearing rights in cases involving CLIA enforcement actions give those rights to laboratories and not to individuals.

- Petitioner served as lab director of Polymedic Clinical Laboratory, a laboratory whose certification was revoked, and is precluded from owning or operating another laboratory for two years from the date of revocation.

Ruling excerpts:

Petitioner acted as Polymedic's director when he executed a CLIA certificate application on Polymedic's behalf in September 1999.

For at least a very brief period of time, Petitioner acted in the capacity of Polymedic's laboratory director, however, that relationship ceased definitively with petitioner's December 1999 telephone conversation with Polymedic's owner.

A failure by Petitioner to apprize the State agency that he was not serving as Polymedic's laboratory director did not mean, as a matter of law, that Petitioner continued to serve as the laboratory director and retained the legal responsibilities of a director.

An individual may be deemed to be a laboratory's director under two circumstances. First, the individual may be a laboratory's director if he or she is performing the duties of the laboratory director. Second, the individual may be a laboratory's director if that individual has agreed to perform the duties of the laboratory director whether or not he or she is actually performing them.

CMS is without authority to impose sanctions against Petitioner.

Other cases referenced:

Carlos A. Cervera, M.D. [Docket No. C-99-797 Ruling Denying HCFA's Motion to Dismiss]
Allstate Medical Laboratory, Inc. [Docket No. C-99-309]
Sentinel Medical Laboratories, Inc. [DAB1762]
Eugene R. Pocock, M.D. [CR527]
RNA Laboratories, Inc., and Ter-Zaharian Medical Clinic [CR829]

Premium Diagnostic Laboratory v. CMS [DAB1790] Docket No. A-01-112

CLIA #: 05D0962262
State: California
Type of Certificate: Compliance
For the DAB: Judith A. Ballard, M. Terry Johnson, Donald F. Garrett

Basis for Sanction(s):

Appeal of ALJ dismissal in CR808. (The ALJ dismissed Petitioner's request for hearing, finding that after CMS' rescission of its sanctions there was no initial determination from which Petitioner could make an appeal.)

Arguments:

Petitioner alleges that:

- it was entitled to a review by the ALJ of what it labeled an abuse of discretion by CMS in imposing sanctions against Petitioner;

- ALJ's dismissal was "erroneous" and "not fair" to Petitioner because it deprived Petitioner of the opportunity to receive damages;

- CMS had damaged Petitioner's reputation and violated its civil rights, as well as caused it to suffer financial hardship due to the loss of business revenue and costs incurred in contesting CMS' actions.

Ruling excerpts:

Petitioner has not provided any legal basis for challenging the ALJ's decision to dismiss its hearing request.

The ALJ correctly determined that, with the withdrawal by CMS of the sanctions imposed on Petitioner, there was no longer any appealable determination before him.

Even if the ALJ found in Petitioner's favor on the merits, he could not grant any greater relief than was already given through the rescission. Petitioner received all the relief that the ALJ had the authority to provide.

Other cases referenced:

Lake Cook Terrace Nursing Center [DAB1745]
Lakewood Plaza Nursing Center [DAB1767]
Schowalter Villa [DAB1688]

Mark Gary Hertzberg, M.D., P.C. v. CMS [DAB1805] Docket No. A-2001-119

CLIA#: 23D0671668
State: Michigan
Type of Certificate: Accreditation
For the DAB: Judith A. Ballard, M. Terry Johnson, Donald F. Garrett

Basis for Sanction(s):

Appeal of ALJ decision in CR805.

Arguments:

Petitioner excepted to each of the ALJ's six findings of fact and conclusions of law (FFCL).

Ruling Excerpts:

The challenged FFCLs are not erroneous and are supported by substantial evidence on the record as a whole.

CMS is not limited to alternative sanctions where a laboratory's actions constitute an egregious violation of its PT responsibilities.

Other cases referenced:

Ward General Practice Clinic [DAB1624]
Edison Medical Laboratories [DAB1713]
Hillman Rehabilitation Center [DAB1663]
Oakland Medical Group, P.C. [DAB1755]
Stanley Boykansky, M.D. [DAB1756]
Garden City Medical Center [DAB1763]
Evette Elsenety, M.D., et al. [DAB1796]

Sol Teitelbaum, M.D. v. CMS [CR863] Docket No. C-01-204

CLIA #: 05D0642499
State: California
Type of Certificate: Registration
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Petitioner prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the revocation of the laboratory he directed (Physicians Independent Laboratory).

Arguments:

Petitioner asserts that:

- CMS' failure to accept the laboratory's Plan of Correction was an abuse of discretion;

- Statement of Deficiencies was procedurally and substantively defective;

- noted deficiencies did not occur during his tenure as laboratory director and therefore he is not subject to sanction as an owner or director;

- he was an employee of the laboratory as a laboratory director and not subject to sanction as an owner or operator;

- he is entitled to a hearing;

- CMS' actions were in retaliation for his appeal actions in connection with Sentinel Medical Laboratories, Inc.

Ruling excerpts:

Summary judgment is entered affirming CMS' determination to revoke the certificate of Physicians Independent Laboratory, the only appealable issue in this case.

By operation of law, and not subject to appeal, Petitioner is prohibited from owning, operating or directing a laboratory for two years.

The two-year prohibition runs from the date of the revocation of the laboratory's certificate pursuant to 42 U.S.C. § 263a(i)(3) and not from the date of this decision.

By accepting the title of "laboratory director" of a laboratory that has or is seeking a CLIA certificate, the director accepts all of the specified regulatory responsibilities and is subject to the authority of CMS and any sanctions specified by law, regardless of the actual employment status of the director.

Other cases referenced:

Sentinel Medical Laboratories, Inc. [CR679] [DAB1762]

Millenium [aka Millennium] Medical Group v. CMS [CR875] Docket No. C-01-207-C-01-217

CLIA #: [11 physician office laboratories]
State: Michigan
Type of Certificate: Compliance
ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

CMS advised Petitioners (11 physician office laboratories) that because they were owned by Millenium Medical Group, a laboratory whose certificate was revoked (Stanley Boykansky, M.D. [CR690] [DAB1756]), it was initiating action to revoke their CLIA certificates under 42 U.S.C. **§** 263(a)(i)(3).

Arguments:

Petitioners asserted that the sanctions set forth in 42 CFR § 493.1840(a)(8) do not extend to clinical laboratories owned by a parent corporation, that were not operated by an owner of the parent corporation, and that did not themselves have any cited deficiencies.

Ruling excerpts:

Millenium owned the Boykansky laboratory, a laboratory which had its CLIA certificate revoked. By law, Millenium is prohibited from owning any CLIA-certified laboratories for two years from that date. CMS was thus plainly authorized to revoke Petitioners' CLIA certificates inasmuch as they are all owned by Millenium.

Other cases referenced:

Stanley Boykansky, M.D. [CR690] [DAB1756]
Elsenety, M.D., et. al. [CR779] [DAB1796]

Caroline D. Zohoury, D.O. v. CMS [CR879] Docket No. C-00-832

CLIA #: 23D0363051
State: Michigan
Type of Certificate: Waiver
ALJ: Jose A. Anglada

Basis for Sanction(s):

Petitioner is precluded from owning or operating a laboratory for a period of two years from October 1999 because Petitioner was an "owner" or "operator" of Rochester Road Clinic, P.C. (RRC), a laboratory whose CLIA certificate was revoked.

Arguments:

Petitioner contends that her father, Badi Zohoury, was the sole owner/operator and Director of RRC at all times, and that CMS has failed to produce evidence to show that Petitioner meets the definition of an "owner of any interest" or "director" of RRC within the prohibited period.

Ruling excerpts:

Summary judgment is appropriate in this case.

CMS has provided prima facie evidence that Petitioner was an owner because, (a) Petitioner said she was an owner, and (b) she held herself out as an owner (or partial owner) by taking affirmative steps consistent with a person having ownership rights.

Petitioner's signature on Form HCFA-1513 (Disclosre of Ownership and Control Interest Statement) was directly below clear warnings of its importance.

Referenced Cases:

Hillman Rehabilitation Center [CR500] [DAB1611]

RNA Laboratories, Inc. and Ter-Zakarian Medical Clinic v. CMS [DAB1820]

Docket No. A-2002-20

CLIA #: 05D0879683; 05D0693081
State: California
Type of Certificate: Compliance
For the DAB: Cecilia Sparks Ford, Donald F. Garrett, M. Terry Johnson

Basis for Sanction(s):

Appeal of ALJ decision in CR829.

Arguments:

Petitioner alleged that certain findings of fact and conclusions of law [FFCLs] are not supported by substantial evidence.

Ruling excerpts:

The ALJ's FFCLs were supported by substantial evidence in the record and were not erroneous.

When the Board reviews an ALJ decision under the substantial evidence standard, it generally accords considerable deference to the ALJ's assessment of witness credibility because the ALJ has the best opportunity to observe the witnesses and weigh the evidence.

The condition established at 42 C.F.R. § 493.801 requires strict compliance.

Other cases referenced:

RNA Laboratories, Inc. and Ter-Zakarian Medical Clinic [CR829]
Ward General Practice Clinic [DAB1624]
Oakland Medical Group, P.C. [DAB1755]
Stanley Boykansky, M.D. [DAB1756]
US Bio-Chem Medical Laboratories, Inc. [DAB1731]
Stanley Boykansky, M.D. [CR690] [DAB1756]

Gen Sys, Incorporated v. CMS [CR889] Docket No. C-00-007

CLIA #: 14D0951154
State: Illinois
Type of Certificate: Registration
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Non-compliance with CLIA conditions and requirements, and the finding of immediate jeopardy at initial survey of Petitioner's laboratory.

Arguments:

Respondent (CMS) moved for summary judgment arguing it is entitled to judgment as a matter of law as there are no material facts in dispute. Petitioner argued that there are material facts in dispute as to every alleged deficiency and that Petitioner was actually in compliance with all CLIA requirements.

Ruling excerpts:

Petitioner bears the burden of showing that there are material facts that are disputed. Summary judgment is entered affirming the determination of Respondent suspending Petitioner's CLIA certificate.

Petitioner did not have a qualified "technical supervisor" because he did not have a bachelor's or higher level degree from an accredited institution in the appropriate discipline, a violation of 42 C.F.R. §493. 1447.

Petitioner did not have a qualified "laboratory director" who fulfilled the duties and responsibilities of laboratory director, a violation of 42 C.F.R. §493.1441.

Other cases referenced:

Garden City Medical Clinic [DAB1763]
Everett Rehabilitation and Medical Center [DAB1628]

Dearborn Family Clinic v. CMS [CR919] Docket No. C-01-293

CLIA #: 23D0367206
State: Michigan
Type of Certificate: Accreditation
ALJ: Marion T. Silva

Basis for Sanction(s):

Non-compliance with CLIA conditions and requirements, and the finding of improper proficiency testing (PT) referral.

Arguments:

Respondent (CMS) moved for summary judgment arguing it is entitled to judgment as a matter of law as there are no material facts in dispute. Petitioner argued that there was no actual referral of PT samples to another laboratory in that the vials containing the proficiency samples were not sent by Petitioner to any other facility.

Ruling excerpts:

Petitioner bears the burden of showing that there are material facts that are disputed. Summary disposition is appropriate in this case.

A laboratory is responsible for the acts of its employees, even when it is unaware of the employees' actions.

Petitioner colluded with another laboratory in the testing of proficiency samples.

The ALJ rejects Petitioner's argument that § 493.801(b)(4) is limited to cases where physical transfer of the testing sample is established.

Petitioner's failure to comply with the standards set forth in 42 C.F.R. § 493.801 constitutes a failure to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.801.

Petitioner did not have a qualified "technical supervisor" because the person so designated did not have a bachelor's or higher level degree from an accredited institution in the appropriate discipline, a violation of 42 C.F.R. §493.1449.

Petitioner failed to comply with the condition of participation stated at 42 C.F.R. § 493.1441 [laboratory director].

CMS is authorized to impose principal sanctions against Petitioner as remedies for Petitioner's noncompliance with CLIA conditions of participation.

Other cases referenced:

Garden City Medical Center [DAB1763]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1611]
Everett Rehabilitation and Medical Center [DAB1628]
Melvin C. Murphy, M.D., P.C. [CR590]
Thyroid Specialty Laboratory [CR501]
Oakland Medical Group, P.C. [DAB1755]

Blanding Urgent Care Center Laboratory [CR438]
Boykansky [DAB1756]

Emil S. Sitto, M.D., and Associates, PLLC v. CMS [CR935] Docket No. C-01-064

CLIA #: 23D0363337
State: Michigan
Type of Certificate: Accreditation
ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

Non-compliance with CLIA conditions and requirements, and the finding of improper proficiency testing (PT) referral.

Arguments:

Respondent moved for summary judgment arguing it is entitled to judgment as a matter of law because no material facts in dispute. Petitioner does not specifically challenge the factual underpinning of CMS' case, but argues that CMS' evidence "does not support the conclusion" that the proficiency testing samples were not integrated into regular patient testing and that patient samples were not tested the same number of times as PT samples.

Ruling excerpts:

Summary judgment is appropriate where, as here, Petitioner has not demonstrated any dispute over genuine issues of material fact.

Petitioner colluded with another laboratory in the testing samples in violation of 42 C.F.R. § 493.801.

Petitioner failed to test the PT samples in the same manner as it tested patients' specimens, as required by 42 C.F.R. § 493.801 and § 493.61.

The statute does not require evidence of actual physical transport.

Petitioner did not comply with the requirements of 42 C.F.R. § 493.1441 (laboratory director) or § 493.1447 (technical supervisor).

Other cases referenced:

RNA Laboratories [DAB1820]
Ward General Practice Clinic [DAB1624]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1611]
Everett Rehabilitation and Medical Center [DAB1628]
Garden City Medical Center [DAB1763]
Oakland Medical Group, P.C. [DAB1755]
Boykansky [DAB1756]
Southfield Medical Clinic [CR667]

Medical Service Laboratories v. CMS [CR936] Docket No. C-00-796

CLIA #: 45D0490579
State: Texas
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Immediate jeopardy involving failure to enroll in a proficiency testing (PT) program.

Arguments:

Petitioner argues that it made arrangements to participate in proficiency testing (PT). Petitioner indicates that schedules for PT "were to be consummated by Petitioner during the week [of the CMS inspection]" but it "did not fully enroll."

Ruling excerpts:

Summary judgment is appropriate as the material facts are not in dispute and the case can be decided as a matter of law.

Petitioner began conducting human testing at a moderate and high level of complexity without enrolling in an approved proficiency testing program in violation of 42 C.F.R. § 493.801.

The CMS declaration that the condition level violation by Petitioner constituted immediate jeopardy for its patients is not subject to review. .

The laboratory owner/operator and laboratory director are prohibited from owning, operating, or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) due to the revocation of the petitioner's CLIA certificate.

Other cases referenced:

Hillman Rehabilitation Center [DAB1611]
Edison Medical Laboratories, Inc. [DAB1713]
Garden City Medical Center [DAB1763]
New Millennium CMHC [CR672]
New Life Plus Center [CR700]
Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. [467 U.S. 837]
Sullivan v. Stoop [496 U.S. 478, 493]
Ward General Practice Clinic [DAB1624]

Carlos A. Cervera, M.D. v. CMS [CR939] Docket No. C-99-797

CLIA #: 05D0959931
State: California
Type of Certificate: Registration
ALJ: Alfonso J. Montano

Basis for Sanction(s):

The laboratory director is precluded from owning, operating, or directing a laboratory for at least two years because of the revocation of laboratory's certification due to misrepresentation between the total annual test volume in the State licensing application (485,000) and that provided in the CLIA application (45,000).

Arguments:

Petitioner argues that:

- because regulations do not specifically define the term "misrepresentation," CMS applied an inaccurate definition of the term and, therefore, has applied an incorrect interpretation to 42 C.F.R. Part 493;

- at the time of the signing and submission of the State application forms, he was not qualified to act as a laboratory director;

- even though he may have been considered a laboratory director, he was an "employee of the organization and as such cannot be held liable for the actions of the employer";

- since 42 C.F.R. §493.1840(a)(8) "singles out one employee to be punished" and is not applicable to all employees, then the regulatory provision is unconstitutional.

Ruling excerpts:

The information contained in the State licensure and CLIA application forms were a misrepresentation of information, and, therefore, subject to sanctions by CMS.

Neither the statute nor the regulations require **specific** intent for the misrepresentation.

Petitioner was the laboratory director at the time of the submission of the State and CLIA applications. At the signing of the State application form, Petitioner held himself out to be the laboratory director.

Petitioner's arguments relating to his alleged status as an "employee" laboratory director are without merit.

Petitioner is properly subject to the two-year prohibition on owning, operating or directing a laboratory.

The ALJ does not have the authority to address Petitioner's assertion that the regulations at issue are unconstitutional.

Other cases referenced:

RNA Laboratories, Inc. and Ter-Zakarian Medical Clinic [CR829]
Eugene R. Pocock, M.D. [CR527]
Sentinel Medical Laboratories, Inc. [DAB1762]
Edward Ming-Che Lai, M.D. [CR848]

Wayne E. Imber, M.D. [CR661] [DAB1740]
Richard A. Fishman, D.O. [CR100]
Serban I. Cociaba, M.D. [CR654]
Morton Markoff, D.O. [CR538]

Alaa Ahmed, M. Sc., Ph.D., (Global Esoteric Reference Labs, Inc.) v. CMS [CR946]

Docket No. C-01-455

CLIA #: 05D0970824
State: California
Type of Certificate: Registration
ALJ: Jose A. Anglada

Basis for Sanction(s):

Revocation of CLIA certificate for a period of at least one year and cancellation of approval to receive Medicare and Medicaid payments due to improper proficiency testing (PT) referral.

Arguments:

Petitioner argues that:

- it was not subject to CLIA requirements at the time of the survey, and since it only possessed a CLIA Certificate of Registration and no California Department of Health Services license was ever issued, it was not qualified to engage in any patient testing;

- the Statement of Deficiencies is inaccurate and fraught with discrepancies;

- CMS made an incorrect inference that there was a referral of PT samples to an outside laboratory;

- all PT testing was done utilizing the laboratory's own equipment and no intentional referral of PT samples occurred;

- samples tested at another laboratory by its PT technician would not be in violation of CLIA because they were tested at the other laboratory after the report to CAP from Petitioner's testing was mailed.

Ruling excerpts:

Petitioner was subject to CLIA requirements at the time of the survey.

Petitioner sent PT samples to another laboratory for analysis which it was certified to perform in its own laboratory.

Petitioner failed to examine PT samples with its regular patient workload.

The laboratory director failed to ensure that PT samples were tested in the same manner as patient samples.

Petitioner did not meet the condition at 493.1441 for laboratory director and laboratory director responsibilities.

Other cases referenced:

Long Medical Laboratory [CR334]

Lackawanna Medical Group Laboratory v. CMS [CR957] Docket No. C-01-191

CLIA #: 39D0892552
State: Pennsylvania
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Revocation of CLIA certificate for a period of at least one year and cancellation of approval to receive Medicare payments due to intentional referral of proficiency testing (PT) samples to another laboratory for analysis, failure to treat proficiency test samples the same as regular patient workload and failure to maintain all required records, violations of 42 C.F.R. § 493.801(1), (2) and (4).

Arguments:

Petitioner argues that:

- it periodically sent PT to another laboratory for "parallel testing" with its regular patient workload;

-sending PT samples to another laboratory for testing is not a violation unless it is also shown that Petitioner submitted the test results to the proficiency test program or that Petitioner failed to treat PT samples like its regular workload.

Ruling excerpts:

CMS' motion for summary judgment is granted.

It is undisputed that Petitioner sent PT samples to another laboratory for testing.

The language of 42 C.F.R. § 493.801(b)(4) is clear that a "laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory." The plain language is that a PT sample may not be sent to another laboratory, either intentionally or unintentionally.

The motives of the laboratory that sends PT samples to another laboratory for analysis that the sending laboratory is certified to perform are irrelevant and not a defense to violation of 42 C.F.R. § 493.801(b)(4).

The fact that the laboratory that sends PT samples to another laboratory for analysis that the sending laboratory is certified to perform and never reports the analysis of the proficiency samples to the proficiency program is irrelevant.

There is no conflict between 42 C.F.R. § 493.801(b)(1), which requires that PT samples be tested in the laboratory with regular patient workload using regular laboratory personnel and procedures, and 42 C.F.R. §493.801(b)(4), which establishes an absolute ban on sending out PT samples to another laboratory.

Other cases referenced:

Garden City Medical Clinic [DAB1763]
Everett Rehabilitation and Medical Center [DAB1628]
Primary Care Medical Group [CR439]
Long Medical Laboratory [CR 334]
Oakland Medical Group [DAB1755]

Southfield Medical Clinic [CR667]

Preferred Family Clinic v. CMS [CR975] Docket No. C-01-254

CLIA #: 23D0869511
State: Michigan
Type of Certificate: Accreditation
ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

Revocation of CLIA certificate for a period of at least one year and cancellation of approval to receive Medicare payments due to intentional referral of proficiency testing (PT) samples to another laboratory and failure to comply with one or more CLIA conditions.

Arguments:

Petitioner argues that CMS' evidence does not prove its allegations.

Ruling excerpts:

Summary disposition is appropriate where, as here, Petitioner has not demonstrated any dispute regarding genuine issues of material fact.

During 1998 and 1999, Petitioner violated 42 C.F.R. §493.801 by colluding with other laboratories in the testing of proficiency samples, and by failing to test the samples in the same manner as it tested patient specimens.

Petitioner did not comply with the requirements of 42 C.F.R. §493.1441 (laboratory director).

CMS is authorized to revoke Petitioner's CLIA certificate and cancel its approval to receive Medicare payments.

Petitioner may not avoid a sanction for deficiencies that affect the overall safety of its testing program by withdrawing its certification for some of its testing.

Other cases referenced:

RNA Laboratories, Inc. [DAB1820]
Ward General Practice Clinic [DAB1624]
Emil S. Sitto, M.D. [CR935]
Garden City Medical Clinic [DAB1763]

Sol Teitelbaum, M.D. v. CMS [DAB1849] Docket No. A-02-570

CLIA #: 05D0642499
State: California
Type of Certificate: Compliance
For the DAB: Judith A. Ballard; M. Terry Johnson; Marc R. Hillson

Basis for Sanction(s):

Petitioner appeal of prohibition from owning, operating or directing another laboratory for two years. [CR863]

Arguments:

Petitioner argues that the ALJ abused his discretion by entering summary judgment without permitting full briefing on the legal issues raised by the hearing request and without providing a hearing on what Petitioner asserted were material facts in dispute.

Petitioner asserts that he was not the laboratory director at the time the deficiencies arose.

Ruling excerpts:

The ALJ did not err in finding that the two-year ban applies to a laboratory director who is also an employee and who is not the licensee under CLIA.

The ALJ did not err in finding that the two-year ban applies to Petitioner since there were no material facts in dispute.

Petitioner's argument that no deficiencies arose during his tenure as laboratory director contains no indication that Petitioner disputed that there were Condition-level deficiencies which arose prior to his tenure and remained uncorrected during his tenure. This undisputed fact would be a sufficient basis for imposing the two-year ban.

Other cases referenced:

Sentinel Medical Laboratories [DAB1762]
US Bio-Chem Medical Laboratories [DAB1731]

St. Charles Health Care v. CMS [CR981] Docket No. C-01-179

CLIA #: 21D0897978
State: Maryland
Type of Certificate: Accreditation
ALJ: Richard J. Smith

Basis for Sanction(s):

Repeated unsuccessful PT performances

Failure to correct standard-level deficiencies within 12 months after the last day of inspection

Failure to submit an acceptable plan of correction

Arguments:

Petitioner states, "we take issue with all the findings and all conclusions relative to the sanctions imposed..."

Petitioner argues further that CMS never explained why Petitioner's plan of correction was not acceptable and what would constitute an acceptable plan of correction.

CMS argues that Petitioner's hearing request is inadequate and dismissal is appropriate.

Ruling excerpts:

Petitioner's hearing request did comply with the content requirement set forth in 42 C.F.R. §498.40(b).

Petitioner failed to submit an acceptable plan of correction, therefore, summary disposition is appropriate in this case.

Opting out of PT testing does not constitute an acceptable plan of correction.

The ALJ sustains CMS' determination to suspend Petitioner's CLIA certificate and to cancel its approval to receive Medicare payments for its services.

Other cases referenced:

Garden City Medical Center [DAB1763]
Everett Rehabilitation and Medical Center DAB1628
Pollock v. American Tel. and Tel. Long Lines [794 F.2d. 860,864 (3rd Cir. 1986)]
Birchwood Manor Nursing Center [DAB1669]
Regency Manor Healthcare Center [DAB1672]
Care Inn of Gladewater [DAB1680]
Fairview Nursing Plaza, Inc [DAB1715]
Alden-Princeton Rehabilitation and Health Care Center, Inc. [DAB1709]

Preferred Family Medicine v. CMS [CR999] Docket No. C-01-806

CLIA #: 23D0364632
State: Michigan
Type of Certificate: Accreditation
ALJ: Richard J. Smith

Basis for Sanction(s):

Revocation due to improper proficiency testing referral, collaboration and non-integration of proficiency testing samples into regular workload.

Arguments:

Petitioner alleges:

- that the regulations require a weighing of factors and a range of sanctions under 42 C.F.R. §1804(d);

- a finding of physical transport is necessary to establish an intentional proficiency testing referral;

- it is not liable for the actions of its testing personnel;

- it is unfair to impose sanctions for conduct that does not result in the loss of its accreditation and occurred in 1998 and 1999 (i.e., doctrine of laches)

Ruling excerpts:

CMS is not bound to ignore non-compliance by a laboratory just because the laboratory is accredited.

Petitioner intentionally referred its PT samples to another laboratory. Where there is an intentional referral, CMS must revoke a laboratory's CLIA certificate.

A finding of physical transport is not necessary to establish an intentional referral under the plain meaning of the CLIA statute and regulations.

Petitioner is liable for the actions of [its employees] whether or not its laboratory director or principal partner had knowledge of the prohibited conduct at the time.

CMS is not bound by an accreditation organization's findings. Accreditation and CLIA certification are not the same.

Neither Congress nor the Secretary has placed a time limit on CMS' exercise of its enforcement authority under CLIA. Imposing such a time limit could undermine CMS' ability to carry out the enforcement purposes of CLIA.

Other cases referenced:

RNA Laboratory, Inc. [DAB1820]
Ward General Practice Clinic [DAB1624]
Preferred Family Clinic [CR975]
Emil S. Sitto, M.D. [CR935]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1611]
Southfield Medical Clinic [CR667]

Stanley Boykansky, M.D. [DAB1756]
Oakland Medical Group [DAB1755]
Mark Gary Hertzberg, M.D. [DAB1805]
Melvin C. Murphy, M.D. [CR590]
Sentinel Medical Laboratories, Inc. [DAB1762]
Blanding Urgent Care Center Laboratory [CR438]

Lackawanna Medical Group Laboratory v. CMS [DAB1870] Docket No. A-03-19

CLIA #: 39D0892552
State: Pennsylvania
Type of Certificate: Compliance
ALJ: Cecilia Sparks Ford, Marc R. Hillson, Judith A. Ballard

Basis for Sanction(s):

Appeal of ALJ Decision in CR957.

Arguments:

Petitioner contends that even though CMS had recognized the section §493.801(b)(1) requirement for consistent treatment of PT samples and patient specimens, the ALJ nonetheless found the Petitioner violated 42 C.F.R. §493.801(b)(4) by intentional referring PT samples to another laboratory. Petitioner alleges it "never knowingly or intentionally" submitted PT results obtained through the parallel testing to its PT vendor as its own.

Petitioner argues that summary judgment on a charge of intentional referral is inappropriate where, as here, it merely intended to comply with the requirements that PT samples be tested in the same manner as all patient specimens.

Ruling excerpts:

The ALJ's conclusions of law are not erroneous and summary judgment is appropriate.

42 C.F.R. §493.801(b)(1) does not conflict with §493.801(b)(4) to prohibit any referral of PT samples for testing that the laboratory is certified to perform.

The fact that Petitioner may engage in parallel testing of some of its patient specimens at another laboratory as part of a quality control program is not a basis for implying an exception to the statutory and regulatory prohibition against referral of PT samples.

42 C.F.R. §493.801(b)(4) clearly prohibits referral "for any analysis" and requires revocation if referral is intentional.

Other cases referenced:

Ward General Practice Clinic [DAB1624]
Edison Medical Laboratories, Inc. [DAB1713]
Mark Gary Hertzberg, M.D. [DAB1805]
US Bio-Chem Medical Laboratories [DAB1731]
Crestview Park Centre [DAB1838]
Everett Rehabilitation and Medical Center [DAB1628]

Medimex Clinical Laboratory v. CMS [CR1025] Docket No. C-01-757

CLIA #: 05D0913816
State: California
Type of Certificate: Compliance
ALJ: Jose A. Anglada

Basis for Sanction(s):

Non-compliance with CLIA Conditions and requirements, and the finding of immediate jeopardy.

Arguments:

Petitioner contends that every deficiency cited by CMS was addressed, and either cured or in the process of being cured, as outlined in the plans of correction it submitted. Petitioner further contends that the deficiencies do not warrant the revocation of its CLIA certificate.

Petitioner also argues that the state agency took eight months to complete its initial report, in which it determined non-compliance with a finding of immediate jeopardy. This delay, contends Petitioner, undercuts the government's position that patients were at risk.

Ruling excerpts:

The presence of one or more Condition-level deficiencies in Petitioner's operations authorizes CMS to impose principal sanctions against Petitioner.

CMS is not barred by the Doctrine of Laches from alleging "immediate jeopardy" to patient health and safety. CMS' finding of immediate jeopardy is not an appealable remedy.

Petitioner had Condition-level deficiencies that posed immediate jeopardy.

Other cases referenced:

Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1611]
Ban Laboratories [CR576]

Alaa Ahmed, M. Sc., Ph.D. (Global Esoteric Reference Labs, Inc.) v. CMS [DAB1878]
App. Div. Docket No. A-03-11

CLIA #: 05D0970824
State: California
Type of Certificate: Accreditation
For the DAB: Judith A. Ballard, Cecilia Sparks Ford, Donald F. Garrett

Basis for Sanction(s):

Appeal of ALJ Decision in CR946.

Arguments:

Petitioner alleges that each of the ALJ's Finding of Fact and Conclusions of Law is not supported by substantial evidence or is erroneous. Petitioner excepts to the ALJ's determination that CMS had established a prima facie case.

Petitioner also disputes the ALJ's conclusion that Petitioner is subject to CLIA requirements because its state license was issued under the laboratory's former name.

Ruling excerpts:

The mistaken reference to the laboratory's former name on the state license is not a basis for finding that Petitioner was not subject to CLIA requirements.

We find that the ALJ's findings of fact are supported by substantial evidence in the record and his conclusions of law are not erroneous.

Other cases referenced:

Ward General Practice Clinic [DAB1624]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1611]
US Bio-Chem Medical Laboratories, Inc. [DAB1731]
South Valley Health Care Center [DAB1691]
Lackawanna Medical Group Lab [DAB1870]

Roy Hollins Western Reference Laboratory v. CMS [CR1055] Docket No. C-03-221

CLIA #: 05D0550504
State: California
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Non-compliance with CLIA Conditions and requirements, and the finding of immediate jeopardy. Owner/operator prohibited from owning, operating or directing a laboratory for two years from the date of revocation.

Arguments:

Petitioner alleges he was not an owner or operator of the lab during the period of the survey, and he requests to reserve his right to appeal the CMS determination that he was owner.

Ruling excerpts:

Petitioner's request for hearing was filed more than 60 days after CMS' notice of intent to impose sanctions.

Petitioner has cited no cause beyond his control as grounds for the late filing of his request for hearing.

Dismissal of a late filed request for hearing is appropriate pursuant to 42 C.F.R. §498.70(c) when the time for filing has not been extended.

The regulations do not specifically provide a right to a hearing to an owner, operator, or director to challenge the application of the two-year statutory ban, which is also not listed in the regulations as an initial decision of CMS or the Secretary.

Other cases referenced:

Hospicio San Martin [DAB1554]

Alani Medical Management Corp. d.b.a. Advanced Diagnostic Services Laboratory v. CMS
Docket No. C-03-203

CLIA #: 05D0943448
State: California
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Failure to meet requirements for enrollment and testing of proficiency testing samples, including engaging in improper proficiency testing referral activities.

Alternative sanction of civil money penalties of $10,000 per occurrence for each instance the laboratory engaged in improper proficiency testing activities.

Issue in this case involves ALJ's "Ruling Denying Motion to Dismiss and Motion for Summary Disposition."

Arguments:

CMS --

CMS moves to dismiss Petitioner's hearing request on the ground that Petitioner does not have "standing" to request a hearing. CMS asserts in its motion that the only basis for Petitioner's hearing request is that CMS should not have imposed civil money penalties against Petitioner and contends that Petitioner concedes the presence of the deficiencies that are the basis for CMS's sanction determinations. CMS argues Petitioner may not challenge CMS' exercise of discretion as to which alternative sanctions to impose.

Petitioner --

Petitioner opposes CMS' motion and cross-moves for summary disposition.

Ruling excerpts:

Petitioner has a right to a hearing because Petitioner's hearing request is not based on a challenge to CMS' discretion to impose civil money penalties.

Petitioner is not challenging the discretionary determination by CMS to impose penalties. Rather, it is challenging the legal authority and conclusions of fact on which CMS' determination rests.

CMS would have authority to impose civil money penalties against Petitioner if Petitioner is found to have referred proficiency testing samples to another laboratory.

(Note: The ALJ denied CMS' motion to dismiss the hearing request and also denied Petitioner's motion for summary judgment.)

Bolsa Medical Group Laboratory, Sheldon Barasch, M.D. v. CMS [CR1079] Docket No. C-01-077

CLIA #: 05D0891062
State: California
Type of Certificate: Compliance
ALJ: Jose A. Anglada

Basis for Sanction(s):

Revocation due to improper proficiency testing referral. Owner/operator prohibited from owning, operating or directing a laboratory for two years from the date of revocation.

Arguments:

Petitioner contends the evidence does not show that its laboratory referred samples to another laboratory in violation of 42 C.F.R. §493.801(b)(4). At most, says Petitioner, its actions constitutes a violation of 42 C.F.R. §493.801(b)(3), for which the sanction of revocation is not mandatory.

Petitioner contends that the laboratory director is without fault because he delegated his responsibilities to other laboratory personnel.

Ruling excerpts:

Petitioner's actions are tantamount to an intentional referral under 42 C.F.R. §493.801(b)(4). ALJ does not agree with Petitioner's narrow construction of the regulations that would require an actual physical transfer of a PT sample before a finding of intentional referral may be made.

The regulations do not provide for lesser sanctions when a laboratory cheats by collaboration as opposed to actual physical referral.

Delegation of responsibilities does not relieve the laboratory director of the duty to provide overall direction and proper management for a laboratory pursuant to 42 C.F.R. §493.1403 and §1407.

As a result of the revocation of the Petitioner's CLIA certificate, laboratory director cannot own, operate, or direct a laboratory for a period of two years.

Other cases referenced:

Oakland Medical Group, P.C. [DAB1755]
Long Medical Laboratory [CR334]

James Bryant, M.D., v. CMS [CR1080] Docket No. C-02-601

CLIA #: 14D0951154
State: Illinois
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction:

Owner/operator prohibited from owning, operating or directing a laboratory for two years from the date of revocation of Gen Sys Incorporated [CR889].

Arguments:

Petitioner alleges that CMS has improperly applied the two-year ban of 42 U.S.C. §263a(i)(3) to him.

Background Information:

Petitioner filed a "Verified Emergency Petitioner [sic] for Expedited Appellate Review" of the Gen Sys decision and its effect upon him with the Appellate Board of the DAB. On June 7, 2002, the Board dismissed the petition for review on grounds that Petitioner was not a party to the Gen Sys proceedings and, thus, the Board assumed there was no record development related to Petitioner and nothing for the Board to review. The Board noted that Petitioner might be able to state grounds that would cause the ALJ to reopen the Gen Sys decision.

Ruling Excerpts:

Petitioner has no right to request a hearing to challenge the CMS notice that he was subject to the two-year ban of 42. U.S.C. 263a(i)(3), but if he was an operator of Gen Sys, as CMS asserts, he has a right to have a hearing prior to revocation of the laboratory's CLIA certificate.

Because Petitioner was not an owner or operator of Gen Sys within the meaning of 42 U.S.C. §263a(i)(3), he is not subject to the two-year ban on owning or operating a clinical laboratory.

Congress intended to apply the two-year ban to owners and operators whose conduct "precipitated the revocation" of the CLIA certificate or if they bore "ultimate responsibility for the conduct" that led to the revocation.

The petition to reopen and revise Gen Sys and/or for a hearing is denied.

Other cases referenced:

Sol Teitelbaum, M.D. [DAB1849]
Edward Ming-Che Lai, M.D. [CR848]
Carlos A. Cervera, M.D. [CR939]
RNA Laboratories, Inc and Ter-Zakarian Medical Clinic [CR829]
Sentinel Medical Laboratories, Inc. [CR679]
Eugene R. Pocock, M.D. [CR527]
U.S. v. Five Gambling Devices [346 U.S. 441 (1953)]
U.S. v. Thirty Seven (37) Photographs [402 U.S. 363 (1971)]

Immuno Biogene, Inc., Charles T. Black, M.D. v. CMS [CR1083] Docket Nos. C-02-272 C-02-552

CLIA #: 05D0542702
State: California
Type of Certificate: Compliance
ALJ: Anne E. Blair

Basis for Sanction:

Revocation due to improper proficiency testing referral and the finding of immediate jeopardy for Condition-level non-compliance. Owner/operator prohibited from owning, operating or directing a laboratory for two years from the date of revocation.

Background Information:

Both the laboratory and the lab director filed timely requests for hearing. The ALJ consolidated the appeals requests.

Arguments:

Petitioner argues that lab had enrolled in required proficiency testing and challenged other proficiency testing requirement issues, including: engaging in inter-laboratory communications with another laboratory about PT; intentionally referring PT to another laboratory for testing; and accepting PT from another laboratory without notifying CMS.

Ruling Excerpts:

Laboratory was not in compliance with the Condition of PT set forth in 42 C.F.R. §493.801.

Laboratory failed to comply with the standard requirement to test PT samples in the same manner as it testing patient specimens, as required by 42 C.F.R. §493.801(b).

Petitioner had essential communications about the PT samples with another laboratory, which were prohibited and in violation of 42 C.F.R. §493.801(b)(3).

Laboratory was engaged in intentionally referring PT to another laboratory for testing and failed to notify CMS of receipt of PT samples from another laboratory for testing.

CMS' finding that laboratory's Condition-level deficiciencies constitute immediate jeopardy to patient health and safety is not subject to review.

Other cases referenced:

Hillman Rehabilitation Center [DAB1611]
Ward General Practice Clinic [DAB1624]
Beechwood Sanatorium [DAB1824]
Alaa Ahmed, M.S., Ph.D, (Global Esoteric Reference Lab, Inc.) [CR946] [DAB1878]
Primary Care Medical Group [DAB439]
RNA Laboratory Inc. and Ter-Zekarian Medical Clinic [CR829]
Lackawanna Medical Group [DAB1870]

White Lake Family Medicine, P.C., v. CMS [CR1109] Docket No. C-02-181

CLIA #: 23D0697765
State: Michigan
Type of Certificate: Compliance
ALJ: Richard J. Smith

Basis for Sanction:

Revocation due to improper proficiency testing referral, collaboration and non-integration of proficiency testing samples into regular workload, as well as Condition-level non-compliance.

Arguments:

Petitioner argues that there is no evidence that it intentionally referred PT samples to another laboratory. Petitioner cites numerous ALJ decisions for the proposition that actual referral of PT samples to another laboratory is required before CMS can impose sanctions.

Ruling Excerpts:

Petitioner's reading of the regulations and prior decisions is misguided. The actual physical conveyance of PT samples from one laboratory to another is not required to trigger the prohibition expressed in 42 C.F.R. §493.801(b)(4), as identical results in PT results can alone establish that improper communication had occurred.

It is not necessary for CMS to produce direct proof that the samples were actually carried, sent or communicated to another laboratory.

Petitioner failed to comply with the regulatory requirements for laboratory director.

Other cases referenced:

RNA Laboratories, Inc. [DAB1820]
RNA Laboratory, Inc. and Ter-Zakarian Medical Clinic [CR829]
Ward General Practice Clinic [DAB1624]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1611]
Garden City Medical Center [DAB1763]
Everett Rehabilitation Medical Center [DAB1628]
Oakland Medical Group [DAB1755]
Emil S. Sitto, M.D. [CR935]
Mark Gary Herzberg [DAB1805]
Stanley Boykansky, M.D. [DAB1756]
Southfield Medical Clinic [DAB667]
New Millenium CMHC, Inc. [CR672]
Oberry Community Mental Health Center [CR986]

William Komaiko, M.D., v. CMS [CR1111] Docket No. C-03-025

CLIA #: 14D0951154
State: Illinois
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction:

Owner/operator prohibited from owning, operating or directing a laboratory for two years from the date of revocation of Gen Sys Incorporated [CR889].

Arguments:

Petitioner alleges that CMS has improperly applied the two-year ban of 42 U.S.C. §263a(i)(3) to him.

Background Information:

CMS notified Petitioner that based on certificate revocation of Gen Sys Incorporated, Petitioner would not be able to own, operate or direct another laboratory for two years from the effective date of the revocation. The notice advised Petitioner that he had a right to request a hearing before an ALJ.

Ruling Excerpts:

There is no regulatory or statutory right to a hearing to challenge the application of the two-year ban.

Owners and operators have a right to request a hearing to challenge the suspension, limitation and proposed revocation of their laboratory's CLIA certificate.

Petitioner had no right to request a hearing to challenge the CMS notice that he was subject to the two-year ban of 42. U.S.C. §263a(i)(3), but if he was an operator of Gen Sys, as CMS asserts, he has a right to have a hearing prior to revocation of the laboratory's CLIA certificate.

Because Petitioner was not an owner or operator of Gen Sys within the meaning of 42 U.S.C. §263a(i)(3), he is not subject to the two-year ban on owning or operating a clinical laboratory.

Congress intended to apply the two-year ban to owners and operators whose conduct "precipitated the revocation" of the CLIA certificate or if they bore "ultimate responsibility for the conduct" that led to the revocation.

Petitioner was not an operator of Gen Sys within the meaning of CLIA for purposes of challenging revocation of the Gen Sys CLIA certificate or for application of the two-year ban. Accordingly, he had no statutory right to participate in the Gen Sys proceedings and he has no standing to request reopening of the Gen Sys decision or to have a hearing. Accordingly, the request for hearing is dismissed.

Other cases referenced:

Sol Teitelbaum, M.D. [DAB1849]
Edward Ming-Che Lai, M.D. [CR848]
Carlos A. Cervera, M.D. [CR939]
RNA Laboratories, Inc and Ter-Zakarian Medical Clinic [CR829]
Sentinel Medical Laboratories, Inc. [CR679]
Eugene R. Pocock, M.D. [CR527]
U.S. v. Five Gambling Devices [346 U.S. 441 (1953)]
U.S. v. Thirty Seven (37) Photographs [402 U.S. 363 (1971)]

Bethesda Pathology Clinical, Inc., v. CMS **Docket No. C-03-566**

CLIA #: 05D0869567
State: California
Type of Certificate: Compliance
ALJ: Anne E. Blair

Background Information:

In Roy Hollins/Western Reference Laboratory (WRL), DAB CR1055, a dismissal determination was made based on untimely filing of a hearing request. As a result of that dismissal, CMS' determination that the WRL was not in compliance with CLIA requirements to the extent of immediate jeopardy to laboratory customers remained in place. Accordingly, CMS's proposed sanctions against WRL were imposed. Because Roy Hollins was an owner of WRL at the time its certificate was revoked, on September 17, 2002, CMS notified Mr. Hollins that, as a result of the action taken against WRL, Mr. Hollins could not own, operate or direct any laboratory until at least August 6, 2004. On November 22, 2002, Mr. Hollins submitted to the State of California's Department of Health Services an application for certification on behalf of Bethesda Pathology Clinical, Inc., and signed as owner. CMS notified Bethesda on March 25, 2003, that it was revoking Bethesda's certification because Mr. Hollins had not transferred ownership of Bethesda, even though he was under a two-year sanction against owning, operating or directing any laboratory until at least August 6, 2004.

Arguments:

Petitioner alleges that CMS has improperly applied the two-year ban of 42 U.S.C. §263a(i)(3) to him.

Ruling Excerpts:

CMS has the authority to revoke the CLIA certificate of any laboratory that is owned, operated or directed by an individual subject to the two-year sanction against owning, operating or directing a laboratory. The stature requires no action by the Secretary to because effective, no discretion is granted the Secretary and no appeal right is specified.

Mr. Hollins has no right to contest the automatically-imposed, two-year statutory ban on his ownership, operation or direction of a laboratory.

Dismissal pursuant to 42 CFR 498.70(b) is appropriate because neither Petitioner Bethesda, with Mr. Hollins as its owner, nor Mr. Hollins as an individual has a right to a hearing.

Other cases referenced:

Roy Hollins/Western Reference Laboratory [DAB CR1055]
Millenium Medical Group [DAB CR875]
Caroline Zohoury, D.O. [DAB CR879]

Vijay Sakhuja, M.D., v. CMS [CR1167] Docket No. C-03-326

CLIA #: 33D0907221
State: New York
Type of Certificate: Compliance
ALJ: Anne E. Blair

Basis for Sanction:

Suspension and revocation of Petitioner's CLIA certificate and cancellation of Medicare and Medicare payment for laboratory services due to condition-level noncompliance resulting in immediate jeopardy to the health and safety of patients.

Arguments:

Petitioner alleges he did not have sufficient time to prepare a plan of correction. Petitioner also made several references to the survey procedures that he apparently felt distorted the survey results.

Ruling Excerpts:

In CLIA cases, the finding of even one condition-level deficiency authorizes revocation of a laboratory's CLIA certificate.

CMS proved by a preponderance of the evidence that Petitioner's laboratory had condition-level deficiencies.

I have no authority to overturn CMS's determination that Petitioner's noncompliance with CLIA requirements presented immediate jeopardy to his patients.

The surveyors' procedures did not invalidate the deficiencies found during the survey of Petitioner's laboratory.

Other cases referenced:

Hillman Rehabilitation Center [DAB 1611]
Medical Services Laboratories [DAB CR936]
Oakland Medicare Group, P.C. [DAB 1755]
RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic [DAB CR829, aff'd DAB 1820]

American Diagnostic Labs (by Ayazar Rahman, Owner and Charles Panchari, M.D., Director, v. CMS [CR1189] Docket No. C-01-433

CLIA #: 05D0954736
State: California
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction:

Revocation of CLIA certification and imposition of civil money penalty (CMP) due to condition level non-compliance posing an immediate jeopardy to the public. In addition, on September 26, 2000 a temporary restraining order was issued by the Superior Court of Los Angeles County ordering owners to not engage in operating a clinical laboratory or any other laboratory in California. In November 2001, Mr. Rahman pled no contest to and was found guilty of two criminal counts for violation of various provisions of the California Business and Professional Code, most notably, unlawfully engaging in clinical laboratory practice without a license.

Arguments:

Petitioner, Mr. Rahman, argued that the examiners who conducted the September 2000 survey were prejudiced against him, came to the laboratory with the intention of shutting it down, and conducted the survey unfairly.

In response to the ALJ's order to the parties to address issues related to the imposition of a CMP, CMS argued that the ALJ had no jurisdiction to review whether its imposition of the CMP was contrary to law.

Ruling Excerpts:

Condition level deficiencies existed at American Diagnostic Labs (ADL) nd there is a basis for revoking the laboratory's CLIA certificate.

Testing at ADL by Mr. Rahman, who was not licensed by the State of California to engage in clinical practice, amounted to a condition level violation of 42 C.F.R. 493.1421.

The imposition of a CMP [in this case] is contrary to CLIA, section 1846 of the Act, and the implementing regulations because the CMP served no remedial purpose. The CMP was not related to accomplishing a remedial purpose as set forth in section 493.1804(a).

Other cases referenced:

Ward General Practice Clinic [DAB 1624]
Edison Medical Laboratories, Inc. [DAB 1713]
Sentinel Medical Laboratories [DAB 1762]
Sol Teitelbaum, M.D. [DAB 1849]
Hillman Rehabilitation Center [DAB1661]
Emerald Oaks [DAB 1800]
Batavia Nursing and Convalescent Center [DAB 1904]
Hanlester Network [DAB 1275]
United States v. Halper [490 U.S. 435]
William Komaiko, M.D. [DAB CR1111]
United States v. Five Gambling Devices [346 U.S. 441 (1953)]
United States v. Thirty-Seven Photographs [402 U.S. 363 (1971)]
Medical Services Laboratories [DAB CR936]
Oakland Medicare Group, P.C. [DAB 1755]

RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic [DAB CR829, aff'd DAB 1820]

Millennium Clinical Laboratories, Inc., v. CMS [CR1212] Docket No. C-04-90

CLIA #: 05D0672667
State: California
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction:

Revocation of Petitioner's CLIA certificate, imposition of a civil money penalty and cancellation of Medicare and Medicare payment for laboratory services due to condition-level noncompliance resulting in immediate jeopardy to the health and safety of patients.

Arguments:

Petitioner argues that the facts do not establish condition-level violations; that CMS has not made a prima facie showing of a condition-level violation; and that, to the extent CMS might have made a prima facie showing, that showing has been rebutted.

Petitioner alleges that the survey protocol used was improper for a recertification survey and invalidates the results of the survey.

Petitioner also maintains that the declaration of immediate jeopardy months after the on-site survey is inconsistent with the existence of immediate jeopardy.

Ruling Excerpts:

Violation of one condition-level deficiency can be grounds for a principal sanction, including revocation of a laboratory's CLIA certificate.

I find nothing in either CLIA or the implementing regulations that supports Petitioner's position that CMS or its agent is required to follow a particular procedure based upon the type of inspection or survey being performed.

The SOM [State Operations Manual] provides surveyors specific and detailed guidance on organizing and conducting a survey, but it is not an inflexible tool and allows the surveyor discretion in executing the survey protocol.

I will not consider the declaration of immediate jeopardy adverse to Petitioner in the case, as I find it not credible.

Other cases referenced:

Edison Medical Laboratories, Inc. [DAB 1713]
Sentinel Medical Laboratories [DAB 1762]
Sol Teitelbaum, M.D. [DAB 1849]
Hillman Rehabilitation Center [DAB 1611]
Emerald Oaks [DAB 1800]
Center Clinical Laboratory [DAB 1526]
Medimex Clinical Laboratory [DAB 1025]
Beverly Health and Rehabilitation Center - Williamsburg [DAB 1748]
Meadow Wood Nursing Home [DAB 1841]

Immuno Biogene, Inc., v. CMS [DAB1946] Docket No. A-04-20

CLIA #: 05D0542702
State: California
Type of Certificate: Compliance
DAB: Judith A. Ballard, Cecilia Sparks Ford, Donald F. Garrett

Basis for Sanction(s):

Appeal of ALJ decision in CR1083

Arguments:

Petitioner [IBI] challenged all of the ALJ's findings of fact and conclusions of law [FFCLS], maintaining that the lab had enrolled in required proficiency testing and challenging other proficiency testing requirement issues, including: engaging in inter-laboratory communications with another laboratory about PT; intentionally referring PT to another laboratory for testing; and accepting PT from another laboratory without notifying CMS. Petitioner argued that there was no inter-laboratory communication because the PT testing for the two laboratories was done separately.

Ruling Excerpts:

"[W]e conclude that IBI's failure to comply with the condition-level requirements... authorizes CMS's revocation of IBI's CLIA certificate, cancellation of IBI's approval to receive Medicare payments for laboratory services, and imposition of a $30,000 CMP."

"We affirm and adopt the ALJ's FFCLS, except FFCLs A.2, A.3 and F, which we modify. Additionally, we adopt FFCLs A.5 and G. The modified and additional FFCLs are:

> A.2. IBI's laboratory director did not attest to the routine integration of the samples into the patient workload, as required by 42 C.F.R. 493.801(b)(1).
>
> A.3. IBI failed to comply with the regulatory prohibition on sending PT samples or portions of samples to another laboratory for an analysis IBI was certified to perform, as set forth in 42 C.F.R. 493.801(b)(4). IBI failed to notify CMS of the receipt of PT samples from another laboratory in violation of 42 C.F.R. 493.801(b)(4).
>
> A.5. IBI failed to comply with 42 C.F.R. 493.801(3) [sic], which prohibits engaging in inter-laboratory communication pertaining to the results of PT samples until after the date for PT reporting.
>
> F. CMS's conclusion that immediate jeopardy existed is fully supportable by the record.
>
> G. IBI's additional arguments are without merit.

Other cases referenced:
Edison Medical Laboratories [DAB1713]
Hillman Rehabilitation Center [DAB1611]
US Bio-Chem Medical Laboratories, Inc. [DAB1731]

White Lake Family Medicine, P.C., v. CMS [CR1109] Docket No. A-04-55 [DAB 1951]

CLIA #: 23D0697765
State: California
Type of Certificate: Compliance
DAB: Daniel Aibel, Judith A. Ballard, Donald F. Garrett

Basis for Sanction(s):

Appeal of ALJ decision in CR1109

Arguments:

In CR1109, the ALJ granted summary judgment for CMS, concluding that CMS had properly imposed the remedies of cancellation of the laboratory's approval to receive Medicare payments for its services, and suspension and revocation off the laboratory's CLIA certification. The laboratory argued that it was entitled to a hearing, taking exception to each of the ALJ's findings and conclusions.

Ruling Excerpts:

We determine that summary judgment is appropriate here since there is no genuine dispute of material fact.

Summary judgment is generally appropriate when the record shows that there is no genuine issue as to any material fact.

The undisputed facts establish that White Lake failed to meet the CLIA conditions for participating in a proficiency testing program and for having a director who fulfills specified duties.

CMS did not need to show that the referral was intentional, nor did it need to show physical transfer of the PT samples in order to revoke White Lake's certificate; under the regulations, failure to participate in a PT program in the manner anticipated by the regulations can be sufficiently serious to warrant revocation, even in the absence of such a showing.

Other cases referenced:

Ward General Practice Clinic [DAB 1624]
Emil S. Sitto, M.D. [CR 935]
Madison Health Care, Inc. [DAB 1927]
Lebanon Nursing and Rehabilitation Center [DAB 1918]
Crestview Parke Care Center [DAB 1836]
Everett Rehabilitation and Medical Center [DAB 1628]
Big Bend Hospital Corp. [DAB 1814]
Celotex Corp. v. Catrett [477 U.S. 317, 322-25 (1986)]
Thelma Walley [DAB 1367]
Matsushita Elec. Industrial Co. v. Zenith Radio [475 U.S. 574, 587 (1986)]
U.S. v. Diebold, Inc. [369 U.S. 654, 655 (1962)]
Anderson v. Liberty Lobby, Inc. [477 U.S. 242, 249, 106 S. Ct. 2505, 91 L.Ed.2d 202 (1986)]
Sagan v. U.S. [242 F.3d 493, 497, 6th Cir., 2003]
Payne v. Pauley [377 F.3d 767 770 (7th Cir., 2003)]
Edison Medical Laboratories, Inc. [DAB 1713]
McCoy v. Harrison [341 F. 3d 600 (7th Cir. 2003)]
Southfield Medical Clinic [DAB667]
RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic [DAB 1820]
Oakland Medicare Group, P.C. [DAB 1755]
Garden City Medical Clinic [DAB1763]

Vijay Sakhuja, M.D., v. CMS [CR1167] Docket No. A-04-105 [DAB1958]

CLIA #: 33D0907221
State: New York
Type of Certificate: Compliance
DAB: Judith A. Ballard, Donald F. Garrett, Daniel Aibel (Presiding Board Member)

Basis for Sanction(s):

Appeal of ALJ decision in CR1167.

Arguments:

Petitioner asserted the ALJ erred in affirming CMS's finding that his plan of correction is unacceptable. He contended that the plan of correction was rejected simply because it was not "artful" and proposed corrections that were "general in nature". He also contended that CMS and the ALJ should have given him "an opportunity to prepare and apply a procedure as laid down by regulations."

Ruling excerpts:

The State procedures that were followed in this case complied with all federal notice and due process requirements. We conclude that the ALJ did not err as a matter of law in considering the evidence. CMS and the State agency afforded [the petitioner] the process required by federal law. The record does not support [petitioner's] contention that the plan of correction was rejected simply because of concerns about its form, nor does it support his contention that he was not given an adequate opportunity to develop an acceptable plan of correction. [Petitioner] must bear responsibility for his own failure to develop an acceptable plan of correction.

We affirm the ALJ Decision and adopt all the FFCLs made by the ALJ.

Other cases referenced:

Vadalia Park [DAB No. 1940]
Beechwood Sanitarium [DAB No. 1906]

Sonali Diagnostic Laboratory v. CMS [CR1267] Docket No. C-02-047

CLIA #: 03D0942441
State: Arizona
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Violations of multiple condition-level requirements with immediate jeopardy to patient health and safety.

Arguments:

Petitioner alleges that:

- He was not aware that the state agency and CMS refused to accept Petitioners' self-evaluation in lieu of satisfactory PT results and that had he known, remedial action could have been taken.

- Errors on reports are minor with no patient harm or impact.

- There was no immediate jeopardy in this case and it was not proper for CMS and the state agency to stop the laboratory operations prior to hearing.

- CMS improperly administratively extended Petitioners' certificate of compliance, suggesting that had CMS not administratively extended Petitioners' CLIA certificate, then Petitioners would not be subject to sanctions.

- Due process was violated because the surveyor did not conduct an exit conference and advise Petitioner that immediate jeopardy was found.

Ruling excerpts:

- The regulations do not permit CMS to accept a "self-evaluation" process in lieu or satisfactory participation in an approved PT program.

- CMS can rely upon the presumption which arises under the regulations that an error which violates the regulation gives rise to potential patient harm.

- A laboratory which performs high complexity testing in a specialty or subspecialty must employ a qualified technical supervisor for each specialty or subspecialty. While a laboratory director may serve as a technical supervisor, the direction must meet the specific qualification requirements of the regulation.

- The regulation is clear that when CMS begins an action to revoke or suspend a laboratory's CLIA certificate, CMS must take action to ensure that the laboratory retains its certificate until a final decision by an ALJ in the event of an appeal.

- It is well settled that the CMS decision to declare immediate jeopardy is not subject to appeal. Petitioner's characterization of an issue related to the declaration of immediate jeopardy as one of denial of due process does not make the declaration of immediate jeopardy a matter subject to review even though it is not subject to appeal.

- There are no constitutional, statutory, or regulatory requirements for an exit conference to be held at the end of a laboratory survey, and there is no decision of a court that suggests that due process requires such a conference.

- Survey procedures specified in the State Operations Manual are not a source of due process rights, but rather, constitute CMS guidance to surveyors.

- The CMP clearly had a remedial purpose of encouraging Petitioners to achieve substantial compliance.

Other Cases Referenced:

Ward General Practice Clinic [DAB 1624]
Edison Medical Laboratories [DAB 1713]
Sentinel Medical Laboratories [DAB 1762]
Teitelbaum v. Health Care Financing Administration [No. 01-70236 - 9th Cir. Mar. 15, 2002]
Hillman Rehabilitation Center [DAB1661]
Emerald Oaks [DAB 1800]
Avol v. Sullivan [883 F.2nd 659 - 9th Cir. 1989]
Beverly Health & Rehabilitation Services v. Thompson [223 F.Supp.2d 73 - D.D.C. 2002]
Cross Creek Health Care Center [DAB 1665]

Rustom Ali, Ph.D., Operator of Scottsdale Medical Laboratory v. CMS [CR1280]
Docket No. C-02-503

CLIA #: 03D0986987
State: Arizona
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Condition-level noncompliance found at initial certification survey.

Background

An initial certification survey for this laboratory was required before a CLIA certification of compliance could be issued. The certification survey found non-compliance with condition-level requirements. CMS noted that while Petitioner was not listed as an owner of laboratory, the owner-of-record was his wife. However, Petitioner owned/directed another laboratory (Sonali Diagnostic Laboratory) facing the possibility of principal sanctions and was informed by the state agency that he would not be issued a certificate to open another laboratory until compliance issues were resolved at this other laboratory.

Arguments:

- Petitioners argue that they did not attempt to circumvent CLIA by establishing laboratory in the name of the wife only.

- Petitioners do not deny the errors observed by the surveyors but assert the errors were corrected and did not amount to a deficiency after correction.

Ruling excerpts:

The preponderance of the evidence establishes that Petitioners were guilty of misrepresentation in obtaining the certificate of registration for Scottsdale because it was not disclosed in the application for the certificate that Petitioner (husband) was an owner with his wife. This misrepresentation in the application provides a basis for revocation under the statute.

Petitioners point to no statute, regulation, or policy that obliges CMS or the state agency to assist in the creation of a laboratory or to act as consultants to a laboratory owner, operator, or director who was having obvious problems such as those Petitioner (husband) seemed to repeatedly demonstrate in the operations of his laboratories. CMS and the state agency were not obliged to serve Petitioners by assisting them to achieve compliance.

Petitioners [husband and wife] are owners, Petitioner [husband] was an operator, and the laboratory director all are subject to the two-year ban on owning, operating, or directing a laboratory subject to CLIA.

This CMP may not be approved as, given the facts of this case, it serves no remedial purpose.

Other Cases Referenced:

Edison Medical Laboratories [DAB 1713]
Ward General Practice Clinic [DAB 1624]

Sentinel Medical Laboratories [DAB 1762]
Teitelbaum v. Health Care Financing Administration [No. 01-70236 - 9th Cir. Mar. 15, 2002]
Hillman Rehabilitation Center [DAB1661]
Emerald Oaks [DAB 1800]
Sonali Diagnostic Laboratories [CR 1267]
Delozier v. Evans [158 Ariz. 490, 763 P.2d 986, 991-92 - Ariz. Ct. pp. 1988]
Batavia Nursing and Convalescent Center [DAB 1904]
Hanlester Network [DAB 1275]

Clinical Immuno Diagnostic Lab, Inc., v. CMS [CR1283] Docket No. C-03-485
CLIA #: 05D0564373
State: California
Type of Certificate: Compliance
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Condition-level noncompliance.

Background:

While representing Petitioners in a prior occurrence of non-compliance, Petitioner's attorney misrepresented in federal district court filings and in communications with CMS representatives, that Petitioner's laboratory had ceased testing, when in fact, the laboratory continued to do testing. Cessation of testing was a major factor in CMS entering into a compromise and settlement with the laboratory to resolve issues from a prior survey.

Arguments:

Petitioners argue that they found no legal precedent or regulatory history that gives meaning to 42 C.F.R. 493.1840(a)(1) [misrepresentation]. They further allege that they should not suffer consequences as a result of their attorney's misrepresentation.

Ruling excerpts:

The misrepresentation of Petitioners' counsel, attributable to Petitioners, is a sufficient basis for the revocation of Petitioners' CLIA certificate.

While CMS is correct that 42 C.F.R. 493.1844(c)(4) provides that its choice of alternative sanctions and the amount of the CMP are not reviewable, 42 C.F.R. 493.1844(c)(4) does not deprive Petitioners of the right to hearing on the issue of whether imposition of an alternative sanction is consistent with section 1846 of the Act, CLIA, and implementing regulations.

The compromise and settlement resolved all issued related to the [prior survey], and the findings and conclusions of that survey may not be cited by CMS as a basis for a CMP.

Other Cases Referenced:

Edison Medical Laboratories [DAB 1713]
Ward General Practice Clinic [DAB 1624]
Sentinel Medical Laboratories [DAB 1762]
Teitelbaum v. Health Care Financing Administration [No. 01-70236 - 9th Cir. Mar. 15, 2002]
Sol Teitelbaum, M.D. [DAB 1849]
Hillman Rehabilitation Center [DAB1661]
Emerald Oaks [DAB 1800]
Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc. [467 U.S. 837, 842-43 (1984)]
Barnhart v. Walton [535 U.S. 212, 217-18 (2002)]
Carlos A. Cervera, M.D. [CR 939]
Acton v. Merle Cosmetics [163 F.3d 605]
Mallott & Peterson v. Director, Office of Workers' Compensation Programs [98 F.3d 1170, 1173]

Open Faith Medical Laboratory v. CMS [CR1295] Docket No. C-04-563

CLIA #: 14D0964737
State: Illinois
Type of Certificate: Accreditation
ALJ: Keith W. Sickendick

Basis for Sanction(s):

Condition-level violations presenting immediate jeopardy to Petitioner's clients and/or the general public.

Background:

After being denied accreditation, Petitioner operated temporarily under a certificate of registration, pending survey by CMS or its agent and issuance of a certificate of compliance. The state agency found the Petitioner was not in compliance with condition-level requirements, including the condition-level requirement established by 42 C.F.R. 98-1441 to have a qualified laboratory director.

Arguments:

CMS alleges that Petitioner is not licensed to practice medicine in the State of Illinois and fails to satisfy the qualification requirements of 42 C.F.R. 1443(b)(1) or (2).

Petitioner acknowledges that the he did not have the qualifications specified by the regulations for a laboratory director and therefore attempted to "secure a licensed physician of the State of Illinois" to become laboratory director. Petitioner alleges that the laboratory now has an agreement with a [qualified] laboratory director.

Ruling excerpts:

There are no genuine issues of material fact in dispute in this case and CMS is entitled to judgment as a mater of law. Accordingly, summary judgment is appropriate.

Because petitioner [owner] was not a qualified laboratory director at the relevant times, Petitioner had no laboratory director ensuring [that the duties] specified by section 493.1407 were being fulfilled.

Other Cases Referenced:

Sentinel Medical Laboratories [DAB 1762]
Teitelbaum v. Health Care Financing Administration [No. 01-70236 - 9th Cir. Mar. 15, 2002]
Sol Teitelbaum, M.D. [DAB 1849]
Hillman Rehabilitation Center [DAB1661]
Edison Medical Laboratories [DAB 1713]
Garden City Medical Center [DAB 1763]
Anderson v. Liberty Lobby, Inc. [477 U.S. 242, 247 (1986)]
Everett Rehabilitation and Medical Center [DAB 1628]
Pollack v. American Tel. and Tel. Long Lines [794 F.2d 860, 864 (3rd Cir. 1986)]

Canal Medical Laboratory v. CMS [CR1374] Docket No. C-03-661

CLIA #: 19D0458960
State: Louisiana
Type of Certificate: Compliance
ALJ: Anne E. Blair

Basis for Sanction(s):

Condition-level deficiencies that posed immediate jeopardy.

Arguments:

Petitioner argues that:

- The older regulations applicable in this case do not specifically require a laboratory to review the "ungraded" proficiency testing results that receive a default score of 100%.

- Unsuccessful proficiency test results for uric acid alone do not establish a sufficient basis for revocation of a laboratory's license.

- Items in its plan of correction that state it "will" do a correction indicates it will do the item in the future.

Ruling excerpts:

Petitioner had been previously instructed, as a result of prior surveys, to review its ungraded proficiency testing results. It was incumbent on Petitioner's laboratory director to review all ungraded proficiency testing results and be able to show CMS surveyors the actions he has taken to assure that, if the analytes had been graded.

My finding is not that unsuccessful proficiency test results for the uric acid analyte alone supports revocation of Petitioner's CLIA certificate in this case, although failing only one condition can support revocation. Petitioner's failure to meet the condition of proficiency testing and the condition of laboratory director fully supports revocation of Petitioner's CLIA certificate.

The expected completion date of a plan of correction is simply that, the expected completion date. The timetable would be meaningless if "will" referred to any time in the future.

Although CMS is authorized to impose a CMP [civil money penalty] when condition-level deficiencies are found, the CMP must serve a remedial purpose. CMS cannot credibly claim that this CMP was related to the remedial purpose of motivating Petitioner to come into and remain in compliance with CLIA requirements after it had determined that no action on the part of Petitioner (other than appeal CMS's findings) would forestall revocation of Petitioner's CLIA certificate.

Other Cases Referenced:

Bowen v. Georgetown Univ. Hosp., [48 U.S. 204, 208 (1988)]
Comprehensive Mental Health Center of Baton Rouge [DAB 1774]
Lakewood Plaza Nursing Center [DAB 1767]
Hillman Rehabilitation Center [DAB1661]
Immuno Biogene, Inc. [DAB 1946]
Edison Medical Laboratories [DAB 1713]

Comprehensive Care of Plantation Key; Hartsville Convalescent Center; Key West Convalescent Center Inc.; and Marathon Manor v. CMS [CR1366] Docket No. C-05-233; C-05-234; C-05-235; C-05-236; Consolidated Docket No.: C-05-233

CLIA #'s:
Comprehensive Care of Plantation Key 10D0279292
Hartsville Convalescent Center 44D0307056
Key West Convalescent Center Inc. 10D0874033
Marathon Manor 10D0866885
Eastern Ozarks Regional Health System 04D0642317

States: Florida - Comprehensive Care of Plantation Key, Key West and Marathon Manor;
Tennessee - Hartsville Convalescent Center

Type of Certificate: Waived

ALJ: Keith W. Sickendick

Basis for Sanction(s):

CMS notified Petitioners that their CLIA certificates were being revoked effective March 23, 2005 due to their common ownership with another laboratory (Eastern Ozarks Regional Health System) which had its CLIA certificate revoked January 12, 2005, and which did not appeal that revocation.

Arguments:

Petitioner argues that:

All five laboratories were owned by individual corporate entities that have the status of separate legal "persons" within the meaning of federal law. Petitioners admit that all five corporations have a common shareholder, but argue that CMS must show that the common shareholder, and not the corporations, owned and operated the laboratories. Petitioners assert that there is no evidence that the common shareholder actually owned and operated the laboratories and the evidence is not such that the corporate veil may be pierced. Petitioners further assert that there is only one shareholder is insufficient for CMS the pierce the corporate veil.

Ruling excerpts:

Although [owner] never admits that he is the sole shareholder of all five corporations, that is clearly the case and he is the real party in interest in this matter. Contrary to the argument of Petitioner's counsel, piercing the corporate veil in the sense of the state court cases cited is not an issue in the case, because "owner" is defined by the CLIA regulations to include shareholders of all but publicly traded corporations. Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded.

Other Cases Referenced:

Hillman Rehabilitation Center [DAB1661]
Edison Medical Laboratories [DAB 1713]

Dimensions Medical Laboratory Inc., v. CMS [CR1390] Docket No. C-05-142

CLIA #: 05D0724776
State: California
Type of Certificate: Compliance
ALJ: Steven T. Kessel

Basis for Sanction(s):

Conditional level deficiencies with immediate jeopardy.

Arguments:

Petitioners argues that:

CMS wrongfully refused to accept the laboratory's plan of correction.

Alternative sanctions consisting of civil money penalties may not be imposed against [Petitioners] personally, in their capacity as owners or operators of Dimensions and the laboratory.

Ruling excerpts:

The issue in this case is whether Petitioners have a right to a hearing either to contest the findings of noncompliance made by CMS or its remedy determinations.

Regulations gave Dimensions and the laboratory the right to request a hearing before an administrative law judge to challenge CMS's finds of noncompliance and its determination to impose remedies against those entities. However, by failing to pursue those rights, Dimensions' and the laboratory allowed the determinations of noncompliance and the imposition of remedies to become administratively final.

The principles of res judicata bar Petitioners from challenging CMS's determination that Dimensions and the laboratory failed to comply with CLIA requirements. Additionally, principles of res judicata bar Petitioners from challenging CMS's authority to impose alternative and principal sanctions.

Whether CMS accepts or does not accept a plan of correction is a discretionary act that is not one of the actions that constitutes an initial determination that give rise to a right to a hearing.

Other Cases Referenced:

Sentinel Medical Laboratories [CR679]
Edward Ming-Che Lai, M.D. [CR848]

Rustom Ali, Ph.D., Sonali Diagnostic Laboratory v. CMS [CR1267] Docket No. C-05-59
Decision No. 2008

CLIA #: 03D0942441
State: Arizona
Type of Certificate: Compliance
DAB: Cecilia Sparks Ford, Sheila Ann Hegy, Judith A. Ballard

Basis for Sanction(s):

Appeal of ALJ Decision CR1267.

Condition-level noncompliance with immediate jeopardy to patient health and safety.

Arguments:

Petitioners take exception to the ALJ's conclusion that Sonali violated the condition-level requirement in section 493.803 for successful participation in proficiency testing.

Petitioners argue that CMS was not permitted to impose alternative and principal sanctions based on the same condition-level violations.

Ruling excerpts:

There is no error in finding a condition-level violation under 493.803 based on the State agency's finding that Sonali had unsatisfactory performance with respect to individual analytes.

Petitioner's ignore the clear provisions of the regulations that "[f]ailure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

Contrary to what Petitioners argue, neither the regulations nor the guidance issued by CMS authorize it to accept a laboratory's self-evaluation in lieu of failing test scores.

Section 493.1606(c) provides that CMS "may impose one or more...alternative sanctions in lieu of or in addition to imposing a principal sanction..."

We affirm and adopt the ALJ's Findings of Fact and Conclusions of Law and affirm the ALJ's decision to uphold CMS's revocation of Sonali's CLIA certificate.

Other Cases Referenced:

Scottsdale Medical Laboratory [DAB 1280]
Edison Medical Laboratories [DAB 1713]
Kaulson Laboratories, Inc. [DAB 642]

James G. Morgan, D.O., Laboratory Director v. CMS [CR1402] Docket No. C-05-620

CLIA #: 23D0376071
State: Michigan
Type of Certificate: Compliance
ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

Noncompliance at immediate jeopardy level.

Dismissal of case.

Background:

Laboratory requested hearing before an administrative law judge after the appeals period had expired. CMS moved to dismiss this case, arguing that Petitioner filed timely to file his request for hearing. Petitioner did not respond to the motion.

Ruling excerpts:

Petitioner did not respond to CMS's motion to dismiss. By failing to respond, Petitioner has, in essence, conceded that no good cause exists for failure to file hearing request timely. Petitioner's hearing request was not filed withhin 60 days and that no good cause has been shown for extending the time for filing.

Other Cases Referenced:

Edison Medical Laboratories, Inc. [DAB 1713]

Rustom Ali, Jahan Ferdous, and Scottsdale Medical Laboratory v. CMS [CR1280] Docket No. A-05-75
Decision No. 2016

CLIA #: 03D0986987
State: Arizona
Type of Certificate: Compliance
DAB: Cecilia Sparks Ford, Sheila Ann Hegy, Judith A. Ballard

Basis for Sanction(s):

Appeal of ALJ Decision CR1280.

Condition-level noncompliance.

Arguments:

Petitioners argue that the ALJ erred in upholding CMS's finding of a violation of the quality assurance condition in section 493.1701.

Petitioners take exception to both the ALJ's conclusion that Petitioner Ali was an owner and to the ALJ's conclusion that Petitioner Ali was an operator.

Petitioners argue that CMS violated 42 U.S.C. 263a(h) by imposing both principal and alternative sanctions "together."

CMS violated the regulations by denying Scottsdale the opportunity to correct its deficiencies prior to revocation.

[Other arguments were made.]

Ruling excerpts:

We affirm the ALJ's decision to uphold CMS's revocation of Scottsdale's certificate of registration and we affirm and adopt the ALJ's Findings of Fact and Conclusions of Law except with respect to Conclusions of Law 4, 5, and 23. [FFCL's 4 and 5 deal with a misrepresentation issue and FFCL 23 deals with ownership.]

Other Cases Referenced:

Edison Medical Laboratories, Inc., [DAB 1713]
Millenium Clinical Laboratories, Inc. [DAB 1212]
Emerald Oaks [DAB 1800]

Clinical Immuno Diagnostic Lab., et al., v. CMS [CR1283] Docket No. A-05-79
Decision No 2036

CLIA #: 05D0564373
State: California
Type of Certificate: Compliance
DAB: Judith A. Ballard, Sheila Ann Hegy, Donald F. Garrett

Basis for Sanction(s):

Appeal of ALJ Decision CR1283. [See CR1283 for additional background.]

Misrepresentation in obtaining a CLIA certificate.

Arguments:

Petitioner argues that:

The laboratory's counsel did not make any statements regarding whether the laboratory had ceased testing, his statements in court filings or in subsequent communications with CMS were not made in obtaining a CLIA certificate, as required by section 263a(i)(1), and do not constitute a misrepresentation. Also, Petitioner's argue that there is no violation of 263a(i)(1) if CMS did not actually rely on the counsel's statement, and that his statements could not be attributable to them.

Ruling excerpts:

Substantial evidence supports the ALJ's finding that the laboratory's counsel, while representing Petitioners, misrepresented in communications with CMS representatives that the laboratory had ceased testing.

Substantial evidence supports the ALJ's finding that Petitioner's misrepresentation that the laboratory had ceased testing was made in the course of obtaining a CLIA certificate.

The ALJ did not err in concluding that the laboratory's counsel's statement that the laboratory had ceased testing constituted a misrepresentation within the meaning of section 263a(i)(1).

The ALJ did not err in concluding that the counsel's misrepresentation was attributable to the laboratory's owners and operators.

Other Cases Referenced:

Richardson v. Perales, 402 U.S. 389, 401 (1971)
Carlos A. Cervera, M.D. CR939

Delmarva Professional Services, Inc., v. CMS [CR1451] Docket No. C-05-424
Decision No 1497

CLIA #: 21D1033018
State: Maryland
Type of Certificate: Compliance
DAB: Carolyn Cozad Hughes

Basis for Sanction(s):

CLIA certification for Delmarva Professional Services, Inc. was revoked due to deficiencies that posed immediate jeopardy to patient health. Dr. Homer R. Yeh, Ph.D., laboratory director, was prohibited from owning or operating a certified clinical laboratory for two years.

Arguments:

Dr. Yeh argues that he should not be considered the lab director because he did not, in fact, perform the duties of lab director, was not qualified to perform those duties, and was rarely even in the lab.

Ruling excerpts:

The sole issue is whether Dr. Yeh "operated" the Delmarva laboratory and is thus subject to CLIA's two-year ban.

A summary disposition is appropriate where, as here, Petitioner has not demonstrated any dispute regarding genuine issues of material fact.

As a matter of law, an individual who holds himself out as the director/operator of a clinical laboratory in order to obtain certification for that laboratory may not subsequently avoid sanction by showing that he failed to perform the statutory and regulatory duties of the position.

Even if the director "reapportions performance" of his responsibilities he remains responsible for ensuring that all duties are properly performed.

The uncontroverted evidence establishes that Dr. Yeh signed Delvarva's initial application for CLIA certification. On that application, he is listed as the lab director. In signing the application, he explicitly agreed to operate the lab "in accordance with applicable standards." Ultimately, CMS could not implement CLIA if applicants were not accountable for their representations.

Other Cases Referenced:

Sol Teitelbaum, M.D. [DAB 1849]
Sentinel Medical Laboratories [DAB 1762]
Caroline D. Zohoury, D.O. [CR879]

Lyle Griffith, M.D. (Laboratory) v. CMS [CR1496] Docket No. C-05-145

CLIA #: 05D0938429
State: California
Type of Certificate: Compliance
DAB: Carolyn Cozad Hughes

Basis for Sanction(s):

Condition-level noncompliance.

Arguments:

Petitioner admitted its laboratory failures but questions the rejection of the laboratory's plan of correction and the process for correcting deficiencies.

Ruling excerpts:

Since Petitioner failed to comply with CLIA conditions, CMS is authorized to impose principal sanctions, including the revocation of the laboratory's CLIA certificate.

The agencies' decision not to accept Petitioner's plan or correction are not "initial determinations," and therefore are not reviewable.

CMS's determination to impose a CMP, and the amount of the CMP imposed are not initial determinations and thus are not reviewable.

Other Cases Referenced:

Ward General Practice Clinic [DAB 1624]
RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic [DAB 1820]
Livingston Care Center [DAB 1871]
Garden City Medical Center [DAB 1763]
Everett Rehabilitation and Medical Center [DAB 1628]
Oakland Medical Group [DAB 1755]
Preferred Family Clinic [CR 875]

Lyle griffith cr1496.pdf

HRT Laboratory, Inc., v. CMS [CR1497] Docket No. C-06-120
Decision No 1497

CLIA #: 05D0643321
State: California
Type of Certificate: Compliance
DAB: Carolyn Cozad Hughes

Basis for Sanction(s):

Condition-level noncompliance.

Arguments:

Petitioner does not challenge CMS's determination that it was not in substantial compliance with four condition-level deficiencies. It contests only CMS's rejection of its plan off correction, arguing that its submissions were "comprehensive and appropriate, and would have [it] into compliance."

Ruling excerpts:

Petitioner's hearing request provides no clue as to the issues or findings challenged or the bases for that challenge. It simply challenges the sanctions and "all of the actions proposed."

Because Petitioner did not contest that it was not in substantial compliance with four condition-level deficiencies, CMS's determination is final and binding.

CMS may suspend, limit, or revoke the CLIA certificate of a laboratory that it is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or state monitoring.

CMS's rejection of Petitioner's plan of correction is not an "initial determination" reviewable in this forum.

Petitioner's hearing request is dismissed.

Other Cases Referenced:

Ward General Practice Clinic [DAB 1624]
Carlton at the Lake [DAB1829]
Alden Nursing Center - Morrow, [DAB 1825]
RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic [DAB 1820]

Physician Laboratory Technology, Inc., v. CMS [CR1607] Docket No. C-03-554

CLIA #: 05D0916240
State: California
Type of Certificate: Compliance
DAB: Alonso J. Montano

Basis for Sanction(s):

Condition-level noncompliance.

Arguments:

Partitioner has argued, in essence, that CMS is making a "mountain out of a molehill." CMS, Petitioner argues, has elevated a simple case of noncompliance regarding minor deficiencies to a matter which will result in the revocation of its CLIA certificate.

Ruling excerpts:

Petitioner has provided no authority or evidence in the statute or the regulations that supports its view that citations are only warranted for "major" deficiencies.

Failure by a laboratory to comply with even a single applicable condition can represent a critical breakdown in one of the major health care delivery or safety systems of the laboratory. Therefore, violation of just one condition-level deficiency can be grounds for a principal sanction, including revocation of a laboratory's CLIA certificate.

In many instances Petitioner admits to the deficiencies, often offering little or no legally defensible position. I find there is a sufficient basis to affirm CMS's revocation of Petitioner's CLIA certificate as well as the other remedies CMS has chosen to impose in this case.

I find that Petitioner provides no basis in the law, case law, or facts that supports its equitable argument that it is improper for CMS to impose a CMP, suspend Medicare payment, and revoke Petitioner's CLIA certificate in this case.

Other Cases Referenced:

Vijay Sakhuja., MD. [DAB1958]
Ward General Practice Clinic [DAB1624]
Edison Medical Laboratories, Inc. [DAB1713]
Sentinal Medical Laboratories, Inc. [DAB1762]
Teitelbaum v. Health Care Financing Admin [No. 01-70236 (9th Cir. Mar. 15, 2002)]
Sol Teitelbaum, M.D. [DAB1849]
Hillman Rehabilitation Center [DAB1611]
Beechwood Sanitarium [DAB1824]

Wade Pediatrics, v. CMS [CR1630] Docket No. C-07-06

CLIA #: 37D0965880
State: Oklahoma
Type of Certificate: Compliance
DAB: Keith W. Sickendick

Basis for Sanction(s):

Improper proficiency testing referral.

Arguments:

Petitioner does not deny that it sent proficiency testing samples to another laboratory for analysis that it was certified to perform. Petitioner asserts, however, that it did not "intentionally" refer PT samples to another laboratory for analysis but only to test the calibration of Petitioner's equipment.

Petitional also argues that CMS should be estopped from revoking its CLIA certificate because a "CMS field investigator" suggested to the laboratory director that it would be beneficial if Petitioner received training and comparison testing from another CLIA certified laboratory, such as that laboratory to which the PT samples were referred.

Ruling excerpts:

A laboratory must not send PT samples or portions of PT samples to another laboratory, intentionally or unintentionally, for analysis which it is certified to perform in its own laboratory, or for any other reason.

The motives of the laboratory that sends PT samples to another laboratory for analysis that the sending laboratory is certified to perform, are irrelevant and not a defense to violation of 42 CFR 493.801(b)(4).

The fact that the laboratory that sends PT samples to another laboratory for analysis that the laboratory is certified to perform, never reports the analysis of the proficiency samples to the proficiency program is irrelevant and not a defense to a violation of 42 CFR 493.801(b)(4).

CMS is not bound or estopped by prior agency action when that action was based on an erroneous interpretation and application of the statute and regulations.

CMS is required to revoke Petitioner's CLIA certificate for a period of not less than one year for sending PT samples to another lab.

Other Cases Referenced:

Garden City Medical Clinic [DAB1763]
Lackawanna Group Medical Laboratory [DAB1870]
Office of Personnel Management v. Richmond
Heckler v. Community Health Services of Crawford County, Inc.

Rustom Ali, et.al., v. United States Department of Health and Human Services
Rustom Ali d/b/a Sonali Diagnostics Laboratory, v. United States Department of Health and Human Services, United States Court of Appeals for the Ninth Circuit No. 06-72265 & 06-71250

CLIA #:03D0942441 [Sonali Diagnostics Laboratory]
03D0986987 [Scottsdale Medical]

State: Arizona
Type of Certificate: Compliance
United States Court of Appeals for the Ninth Circuit [No. 06-72265 & 06-71250]

Basis for Sanction(s):

Condition level noncompliance [CR1267]
Misrepresentation [CR1280]

Arguments:

Appeal of the final decisions of the Departmental Appeals Board upholding the revocation of the Scottsdale Medical Laboratory's (SML) and Sonali Diagnostic Laboratory's (SDL) certificates of registration issued under the Clinical Laboratory Improvement Amendments of 1988.

Ruling excerpts:

[Note: both decisions by the Ninth Circuit in these related cases are listed as "Not for Publication".]

The DAB did not abuse its discretion by upholding the agency's finding that SML committed two condition-level violations. Thus, HHS was authorized to revoke SML's CLIA certificate.

The DAB did not abuse its discretion by concluding that HHS was authorized to stop SDL testing operations prior to a hearing because HHS's constituent enforcement division found immediate jeopardy to the public safety due to condition-level deficiencies.

The DAB did not abuse its discretion by concluding that SDL received the required five-day notice prior to the effective date of the sanctions.

The DAB did not abuse its discretion by concluding that HHS is authorized to simultaneously impose intermediate and principal sanctions for non-compliance.

Other Cases Referenced:

Wash. State Health Facilities, Ass'n v. State of Wash., Dept of Soc. And Health Servs., 879 F.2d 677, 681 (9th Cir. 1989)

HRT Laboratory, Inc., v. CMS [CR1497] Docket No. A-07-22
Decision No. 2118

CLIA #: 05D0643321
State: California
Type of Certificate: Compliance
DAB: Judith Ballard, Leslie Sussan, Sheila Ann Hegy

Basis for Sanction(s):

[This is an appeal before the Departmental Appeals Board of CR1497 (ALJ Decision dated August 31, 2006).]

The ALJ dismissed the hearing request on the grounds that Petitioner did not dispute that it was not in substantial compliance with CLIA requirements and challenged only the rejection of its proposed plan of correction, an action that the ALJ determined is not appealable.

Arguments:

Petitioner argues that the ALJ erred in determining that the rejection of the Petitioner's plan of correction was not an "initial determination" under 42 C.F.R. 493.1844 and was thus not subject to review by the ALJ. Petitioner argues that the rejection of its POC was an appealable initial determination because it was the basis for CMS's decision to revoke Petitioner's CLIA certificate.

Ruling excerpts:

We find no merit to Petitioner's arguments on appeal.

The CLIA regulations make clear that it is a laboratory's concompliance with CLIA requirements that is the basis for a decision by CMS to impose sanctions. Since the regulations authorize CMS to impose sanctions for noncompliance with CLIA regulations, an appeal of CLIA sanctions necessarily addresses whether a laboratory was in substantial compliance with CLIA requirements, and not whether corrective actions the laboratory proposed might have brought it into compliance.

The Board has held that a laboratory's closing has no bearing on whether the laboratory had any condition-level deficiencies at the time it was surveyed, which remains relevant despite the closing, as no person who has owned or operated a laboratory which has had its CLIA certificate revoked may, within two years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued.

Other Cases Referenced:

Edison Medical Laboratories, Inc. [DAB1713]
U.S. Bio-Chem Medical Laboratories, Inc. [DAB1731]
Rustom Ali, Jahan Ferdoes, and Scottsdale Medical Laboratory [DAB2016]
Ali v. U.S. Dept. of Health and Human Services [2007 WL 2437809]
Immuno Biogene, Inc. [DAB1946]
Center Clinical Laboratory [DAB1526]

Wade Borg, M.D., v. CMS [CR1688] Docket No. C-07-520

CLIA #: 19D0979152
State: Louisiana
Type of Certificate: Compliance/Provider-Performed Microscopy Testing
DAB: Jose A. Anglada

Basis for Sanction(s):

Petitioner was found out of compliance with the condition for laboratory director, laboratories performing PPM procedures (42 CFR 493.1355), and the condition for inspection requirements (42 CFR 493.1771). The laboratory was conducting testing for speciments outside the scope of its CLIA microscopy certificate, testing was being performed in the absence of appropriate supervision, and the testing was done be personnel lacking a license issued by the State of Louisiana.

Arguments:

Petitioner concedes that he did not dispute the survey findings, but argues that the sanction is too severe.

Ruling excerpts:

The issues in this case are whether the Petitioner failed to comply with one or more conditions of participation under CLIA, thereby giving CMS the authority to impose sanctions against Petitioner, and if so, whether CMS has abused its discretion by choosing revocation as the sanction for Petitioner's noncompliance.

CMS's determination that Petitioner incurred condition-level deficiencies is final and non-reviewable. Petitioner is in violation of 42 CFR 493.1355 and 1771. CMS is, therefore, justified in imposing sanctions for noncompliance with condition-level deficiencies.

The exisitence of either of the two condition-level deficiencies in this case is sufficient to support the principal sanction of revocation of Petitioner's CLIA certificate. The condition-level deficiencies present in this case create a significant risk of inaccuracy and unreliability detrimental to the health of the American public.

Other Cases Referenced:

Edison Medical Laboratories, Inc. [DAB1713]

Daniel M. Stewart, v. CMS [CR1723] Docket No. C-07-429
Decision No. CR1723

CLIA #: 23D0363803
State: Michigan
Type of Certificate: Compliance
DAB: Steven T. Kessel

Basis for Sanction(s):

Intentional PT referral, condition level noncompliance, laboratory director requirements.

Arguments:

Petitioner argued that it did not intentionally refer proficiency testing samples to another facility and tested samples in a manner consistent with patient samples.

Ruling excerpts:

The undisputed material facts establish that Petitioner contravened two CLIA conditions of participation becuase it failed to test proficiency testing samples in the same manner as patients' specimens and because it failed to participate successfully in a proficiency testing program.

Any failure by a laboratory to test proficiency testing specimens exactly as it tests other specimens of the same type, and as part of its integrated patient testing process, is a violation of the proficiency testing condition and also establishes that the laboratory failed to comply with the condition requiring it to participate successfully in an approved proficiency testing program.

The facts alleged by CMS show that Petitioner sent its proficiency testing samples to an individual who was located at a considerable distance from Petitioner's laboratory where he tested those samples using his own equipment. There is no significant dispute about these facts.

There is no abuse of discretion by CMS if it chooses to impose revocation as a remedy where a laboratory has filed to comply with a CLIA condition (42 C.F.R. 493.1806(b)). The regulation makes it plain that the remedy of revocation is within CMS's discretionary authority so long as there is a condition level noncompliance.

I grant summary disposition to CMS thereby sustaining its determination to revoke the CLIA certificate of Petitioner.

Other Cases Referenced:

Ming-Che Lai [CR 848]
California Medical Associates [CR476]

Wade Pediatrics, v. CMS [CR1630]
App. Div. Docket No. A-08-06
Decision No. 2153

CLIA #: 37D0965880
State: Oklahoma
Type of Certificate: Compliance
DAB: Leslie A. Sussan, Constance B. Tobias, Judith A. Ballard

Basis for Sanction(s):

Appeal of CR1630.

Arguments:

Wade's arguments are based on three general propositions. First, Wade asserts that the express language of CLIA prohibits only the intentional referral of PT samples allowed the PT samples to be tested in another l aboratory only as part of a comprehensive training and equipment testing program and submitted only its own results to WSLH, the PT testing organization. According to Wade, the ALJ erred in concluding that the motive for sending PT samples to another laboratory is irrelevant. Second, Wade argues that the legislative history of CLIA indicates that Congress' intent was to prohibit only referrals made in order to falsify or alter results. Therefore, Wade argues, CMS's regulations prohibiting any referral for anyreason whatsoever do not constitute a reasonable construction of the statute. Third, Wade asserts that its claim of estoppels (based on the combination of advice allegedly given Wade by a CMS field investigator and CMS's acceptance of Wade's plan of correction for deficiencies previously found in its PT performance) should be considered and that, under these facts, imposing revocation amounts to civil entrapment.

Ruling excerpts:

We conclude that the ALJ properly granted summary judgment to CMS although our rationale differs in some respects from that set out in the ALJ Decision. We conclude that Wade intentionally referred proficiency testing samples to another laboratory for analysis that Wade was certified to perform. Accordingly, revocation of Wade's certificate for at least one year was required by statute and regulation and cancellation of Medicare payments was authorized.

The statutory provision at 42 U.S.C. 263a(i)(4) requires the Secretary to revoke a certificate if the Secretary determines that a laboratory has intentionally referred a PT sample to another laboratory for analysis that it is certified to perform. Nothing in the statute, however, precludes the Secretary from also establishing a regulatory requirement that laboratories not send PT samples to other laboratories or from considering a violation of that prohibition in determining whether a laboratory has met the condition for PT enrollment and testing and, if so, what sanction to apply.

There is no language in the statutory provision indicating that Congress considered a referral improper only when the results obtained in the referral laboratory were reported to the PT organization or agency. Thus, we reject Wade's contention that CMS may take action against a laboratory that refers PT samples to another laboratoryfor analysis only if the results of that analysis are reported by the referring laboratory to the PT organization or agency.

Reading the regulations in light of their history makes clear that revocation for at least one year is required only if CMS determines that a laboratory made a knowing and willful referral to another laboratory of a PT sample for analysis thatit was certified to perform. Under the regulations, CMS may revoke a certificate where the referral was non-intentional, butonly if it determines that a condition level deficiency

exists. This does not mean, as Wade suggests, that intentional referral will be found only if a laboratory had specific intent to violate CLIA requirements.

The ALJ concluded, and we agree, that a laboratory's motive in sending PT samples to another laboratory for analysis is irrelevant in determining whether the prohibition on sending PT samples to another laboratory has been violated.

Wade proffered no evidence from which one could reasonably infer that Wade reasonably relied on CMS's actions in sending its PT samples to Muskogee Regional Medical Center.

NOTE: See United States Court of Appeals Decision filed June 2, 2009 --
Petition for Review from the Departmental Appeals Board of the Department of Health and Human Services App. DIV. Docket No. A-08-06 Decision No. 2153

Other Cases Referenced:

Edison Medical Laboratories, Inc. [DAB1713]
Ward General Medical Practice Clinic [DAB1624]
White Lake Family Medicine, P.C., [DAB1951]
Lackawanna Group Medical Laboratory [DAB1870]

Stat Lab I, Inc., v. CMS [CR1743] Docket No. C-07-486
Decision No. CR1743

CLIA #: 19D0990153
State: Louisiana
Type of Certificate: Compliance
DAB: Richard J. Smith

Basis for Sanction(s):

Condition level noncompliance: 42 CFR 493.1250 (conditions for a laboratory to monitor and evaluate the overall quality of the analytic systems it employs), 42 CFR 493.1403 (conditions to be met by the individual holding the laboratory director position), and 42 CFR 493.1409 (conditions that must be met be the individual holding the technical consultation position).

Arguments:

Petitioner argues that there are material facts in dispute as to each of the alleged condition-level deficiencies and that Petitioner was actually in compliance with all CLIA requirements at the time of the revisit survey.

Petitioner avers that in light of its history of cooperation, the penalties proposed by CMS should be reduced. Petitioner states that the revocation of its CLIA certiifcate and cancellation of its Medicare participation are too severe.

Ruling excerpts:

There are no material issues of facts regarding at least one of the condition-level violations, and therefore, judgment should be entered for CMS on those violations as a matter of law.

The law is clear: laboratories that do not meet CLIA conditions may not be certified for participation in the CLIA program.

Failure by a laboratory to comply with even a single applicable condition can represent a critical breakdown in one of the major health care delivery or safety systems of the laboratory. There is nothing in the regulations that gives me authority to review CMS's exercise of its discretionary authority. I may not subsitute my judgment for that of CMS where condition-level noncompliance has been found and where CMS chooses to impose one or more of the principal sanctions provided by the regulations.

Other Cases Referenced:

RNA Laboratories [DAB1820]
Vijay Sakhuja, M.D. [DAB1958]
Edison Medical Laboratories, Inc. [DAB1713]
Garden City Medical Center [DAB1763]
Ward General Practice Clinic [DAB1624]

Hematology & Oncology Services, LLC, v. CMS
Docket Nos. C-08-116, C-08-148, C-08-161, C-08-167, C-08-172
Decision No. CR1754, CR1755, CR1756, CR1757, CR1758

CLIA #: 19D0457265, 19D0722517, 19D0722518, 19D0883278, 19D0939261
State: Michigan
Type of Certificate:
DAB: Steven T. Kessel

Basis for Sanction(s):

CMS based its determination to revoke in each case on the provisions of 42 CFR 493.1840(a)(8). The regulation directs CMS to revoke the CLIA certificate of any laboratory that is owned or operated by an individual or entity who owned or operated another laboratory whose CLIA certificaste is revoked within the preceding two years. In each of the cases CMS determined that the laboratory was owned by the same individual or entities who owned another laboratory (Hammond Laboratory) whose CLIA certificate was revoked less tha two years previously.

Arguments:

Petitioners argue that CMS never, in fact, revoked the Hammond laboratory's CLIA certificate because the Hammond laboratory ceased all operations and surrendered its CLIA certificate prior to the date when CMS purported to revoke it.

Ruling excerpts:

The sole issue in these cases is whether CMS was mandated to revoke each Petitioner's CLIA certificate based on a prior revocation of the Hammond laboratory's CLIA certificate.

CMS's deterination to revoke the Hammond laboratory's CLIA certificate is administratively final. The Hammond laboratory failed to challenge CMS's revocation determination. Petitioners cannot now challenge that determination. Therefore, and as a matter of law, the CLIA certificate of the Hammond laboratory was revoked within the two years preceding the revocation determinations in these cases and CMS is authorized to revoke Petitioners' CLIA certificates.

CMS is not denied authority to revoke a laboratory's CLIA certificate in the circumstance where the laboratory has previously gone out of business. CLIA could be rendered ineffective is a laboratory owner was able to avoid its enforcement provisions simply by closing the laboratory's doors. Revocation of Petitioners' CLIA certifications is mandatory.

Other Cases Referenced:

None.

Mahmoud H. Aly, M.D., v. CMS [CR1807] Docket No. C-08-51
Decision No. CR1807

CLIA #: 33D0949772
State: New York
Type of Certificate: Compliance
DAB: Steven T. Kessel

Basis for Sanction(s):

Failure to comply with CLIA proficiency testing requirements.

Arguments:

Petitioner failed to respond to administrative law judge request for pre-hearing exchange.

Ruling excerpts:

An ALJ may dismiss a party's request for hearing where that party has abandoned it. "Abandonement" occurs when a party fails to appear at a pre-hearing conference or hearing without previously showing good cause for failing to do so and where the party fails to respond with good cause to an administrative law judge's order to show cause. 42 CFR 498.69(b)

A party loses his or her right to a hearing where he or she fails to completely comply with the orders of the administrative law judge.

Other Cases Referenced:

None.

Family Practice Medical Center, v. CMS [CR1819] Docket No. C-08-226
Decision No. CR1819

CLIA #: 14D0976937
State: Illinois
Type of Certificate: Compliance
DAB: Jose A. Anglada

Basis for Sanction(s):

Condition-level deficiencies that constituted immediate jeopardy.
Arguments:
Petitioner contends that a letter from CMS addressing its "allegation of compliance," constitutes a "reconsidered or revised determination." Consequently, argues Petitioner, the time to file a request for hearing was no longer 60 days from the date of the notice of remedies, but rather, 60 days from CMS's issuance of the "reconsidered or revised determination."

Ruling excerpts:

Petitioner did not file a timely request for hearing.

Section 498.40(a)(2) of 42 C.F.R. expressly provides that:

[an] affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended . . . .

The filing of Petitioner's request was clearly beyond the 60 days stipulated in the regulations. Also, 42 CFR §498.22(b)(3) provides that the receipt of the notice of an initial determination "will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later." The five-day presumption set forth at 42 CFR. § 498.22(b)(3) is of no consideration here, not only because Petitioner received CMS's notice two days after its issuance, but also because Petitioner was 17 days late in filing its hearing request.

Other Cases Referenced:

None

Wade Pediatrics, v. CMS
United States Court of Appeals, 10th District

CLIA #: 37D0965880
State: Oklahoma
Type of Certificate: Compliance

Basis for Sanction(s):

Appeal of CR1630.

Ruling excerpts:

Wade Pediatrics checked its answers with those of another lab before submitting its results to the government. The problem is that the government's proficiency testing program seeks to assess the competency of each lab's independent work. Sharing answers defeats the purpose of the exercise. Even more pointedly, sharing answers violates the clear and unambiguous terms of a federal statute.

To 'refer' means 'to commit, submit, hand over (a question, cause, or matter) to some special or ultimate authority for consideration, decision, execution.' Without doubt, Wade committed, submitted, or handed over for consideration its proficiency testing samples … for analysis.

Wade is like the student who protests that he did not cheat on his exam because he did not hand in someone else's work buy merely checked his answers against those of another student. But peering over the shoulderof another student in the middle of an exam to check one's answer is as much cheating as handing in someone else.

Other Cases Referenced:

None

Associated Internists, P.C., v. CMS
[CR2005]

CLIA #: 23D0983891
State: Michigan
Type of Certificate: Compliance
DAB: Steven T. Kessel

Basis for Sanction(s):

Condition level non-compliance including immediate jeopardy.

Arguments:

Petitioner submitted a written allegation of compliance and a plan of correction. CMS determined that the Petitioner had removed immediate jeopardy but that the plan of correction did not satisfactorily address the substance of the deficiencies.

Petitioner requested "an appeal to remove the sanctions imposed.".

Ruling excerpts:

Petitioner's hearing request is deficient. It fails to come to grips with nearly all of the noncompliance findings on which CMS based its remedy determination, and for that reason, it does not comply with the specificity requirements of 42 CFR 498.40(b)(1) and (2). I dismiss the hearing request because it does not state an issue that I may hear and decide.

Other Cases Referenced:

None

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Departmental Appeals Board
Civil Remedies Division

In the Case of: Allstate Medical Laboratory, Inc.,

Petitioner,
v.

Health Care Financing Administration.

Docket No. C-99-309
DATE: October 6, 1999

RULING

The purpose of this ruling is to decide whether Pantaleon de Jesus, M.D., the director of Allstate Medical Laboratory, Inc., has a right to a hearing and, if so, the scope of that hearing right.

Forr the reasons set forth below, I have determined that Dr. de Jesus has a right to a hearing, which flows from the sanctions imposed by HCFA against Allstate Medical Laboratory, Inc. (Allstate). Accordingly, I deny HCFA's Motion to Dismiss.

Backqround

In a January 8, 1999 letter (Notice), HCFA informed Dr. de Jesus and Allstate that because it had not received any response from de Jesus as to why certain proposed sanctions should not be imposed, it was imposing the following sanctions as proposed in earlier letter dated December 23, 1998 [see footnote 1 below].

(1) a directed Plan of Correction of cease testing effective December 28, 1998, and submission of a client list of all clients since February 20, 1998;

(2) a civil money penalty of $10,000 per day for December 28 through December 30, 1998 for a total of $30,000;

(3) suspension of the laboratory's CLIA certificate and cancellation of Medicare and Medicaid payments effective December 31, 1998; and

(4) revocation of the laboratory's CLIA certificate effective February 21, 1999.

HCFA informed Dr. de Jesus further that, upon revocation of the laboratory's CLIA certificate, he would be prohibited from owning, operating, or directing a laboratory for at least two years from the date of the

revocation. HCFA noted that Dr. de Jesus was currently directing five other laboratories besides Allstate, which was in itself a violation of the CLIA regulations.

Dr. de Jesus filed a request for hearing dated February 11, 1999 [see footnote 2 below]. His letter did not make any reference to the January 8, 1999 Notice letter sent by HCFA to Allstate, but stated at the end that it was a "formal request for a hearing on HCFA's actions affecting Dr. de Jesus." In his letter, Dr. de Jesus asserted, among other things, that "he [was] not responsible for the deficiencies listed in the survey report."

HCFA filed a motion to dismiss Dr. de Jesus, hearing request. In the alternative, and in accordance with numbered paragraph 2.D. of my June 18, 1999 Order, HCFA also filed its report of readiness to present evidence for adjudication of the case. Dr. de Jesus filed a response brief in which he opposed HCFA's motion.

The Parties' Positions

HCFA asserts that, under the CLIA statute and the regulations, Dr. de Jesus as an individual and in his capacity as the laboratory director is not a proper party to contest any of the sanctions imposed against the laboratory and does not otherwise have any right to a hearing to challenge the two-year prohibition against his owning or operating a laboratory. HCFA argues that only the laboratory is a proper party to challenge the sanctions imposed by HCFA. In response, Dr. de Jesus argues that he is an "affected party" under 42 C.F.R. § 498.2 and has the right to a hearing, which right flows from the sanctions imposed by HCFA against the laboratory. Dr. de Jesus relies on *Eugene R. Pocock, M.D.*, DAB CR527 (1998) to support his contention that a person who is alleged to be an "operator" of a laboratory under the regulations has a direct right to appeal the prohibition against owning or operating (or directing) a laboratory for at least two years, resulting from a CLIA revocation.

DISCUSSION

I have considered the arguments of the parties and the applicable statutory and regulatory provisions. My analysis begins with an examination of HCFA's Notice dated January 8, 1999. HCFA's Notice is addressed to "Pantaleon De Jesus, M.D., Director" and "Allstate Medical Laboratory, Inc." Thus, on its face, the Notice names Dr. de Jesus as one of the addressees, and refers to him in his capacity as the laboratory director.

The principal sanction affecting Dr. de Jesus as an individual is that he is now prohibited from owning or operating (or directing) a laboratory for at least two years from the date of Allstate's CLIA certificate revocation, which became effective February 21, 1999. Dr. de Jesus' ability to have any meaningful involvement with any other laboratory as a director is now effectively suspended for a two-year period.

In its brief, HCFA recognizes that under 42 U.S.C. § 263a(i)(1), reasonable notice and opportunity for hearing must be given to the owner or operator of the laboratory before a laboratory's certificate may be suspended, revoked, or limited. HCFA contends, however, that the statute does not give any hearing rights to laboratory owners and operators who become prohibited from owning or operating other laboratories for two years following a CLIA certificate revocation. See 42 U.S.C. 263a(i)(3). HCFA asserts that only laboratories have been afforded hearing rights under-the CLIA statute and regulations.

In light of my analysis in *Pocock*, I find that HCFA's assertion that only laboratories are the proper parties to request a hearing to challenge HCFA's sanctions is without merit. The fact that the statutory provision at 42 U.S.C. § 263a(i)(1) references the laboratory's owner or operator signifies that these individuals have standing and would be parties in interest in proceedings which affect a laboratory's CLIA certificate. Simply put, in an administrative proceeding such as the one before me, a laboratory is merely a legal entity. For this reason, a laboratory and its owner and operator are essentially one and the same for purposes of contesting any adverse

actions initiated by HCFA. A laboratory's owner and/or operator are the only individuals who could possibly represent its interests. Accordingly, I conclude that a laboratory, its owner, and its operator, all have equal standing and all possess a right to be heard on sanctions imposed by HCFA against the laboratory. I conclude further that a laboratory owner or operator has a right to a hearing to challenge the mandatory two-year prohibition against owning or operating a laboratory, as set forth in 42 U.S.C. § 263a(i)(3).

Moreover, I disagree with HCFA's argument that Dr. de Jesus is not an "affected party" within the meaning of 42 C.F.R. § 498.2. The regulation at 42 C.F.R. 498.2 defines the term "affected party" as follows:

. . . a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part . . . .

Because Dr. de Jesus is a physician, there can be no dispute that he is also a "practitioner." HCFA's determination to impose sanctions against Allstate adversely affects Dr. de Jesus' rights since, as a result, he will be prohibited for two years from owning or operating a laboratory. Thus, due to HCFA's sanctions, Dr. de Jesus can be characterized as a "practitioner that is affected by an initial determination issued under this part," and therefore falls within the definition of "affected party" under 42 C.F.R. § 498.2. Because Dr. de Jesus is an "affected party," he is entitled to a hearing under 42 C.F.R. §§ 498.40 and 498.42.

It is nonsensical to state that when the statute and the regulations refer to adverse actions taken against the "laboratory", that no individual has a right to a hearing. HCFA's attempt to "play down" the role of a laboratory's owner or operator in the context of appealing adverse actions is contrary to what is reasonable or fair. A laboratory's owner and operator play essential roles in the functioning and conduct of the laboratory. To exclude a laboratory's owner and operator from having hearing rights would cause an outcome that is unacceptable and raises questions of fairness and due process.

The regulation at 42 C.F.R. § 493.2 defines the term "operator" to include "[a] director of the laboratory if he or she meets the stated criteria." HCFA, in its Notice, has named Dr. de Jesus, indicating that he is the director of the laboratory. Were I to accept HCFA's position that Dr. de Jesus, as Allstate's director, is not a proper party and is without any right to a hearing, he would be precluded from asserting in these proceedings that he is not an "operator," as that term is defined in the regulations.

In conclusion, as I interpret 42 C.F.R. § 498.2, Dr. de Jesus has the status of an "affected party" and therefore, has a right to a hearing under 42 C.F.R. § 498.40. The scope of Dr. de Jesus's hearing right encompasses the following issues:

1) whether or not Dr. de Jesus is an "operator" as defined in the regulations;

2) whether any of the laboratory activities which are alleged to be deficiencies were in violation of federal regulatory standards for a laboratory;

- whether any of the alleged deficiencies, if proven, are

subject to sanctions; and

4) whether any of the alleged deficiencies occurred while Dr. de Jesus was an operator, assuming he is found to be an operator.

Edward D. Steinman
Administrative Law Judge

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ATTACHMENT II RULING FOOTNOTES:

(1) In its earlier letter dated December 23, 1998, HCFA informed Dr. de Jesus and Allstate that it concurred with the State agency's November 12, 1998 survey findings and its recommendations, and would be imposing sanctions against Allstate. HCFA recounted that at the November 12, 1998 survey, the State agency had found Allstate to be out of compliance with several conditions under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as numerous standard-level deficiencies. Based on these findings, the State agency had determined that immediate jeopardy to patient health and safety existed and directed Allstate to take immediate action to remove the jeopardy situation. HCFA stated in this letter that "due to your failure to remove jeopardy and correct all cited deficiencies, and your failure to properly report a change in ownership within the 30 day time frame as required by 42 C.F.R. § 493.51," it would impose the sanctions of a civil money penalty, directed plan of correction, suspension and revocation of Allstate's CLIA certificate, and cancellation of Allstate's approval to receive Medicare payments. HCFA stated further that under 42 U.S.C. § 263a(i)(3) and 42 C.F.R.§ 493.1840(a)(8), the present owner or operator (including director) would be prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the CLIA certificate revocation. HCFA concluded the letter by giving ten calendar days to Allstate to submit any written evidence or other information against the imposition of the proposed sanctions.

(2). Allstate, through its owner, also filed a request for hearing dated January 14, 1999, which contested only the imposition of the CMP. As a result, revocation of Allstate's CLIA certificate became effective February 21, 1999.

In the Case Of: Carlos A. Cervera, M.D.,
Director, San Fernando Diagonostic Laboratory, Inc.
Petitioner

V.

Health Care Financing Administration.

RULING DENYING HCFA'S MOTION TO DISMISS AND GRANTING EXTENSION OF TIME FOR SUBMISSION OF READINESS REPORTS

In its motion, dated December 3, 1999, HCFA contends that Dr. Cervera does not have the right to an appeal in a matter involving sanctions taken by HCFA under the Clinical Laboratory Improvement, Amendments of 1988 (**CLIA**), against San Fernando Diagnostic Laboratory, Inc. HCFA persists in its contention even though the letter imposing sanctions against the laboratory, dated June 17, 1999, was addressed to Dr. Cervera, and even though the sanctions proposed included a two year ban on his owning or directing a laboratory.

On August 1.0, 1999, Dr. Cervera appealed the HCFA determination, and asked that his letter be considered a request for a hearing. Dr. Cervera essentially argued that he never acted as Director of the laboratory in question, that to his knowledge the laboratory never opened, and that he did not have a contract with the laboratory, among other statements in his letter.

The issues raised by this motion have been fully addressed by Judge Steinman in his order in *Allstate Medical Laboratory, Inc,* Docket No. C-99-309, October 6, 1999. (Copy attached). I adopt Judge Steinman's rationale in *Allstate.* In particular, I find that Dr. Cervera is an "affected party" within the meaning of 42 C.F.R. § 498.2, and that to cite Dr. Cervera as laboratory director and prohibit him from owning or operating a laboratory for two years, while at the same time denying him the same right to a hearing that the laboratory has raises significant issues of fairness and due process.

Accordingly, HCF's motion is denied.

The parties are instructed to promptly submit the report of readiness to present evidence as per my September 30, 1999 Order in this case. Since recent correspondence has demonstrated that the parties are having some difficulties regarding communicating with each other I will extend the date of filing this report to **January 10, 2000.** L will set up a prehearing conference in this matter during the week of **January 24, 2000.**

It is so ordered.

Marc R. Hillson
Administrative Law Judge

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Physicians Independent Laboratory, Inc., a California corporation; Sahibzada A. Akhtar, an individual,

Plaintiffs,

vs.

Donna Shalala, In Her Official Capacity As Secretary Of The United States Department Of Health and Human Services; Wayne Moon, In His official Capacity As Director of CLIA Operations, Health Care Financing Administration; Diana M. Bonta, R.N., Dr. P.H., Director of The California Department of Health Services.

Defendants.

CV 00-12209 SVW (CWx)

ORDER DENYING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I. Introduction

This is an action for preliminary injunctive relief pending an ALJ hearing brought by Plaintiffs, Physicians Independent Laboratory, Inc. ("PIL") and Sahibzada A. Akhtar (hereinafter "Plaintiffs" or “PIL” to require the Secretary of the United States Department of Health and Human Services ("the Secretary") to reverse its prior action that revoked the operating license of Mr. Akhtar's clinical laboratory (its "CLIA certificate") without first complying with the ALJ hearing requirements set forth in 42 C.F.R. 493-1840(d) (2).

Additionally, Plaintiffs ask the Court to order that any monies withheld from Medicare payments previously earned be immediately released to Plaintiffs and that any action to cancel Plaintiffs, approval to receive Medicare payments for services rendered be revoked and reinstated retroactively until such time as Plaintiffs receive a hearing before an ALJ.

Plaintiffs' motion for this Court to issue a mandatory injunction to retroactively restore Plaintiffs' CLIA certification and reinstatement of its medicare reimbursements is denied.

II. Statement of Facts

The California Department of Health Services, Laboratory Field Services (the "State Survey Agency"), acting as the agent of the Secretary, conducted a survey of PIL between August 17, 1999 and December 13, 1999, which identified PIL's violation of nine separate CLIA "Conditions of Participation" and numerous “standard level' CLIA requirements.

Under cover of letter dated January 20, 2000, the State Survey Agency provided PIL with a 334-page report of the documented deficiencies. The subject line of the January 20, 2000 correspondence stated "Condition-Level Deficiencies and Not Immediate Jeopardy." The January 20, 2000 letter asked PIL to submit a “credible allegation of compliance” along with evidence documenting correction. PIL submitted what it believed to be a conforming plan of correction in April of 2000. By letter dated June 21, 2000, the State Survey Agency provided PIL with reasons why the April 2000 plan was not acceptable. A second correction plan, submitted by PIL on July 13, 2000, was also found to be unacceptable. PIL submitted a third correction plan dated July 25, 2000.

The State Survey Agency referred the matter to the Secretary. The Secretary accepted the State's recommendation for sanctions. Accordingly, by notice dated September 22, 2000, the Secretary informed PIL's director and owner that the Secretary was imposing certain

sanctions including the suspension of the laboratory's CLIA certificate, effective October 6, 2000, and revocation of the laboratory's CLIA certificate, effective November 20, 2000. The September 22, 2000 notice informed PIL that even if it exercised its right to an ALJ hearing, the Secretary would maintain the CLIA certificate suspension prior to and during the hearing.

The September 22, 2000 notice, informing the Plaintiffs of the license suspension and revocation, stated "due to your failure to comply with reasonable requests for information that is necessary to determine your laboratory's compliance with performance standards set by law and its eligibility for a CLIA certificate of compliance" the suspension and revocation were imposed.

On October 2, 2000, PIL submitted materials directly to the Secretary in support of the laboratory's claim that the previously notice sanctions should not be imposed. The Secretary notified PIL, four days later by letter dated October 6, 2000, that "[w]e have carefully reviewed the materials your laboratory submitted on October 2, 2000 and determined that your laboratory has never come into compliance in correcting the deficiencies cited at the December 13, 1999 survey."

The Secretary notified PIL by letter dated October 17, 2000 that the submission was "entirely unacceptable as it failed to either address the deficiencies cited or to show that the alleged correction plan was every implemented." The sanctions were thereafter imposed in accordance with the schedule set forth in the September 22, 2000 notice, including the October 6, 2000 suspension of PIA's CLIA license.

III. State Defendants

It appears to be uncontroverted that the relief sought by Plaintiffs is within the sole authority of the Secretary. Therefore, for that reason, all state defendants and their agents are dismissed from this action, and the Court need not address the state defendants' Eleventh Amendment concerns.

IV. Jurisdiction Over Federal Defendants

The Secretary argues that this Court has no jurisdiction to issue equitable relief to the Plaintiffs because 42 U.S.C. § 263(a) (k) confers jurisdiction upon the Circuit Court for appeal of final agency action. 42 U.S.C. § 263(a)(k) states, in relevant part: "[a]ny laboratory which ... has had its certificate suspended, revoked, or limited ... may, at any time within 60 days after the date the action of the Secretary … becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principle place of business for judicial review of such action." 42 U.S.C. § 263a(k).

It is uncontroverted that the provision is applicable here, and it is equally clear that, by its language, that its grant of jurisdiction to the circuit court is not exclusive. There is no specific provision for alternative jurisdiction in the district court, although clearly the district court has general subject matter jurisdiction.. The Defendants argue that even though the grant of jurisdiction is not exclusive, the Ninth Circuit in Public Utility Commr. v. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir. 1985) mandates that this court read the permissive language of
42 U.S.C. § 263(a)(k) as conferring exclusive jurisdiction on the circuit court.

In Bonneville Power Administration, the Ninth Circuit held that in a rulemaking proceeding "'where a statute commits review of final agency action to the court of appeals, any suit seeking relief that might affect the court's future jurisdiction is subject to its exclusive review." Public Utility Commr. v. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir., 1985). The Defendants are correct that the Ninth Circuit's holding is applicable even if the grant of jurisdiction to the circuit court is not exclusive. Id. at 625-628. However, the holding of the Ninth Circuit in Bonneville Power Administration is inapplicable here because the suit in this case does "not affect the court's future jurisdiction."

The plaintiff in Bonneville Power Administration challenged the constitutionality of ongoing agency rulemaking proceedings to revise certain rate formulas. Clearly, if the district court had ruled on the constitutionality of rate proceedings in Bonneville Power, the Ninth Circuit court's "future jurisdiction" would be affected in the sense that the Ninth Circuit would adjudicate these matters in an appellate posture and then only if the parties appealed. Here, this Court is only being asked to grant temporary relief pending the outcome of an administrative proceeding, rather than determine whether a rulemaking proceeding is constitutional. Our relief in this case is confined to requiring the agency to following its own regulations, pending the outcome of an administrative proceeding that the agency failed to properly provide. PIL's appeal from any ALJ ruling would be to the Ninth circuit. Therefore, this Court has jurisdiction to grant plaintiffs a preliminary injunction pending an ALJ hearing.

V. Exhaustion of A,4-inistrative Remedies

In Darby **v.** Cisneros, 509 U.S. 137, 144-146 (1993), the Court explicitly held that federal courts have no authority to require plaintiffs to exhaust administrative remedies prior to seeking judicial review under the APA unless a statute or agency regulation specifically mandates exhaustion as a prerequisite to judicial review. See also, Ciba-Geigy Corp. v. E. P. A., 46 F.3d 1208, 1210 & n. 2 (D.C. Cir. 1995) (summarizing the holding of Darby as "courts cannot require exhaustion of administrative remedies where, as here, it is not expressly required by statute or agency rule").

The Supreme Court in Darby explained that "[a]gencies may avoid the finality of an initial decision, first, by adopting a rule that an agency appeal be taken before judicial review is available, and, second, by providing that the initial decision would be inoperative pending appeal." Darby, 509 U.S. at 137. Clearly, the agency has not provided that its initial decision would be inoperative.

As explained in Darby, "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." Defendant argues that 42 U.S.C. § 263(a)(i) and the regulation promulgated in 42 C.F.R. § 493.1844 impose a statutory requirement of exhaustion.

The Court disagrees. 42 U.S.C. § 263(a)(i) merely states that "[t]he opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation." 42 C.F.R. § 493.1844(f)(1) states "[a]ny laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing."

Without argument or citation, Defendants assume that these provisions specifically provide for exhaustion. However, an examination of other statutory provisions demonstrate the Congress was able, when it so desired, to clearly mandate exhaustion. For example, relating specifically to the Department of Agriculture and its agencies, 7 U.S.C. § 6912(e), titled, Exhaustion of Administrative Remedies, provides: "[n]otwithstanding any other provision of law, a person shall exhaust all administrative appeal procedures established by the Secretary or required by law before the person may bring an action in a court of competent jurisdiction against" the agency and its agents. 7 U.S.C. § 6912(e). Here, however, no such statutorily-mandated exhaustion requirement exists and under Darby none can be required by this Court.

VI. Finality of Agency Action

The APA permits "'non-statutory" judicial review only of "final agency action." 5 U.S.C. § 704. See, Bell v. New Jersy, 461 U.S. 773, 778 (1983) (.recognizing "strong presumption" that judicial review will be available only when agency action has become final). In order for agency action to be final, there must be a "direct and immediate impact." Franklin v. Massachusetts, 505 U.S. 788, 796-97 (1992). Two conditions.will satisfy this requirement. First, "the action must mark the consummation of the agency's decision making process ... [and] ... it must not be of a merely tentative or interlocutory nature ... second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 177 (1997). Determination of finality of agency action for purposes of APA review is to be made in a pragmatic way. See, Pennzoil Co. v. Federal Energy Regulationry Comm'n, 645 F.2d 394, 399 (5th Cir. 1981).

Defendant has asserted that the revocation of the CLIA certification is not final agency action and that it will only become final agency action upon the exhaustion of administrative remedies.[1] Defendant confuses two analytically distinct doctrines. As the Supreme Court stated in Darby v. Cisneros, 509 U.S. 137, 144 "[T]he finality requirement is concerned with whether the initial decision maker has arrived at a definitive position on the issue that inflicts an actual, concrete injury; the exhaustion requirement generally refers to administrative and judicial procedures by which an injured party may seek review of an adverse decision and obtain a remedy if the decision is found to be.unlawful or otherwise inappropriate." See e.g., Association of National Advertisers v. FTC, 627 F. 2d 1151, 1157 (1980) ("'The jurisdictional difficulty arises out of the requirement of finality, a related doctrine which also comes into play in this case, and which overlaps the requirement of exhaustion of administrative remedies but is analytically distinct.")

Here, Defendant does not assert that Plaintiff must proceed through an administrative review process. In fact, 42 U.S.C. § 263(a)(k) merely provides that "any laboratory ... may .. petition for review." If administrative appeals are not mandated the action is final. Darby v. Cisneros, 509 U.S. 137, 137-138 (1993) ("[s]ince neither the National Housing Act nor applicable HUD regulations mandate further administrative appeals, the ALJ's decision was a 'final' agency action.") Therefore, the finality of an action is not affected by the. mere availability of an administrative remedy.

Additionally, from a pragmatic standpoint, the revocation of the CLIA license is final agency action. It is quite clear that the rights of the Plaintiff are dramatically affected by the revocation of its operating license and that the revocation "imposes an obligation, denies a right, or fixes a legal relationship." United States Dep't of Justice v. Fed. Labor Relation Auth., 727 F.2d 481, 493 (5th Cir. 1984). Therefore, the Court finds that revocation of the Plaintiff's CLIA certification was final agency action under the APA.

VII. A Pre-Deprivation Hearing Was Required

It seems clear to the Court, and Defendants do not argue to the contrary in their motions, that the suspension and revocation should have followed rather than proceeded a hearing.

The Code of Federal Regulations state that only in specific instances may an agency revoke a CLIA license prior to a hearing before an ALJ. Section 493-1840(d) states, in relevant part: "'HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision that upholds suspension or limitation" except when "(i) The laboratory's deficiencies pose immediate jeopardy; (ii) The laboratory has refused

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[1.] At oral argument, the Secretary stated chat because the imposition of its various sanctions including the license suspension was not final agency action, neither this court nor the Ninth Circuit could enjoin the agency from suspending plaintiff's license even if a violation of constitutional rights or the agency's own regulators had occurred. This represents a reversal of the Secretary's position taken at oral argument in. their opposition to the plaintiff's motion for a temporary restraining order when the Secretary represented that the action was final and that immediate relief was available from the Ninth Circuit. Either way, the court finds the Secretary's argument incorrect, and believes that this Court has jurisdiction to review the matter.

a reasonable request for information or work on material; (iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operations."

It appears, at least from the record presented to the court that none of the sections of section 493.1840(d)(2) apply.

An agency may not rely on after the fact rationalizations to justify its actions. SEC v. Chenery Corp., 332 U.S. 194 (1947). Therefore, the statement submitted in the various declarations on behalf of Plaintiff now claiming that there may be other reasons, including health dangers for the suspension and revocation of the CLIA license, are not considered in our review of the Secretary's decisions.[2] At the time of the decision, the deficiencies cited in the Statement of Deficiencies issued by the State DHS as a result of the on-site inspection survey of the laboratory premises in August 1999 were determined by "State DHS" to be "not immediate jeopardy." Therefore, the Secretary cannot justify its decisions under the first exception by post-hoc submissions alleging potential health related harms.

An agency may "not proffer conclusory statements or unsubstantiated claims in defense of its decisions." National Treasury Employees Union v. Horner, 654 F. Supp. 1159, 1163 (D.C.

[2.] If the Secretary believes that there are genuine health issues and that it merely made a mistake in justifying its suspension and revocation of the license on a different grounds it may resort to 42 U.S.C. § 263(a)(j) which provides for injunctive remedies whenever "the Secretary has reason to believe that the continuation of any activity by a laboratory would constitute a significant hazard to the public health the secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity."

Cir. 1987). Yet the Secretary has done precisely that here. While it claims that "due to [PIA's] failure to comply with reasonable requests for information" the CLIA certificate was suspended, defendants in their submissions to this Court have not produced evidence of a single non-compliance with a request for information. Rather, the record establishes that Plaintiff was very forthcoming with information and that this information was the basis upon which the violations were found.[3]

It is quite clear that the allegation of failure to provide information is conclusory, as it is not mentioned in the Defendants' pleadings, declarations, and any other evidence before this Court. Therefore, the second exception is inapplicable.

Finally, the Secretary does not contest that the third exception is applicable. Because no exception applies, the Code of Federal Regulations required that PIA be granted a hearing prior to the revocation of its license.

VIII. Standard For Preliminary Injunction

The standard for a preliminary injunction balances the plaintiff's likelihood of success against the relative hardship to the parties. Sun Microsystems, Inc. v. Microsoft Corp., 188 F.3d 1115, 1118 (9th Cir. 1999). Generally, to obtain a preliminary injunction, plaintiff is required to demonstrate either: (1) a likelihood of success on the merits and the possibility of

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[3.] Defendants do not contest that over 2,300 pages of documentation responding to the deficiencies were filed. This does not include additional original business records of PIA.

irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in its favor. Id. These two alternatives represent "extremes of a single continuum," rather than two separate tests. Id. (quoting Sega Enters, v. Accolade, Inc., 977 F.2d 1510, 1517 (9th Cir. 1992). Thus, the greater the relative hardship to plaintiff, the less probability of success must be shown. See, National Ctr-. For Immigrants Rights v. INS, 743 F.2d 1365, 1369 (9th Cir. 1984).

a. Irreparable Injury

Plaintiff alleges that, without its operating license, the laboratory will be forced to close, and its employees will have to find other work. Defendants direct our attention to cases holding that a preliminary injunction is an inappropriate remedy where the potential harm to the plaintiff is strictly financial. This is true as general rule, but an exception exists where the potential economic loss is so great as to threaten the existence of the plaintiff's business. See, Wright and Miller, Federal Practice and Procedure: Civil § 294B, Doran v. Salem Inn, Inc., 422 U.S. 922 (1975) (threat of bankruptcy constitutes irreparable harm); John B. Hull, Inc. v. Waterbury Petroleum, 588 E.2d 24 (2nd Cir. 1978), cert. denied, 440 U.S. 960 (1979) (possibility of going out of business is irreparable harm); Tri-State Generation v. Shoshone River-Power, Inc., 805 F.2d 351 (10th Cir. 1986) (threat to trade or business viability is irreparable harm; Milsen Co. v. Southland Corp., 454 F.2d 363 (7th Cir. 1971) (irreparable harm found where, without injunction, movants would lose businesses and their ability to carry on their lawsuit would have been crippled, if not destroyed.) However, Plaintiffs' claim that it is suffering irreparable harm is placed into question by the actions of Plaintiffs' to delay their ALJ hearing. Most recently, Plaintiffs' filed for a sixty day extension of the ALJ hearing previously scheduled for January 22, 2001. Although the Court finds that there is certainly a possibility of irreparable harm here, the Court need not decide this matter because the Plaintiffs have failed to prove a likelihood of success on the merits sufficient to warrant a grant of a preliminary injunction.

b. Likelihood of Success On The Merits Regarding CLIA Revocation

The Secretary makes a number of arguments as to why PIL will not succeed on the merits. First, the secretary argues that exhaustion is required. This argument is addressed and rejected in a previous section. Second, the Secretary argues that because PIA is likely to lose before the ALJ that it has little chance of success on the merits.

Plaintiffs do not allege that they have a high likelihood of retaining their CLIA license after a full hearing on the merits before an ALJ. Rather, Plaintiffs argue that the Court should not look to the probable resolution of the ALJ hearing to determine likelihood of success on the merits, but rather look to the likelihood that Plaintiffs deserved a hearing prior to suspension and revocation of the CLIA license.

As previously discussed, the Court finds that a hearing was required prior to deprivation of the Plaintiff's CLIA certificate. However, Plaintiff is incorrect in his assertion that, in applying the likelihood of success on the merits standard in the context of preliminary injunctions, as opposed to a claim for other relief, Courts look only to the question of whether proper procedures were provided.

In Wheeler v. Office of the Controller Currency of The United States, 1998 WL 872945 (N.D. Tex. 1998), Plaintiff petitioned a federal district court for review of a Temporary Cease and Desist Order issued by the Office of the Controller of the Currency. Plaintiff sought preliminary and permanent injunctive relief to set aside the OCC's Order. Plaintiff alleged that the OCC was without authority to issue the Order against him, and, therefore, the issuance of the order should be enjoined. The Court found that, in the context of examining the likelihood of success for a preliminary injunction "the issue of whether the OCC had statutory authority to issue the Order is entwined with the issue of whether [Plaintiff] is likely to prevail on the merits of the underlying action." Id. at 6. c.f., D'Amico v. United States Svc. Indus., Inc., 867 F. Supp. 1075, 1088 (D.D.C. 1994) (stating, in dicta, that the "a substantial case or the merits in the underlying proceeding before the “Board” is required to meet the likelihood of success on the merits standard for a preliminary injunction).

Similar to the Plaintiff in wheeler, the Plaintiffs in this case have alleged failure to provide a pre-hearing deprivation is sufficient to grant a preliminary injunction, without regard to the success of the underlying claim. The Court in Wheeler disagreed with that assertion. Plaintiff cites no authority for the proposition that likelihood of success on the merits is to be judged by looking at a procedural matter rather than the substantive underlying issue. Plaintiff has, therefore, failed to meet his burden of proof that he has sufficient likelihood of success on the merits to warrant a grant of a preliminary injunction.

c. Likelihood of Success On The Merits Regarding Medicare Repayments

With regard to Plaintiff's request that this Court reinstate its eligibility to receive Medicare payments, the Court finds that the Plaintiff has not demonstrated that its has a right, either originating from due process or the Code of Federal Regulations, to a hearing prior to revocation of its eligibility to receive Medicare reimbursements.

ix. Conclusion

Therefore, Plaintiffs' motion for preliminary injunction to retroactively restore his CLIA license is denied. Plaintiffs' request that any Medicare monies withheld be released is denied at this time, subject to a supplementation to plaintiff's pleading that demonstrates a right to a hearing prior to the revocation of those benefits.

IT IS SO ORDERED.

DATED: 1/24/2001

STEPHEN V. WILSON
UNITED STATES DISTRICT JUDGE

EDISON MEDICAL LAB., INC.,

Petitioner

v.

HEALTH CARE FINANCING ADMINISTRATION

ON APPEAL FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL APPEALS BOARD APPELLATE DIVISION
(DAB App. Div. No. A-99-96)

Argued: January 25, 2001
Before: NYGAARD, ALITO, and RENDELL, Circuit -Judges.

JUDGMENT

This cause carne to be heard on the record from the Department of Health and Human Services Departmental Appeals Board Appellate Division on January 25, 2001.

After careful review and consideration of all contentions raised by the appellant, it is hereby ORDERED and ADJUDGED that the judgment of the Department of Health and Human Services entered on December 23, 1999, be and is hereby affirmed, all in accordance with the opinion of this Court.

Costs taxed against appellant

ATTEST:

Clerk

DATED: February 15, 2001

Certified as a true copy and issued in lieu of a formal mandate on April 9, 2001.
Teste:

Clerk, United States Court of Appeals for the Third Circuit

UNREPORTED / NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 00-3138

EDISON MEDICAL LAB., INC.,

Petitioner

V.

HEALTH CARE FINANCING ADMINISTRATION,
Respondent

ON APPEAL FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTNENTAL APPEALS BOARD APPELLATE DIVISION

(DAB App. Div. No. A-99-96)

Argued: January 25, 2001

Before: NYGAARD, ALITO, and RENDELL, Circuit Judges.

(Opinion Filed: February 15, 2001)

MEMORANDUM OPINION OF THE COURT

Kenneth B. Falk (Argued)
Deutch & Falk
843 Rahway Avenue
Woodbridge, NJ 07095

Counsel forPetitioner

David W. Ogden,
Assistant Attorney General
Robert J. Cleary,
United States Attorney
Scott R. McIntosh,
Attorney, Appellate Staff
Constance A. Wynn,
Attorney, Appellate Staff
(Argued)
Civil Division, Room 9550
Department Of Justice
601 D Street, N.W.
Washington, DC 20530-0001

Counsel for Respondent

ALITO, Circuit Judge:

Petitioner Edison Medical Laboratories, Inc. appeals the December 23, 1999 decision of the Department of Health and Human Services Departmental Appeals Board upholding the suspension and subsequent revocation of Petitioner's certificate of accreditation for failure to meet condition-level requirements of the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and regulations promulgated thereunder at 42 C.F.R. Part 493. After careful review of the record and arguments advanced by Petitioner, we have determined that the findings of the Departmental Appeals Board are supported by substantial evidence. Accordingly, pursuant to our jurisdiction under 42 U.S.C. § 263a(k) (3), we affirm the action of the Department of Health and Human Services in revoking Petitioner's certificate of accreditation.

TO TBE CLERK OF THE COURT:

Kindly file the foregoing Opinion.

/s/Samuel A. Alito

Circuit Judge

MAY 10 2001

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Physicians independent Laboratory, Inc., a California corporation; Sahibzada A. Akhtar, an individual,

Plaintiffs,

vs.

Donna Shalala, In Her Official Capacity As Secretary Of The United States Department of Health and Human Services; Wayne Moon, In His Official Capacity As Director of CLIA Operations, Health Care Financing Administration; Diana M. Bonta, R.N., Dr. P.H., Director of The California Department of Health Services.

Defendants.

CV 00-12209 SVW (CWx)

ORDER GRANTING DEFENDANTS, MOTION TO DISMISS

I. Introduction

Plaintiff Physician's Independent Laboratory, Inc. (“PIL") and Akhtar filed this action on November 16, 2000, seeking preliminary injunctive relief pending an ALJ hearing, to require the Secretary of the United States Department of Health and Human Services (“the Secretary”) to reverse its prior action that revoked the operating license of Mr. Akhtar's clinical laboratory (its “CLIA certificates”) without first complying with the ALJ hearing requirements set forth in 42 C.F.R. 493.1840(d) (2).

Additionally, Plaintiffs asked this Court to order that any monies withheld from Medicare payments previously earned be immediately released to Plaintiffs and that any action to cancel Plaintiffs approval to

receive Medicare payments for services rendered be revoked and reinstated retroactively until such time as Plaintiffs receive a hearing before an ALJ.

This Court denied in our January 25, 2001 (the "January 25, 2001 Order") Plaintiffs' request to issue a mandatory injunction to retroactively restore Plaintiffs' CLIA certification and reinstate its medicare reimbursements because Plaintiffs did not demonstrate a substantial likelihood of success of the merits after an ALJ hearing.

In its second amended complaint now pending before the court, Plaintiffs, seek money damage against Donna Shalala and Wayne Moon and Mary Jew as Federal employees acting in their official capacities. Defendants bring a motion to dismiss all causes of action in the second amended complaint arguing that this Court is without jurisdiction to grant the relief sought by the Plaintiffs, that a Bivens action is not available to Plaintiffs, and that Plaintiffs must exhaust administrative remedies. Defendant motion to dismiss is granted.

II. Statement of Facts

The California Department of Health Services, Laboratory Field Services (the "State Survey Agency), acting as the agent of the Secretary, conducted a survey of PIL between August 17, 1999 and December 13, 1999, which identified PIL's violation of nine separate CLIA “Conditions of Participation” and numerous "standard level" CLIA requirements.

Under cover of letter dated January 20, 2000, the State, Survey Agency provided PIL with a 334-page report of the documented deficiencies. The subject line of the January 20, 2000 correspondence stated "Condition-Level Deficiencies and Not Immediate Jeopardy." The January 20, 2000 letter asked PIL to submit a “credible allegation of compliance” along with evidence documenting correction. PIL submitted what it believed to be a conforming plan of correction in April of 2000. By letter dated June 21, 2000, the State Survey Agency provided PIL with reasons why the April 2000 plan was not acceptable. A second correction plan, submitted by PIL on July 13, 2000, was also found to be unacceptable. PIL submitted a third correction plan dated July 25, 2000.

The State Survey Agency referred the matter to the Secretary. The Secretary accepted the State’s recommendation for sanctions. Accordingly, by notice dated September 22, 2000, the Secretary informed PIL's director and owner that the Secretary was imposing certain sanctions including the suspension of the

laboratory's CLIA certificate, effective October 6, 2000, and revocation of the laboratory's CLIA certificate, effective November 20, 2000. The September 22, 2000 notice informed PIL that even if it exercised its right to an ALJ hearing, the Secretary would maintain the CLIA certificate suspension prior to and during the hearing.

The September 22, 2000 notice, informing the Plaintiffs of the license suspension and revocation, stated "due to your failure to comply with reasonable requests for information that is necessary to determine your laboratory's compliance with performance standards set by law and its eligibility for a CLIA certificate of compliance" the suspension and revocation were imposed.

On October 2, 2000, PIL submitted materials directly to the Secretary in support of the laboratory's claim that the previously notice sanctions should not be imposed. The Secretary notified PIL, four days later by letter dated October 6, 2000, that "[w]e have carefully reviewed the materials your laboratory submitted on October 2, 2000 and determined that your laboratory has never come into compliance in correcting the deficiencies cited at the December 13, 1999 survey."

The Secretary notified PIL by letter dated October 17, 2000 that the submission was "entirely unacceptable as it failed to either address the deficiencies cited or to show that the alleged correction plan was every implemented." The sanctions were thereafter imposed in accordance with the schedule set forth in the September 22, 2000 notice, including the October 6, 2000 suspension of PIA's (sic) CLIA license.

In a letter dated November 7, 2000, from PIL's attorney, which was received by HCFA on November 20**,** 2001, PIL requested a hearing before an ALJ. In a letter dated November 21, 2000**,** HCFA requested that an administrative law judge be assigned to this administrative action. The matter was set for a hearing on January 22, 2001.

However, Plaintiffs refused to participate in an ALJ hearing. On or about January 18, 2000, PIL requested a continuance of the administrative hearing or, in the alternative, withdrawal of its request for a hearing. The administrative law judge issued an Order Dismissing the Case on January 23, 2001. This Order has become final.

III. discussion

a. Jurisdiction Over Federal Defendants

Plaintiffs previously brought a motion for a preliminary injunction which this Court denied in our January 25, 2001 Order. In opposition to Plaintiffs' motion for a preliminary injunction Defendants argued that this Court has no jurisdiction to grant equitable relief to the Plaintiffs because 42 U.S.C. § 263(a) (k) confers jurisdiction only upon the Circuit Court for appeal of final agency action under the CLIA. The Court found that "this Court has jurisdiction to grant Plaintiffs a preliminary injunction pending an ALJ hearing." See January 25, 2001 order.

Defendants now argue that, because Plaintiffs have declined to participate in any ALJ hearing and seek monetary rather than preliminary injunctive relief pending an ALJ hearing, that this Court no longer has jurisdiction over this matter. Defendants are correct.

42 U.S.C. § 263(a) (k) of the Clinical Laboratory Services Amendment of 1988 states, in relevant part: "[a]ny laboratory which ... has had its certificate suspended, revoked, or limited ... may, at any time within 60 days after the date the action of the Secretary …becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has it principle place of business for judicial review of such action." 42 U.S.C. § 263a(k).

It is uncontroverted that the provision is applicable here, and it is equally clear that, by its language, its grant of jurisdiction to the circuit court is not exclusive. There is no specific provision for alternative jurisdiction in the district court, although the district court has general subject matter jurisdiction.

The Defendants argue that even though the grant of jurisdiction in 42 U.S.C. § 263(a) (k) is not exclusive, the Ninth Circuit in Public Utility Commr. V. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir. 1985) mandates that this court read the permissive language as conferring exclusive jurisdiction on the circuit court. The Ninth Circuit in Bonneville Power stated that "where a statute commits review of final agency action to the court of appeals, any suit seeking relief that might affect the court's future jurisdiction is subject to its exclusive review." Id. Jurisdiction is exclusive in the Court of Appeals "even in the absence of an express statutory command of exclusiveness." Id. citing Central Lincoln Peoples Utility District v. Johnson, 735 F.2d 1101, 1109 (9th Cir. 1984) (Central Lincoln II); Assure Competitive Transportation, Inc. v. United States, 629 F. 2d 467, 470-72 (7th Cir. 1980),cert. denied, 449 U.S. 1124 (1981); Nevada Airlines, Inc. v. Bond, 622 F.2d 1017, 1020 (9th Cir. 1980); City of

Rochester v. Bond, 603 F. 2d 927, 935 (D.C. Cir. 1979); UMC Industries v. Seagorg, 439 f. 2d 953, 955 (9th Cir. 1971).

This Court acknowledged Bonneville Power in Plaintiffs' motion for a preliminary injunction but found Bonneville Power to be inapplicable to a request for a preliminary injunction pending an ALJ hearing because the Ninth Circuit would receive Plaintiffs' appeal from an ALJ hearing in the same posture as it otherwise would whether or not the district court granted temporary relief.

Although granting temporary relief would not affect the posture of this case before the Ninth Circuit, allowing Plaintiffs to proceed in this action would deprive the Ninth Circuit of the experrtise of the ALJ in this matter because Plaintiffs' appeal would, of course, be directly to the Ninth Circuit. Plaintiffs in this case, as the Plaintiffs in Bonneville Power attempted to do, seek to challenge agency proceedings on constitutional grounds in the district court. Bonneville Power provides that a statutory review mechanism providing for an ALJ hearing followed by an appeal within the agency, and subsequent appeal to the Ninth Circuit is Plaintiffs' exclusive remedy even if the statutory language is only permissive.

Therefore, this Court lacks jurisdiction over Plaintiffs, causes of action.

b. Exhaustion of Administrative Remedies

Previously, Defendants argued that the CLIA requires exhaustion of administrative remedies prior to judicial review of any kind - including a request for preliminary injunctive relief under the APA. This Court found, citing the United States Supreme Court in Darby v. Cisneros, 509 U.S. 137, 144-146 (1993), that federal courts have no authority to require plaintiffs to exhaust administrative remedies prior to seeking judicial review under the APA unless a statute or agency regulation specifically mandates exhaustion as a prerequisite to judicial review. As explained in Darby, "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by the agency rule as a prerequisite to judicial review." Id.

Although the judicially created doctrine of exhaustion cannot be applied to actions brought under the APA, "the exhaustion doctrine continues to apply as a matter of judicial discretion in cases not governed by the APA." Id. Therefore, in Bivens actions, a district court has discretion in its application of the judicially created exhaustion doctrine. See Stauffer Chemical Co. V. FDA, 670 F. 2d 106, 107 (9th Cir. 1982); SEC v. G.C. George Securities, Inc., 637 F. 2d 685, 687-88 (9th Cir. 1981) ; Reid v. Engen, 765 F. 2d at 1462;

United States v. California Care Corp., 709.F. 2d at 1248; Southeast Alaska Conservation Council, Inc. V. Watson, 697 F. 2d 1305, 1309 (9th.Cir. 1983); Aleknagik Natives Ltd. v. Andrus, 648 F. 2d 496, 500 (9th Cir. 1980).

The Ninth Circuit, in Montgomery v. Rumsfeld, 572 F. 2d 250, 252-53 (9th Cir. 1978), explained that exhaustion of administrative remedies was either "specifically required by statute" or "judicially developed." Id. In Montgomery, the Ninth Circuit stated that, in determining whether to apply the judicially developed doctrine of exhaustion "[t]he district judge should carefully weigh the need for an administrative record for proper judicial review, the agency's interests in applying its expertise, in correcting its own errors, and preserving the efficacy and independence of its administrative system, and particularly, the district court should carefully consider "whether allowing all similarly situated individuals to bypass the administrative avenue in question would seriously impair the agency's ability to perform its functions." Id. at 254.

In applying these factors, the Court finds that Plaintiffs must exhaust their administrative remedies and seek its appeals through the process described in 42 U.S.C. § 263(a) (k).

First, the Court finds that there is a significant need for an administrative record and a strong interest in the agency applying its expertise. Plaintiffs argues that the revocation of its license prior to an ALJ hearing was forbidden by 42 C.F.R. § 493.1840(d). Defendants argue that their revocation was proper because under, Section 493.1840 (d) , "the laboratory [had] refused a reasonable request for information or work an material." Deciding whether a laboratory has sufficiently complied with requests for information seeking to probe its safety and compliance with complex regulations is a task significantly better suited for an ALJ.

Second, allowing all similarly situated individuals to bypass the statutory procedures by refusing to attend an ALJ hearing significantly undermines the Clinical Laboratory Amendment of 1998, 42 U.S.C. § 263, which clearly states that violations of regulations promulgated under it should receive initial scrutiny by an ALJ. Therefore, even if the Court could properly exercise jurisdiction in this matter, it would require Plaintiffs to exhaust their administrative remedies before appealing an adverse decision as set forth in 42 U.S. C. § 263 (a) (k).

III. Conclusion

Defendants' motion to dismiss is granted.

IT IS SO ORDERBD.

DATED: *5/9/2001*

STEPHEN V. WILSON

UNITED STATES DISTRICT JUDGE

United States Attorney
STUART A. MINKOWITZ
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2925
SAM-2692

ORIGINAL FILED
JUN 1 8 2001

WILLIAM T. WALSH, CLERK

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,
Plaintiff,

v.

EDISON MEDICAL LABORATORY SERVICE CORPORATION,
Defendant.

Hon.

Civil Action No. 01-2872 [(k?)sh]

ORDER TO SHOW CAUSE AND TEMPORARY RESTRAINING ORDER (Fed. R. Civ. P. 65(a), (b); 42 U.S.C. § 263a(j) and 42 C.F.R. § 493.1846)

TO: KENNETH B. FALK, ESQ.
Deutch & Falk
843 Rahway Ave.
Woodbridge, NJ 07095-3699

THIS MATTER HAVING BEEN opened by the plaintiff, by and through its counsel, Robert J. Cleary, United States Attorney for the District of New Jersey (Stuart A. Minkowitz, Assistant U.S. Attorney appearing), upon an application for an Order to Show Cause and a Temporary Restraining Order, and the Court having considered the Complaint and the papers filed therewith, and it appearing to the Court that defendants continue to commit the acts specified in this Order, and that unless restrained by the Court, the defendants will cause a significant hazard to the public health before notice can be given and the defendant or defendant's attorney can be heard in opposition to the granting of a temporary restraining order, and for good cause having been shown; therefore

IT IS on this **18th** day of June, 2001 at **4:00** a.m/**[p.m,]**

ORDERED THAT:

1. Plaintiff's application for an Order to Show Cause and a Temporary Restraining Order be and is hereby granted.

2. Pursuant to 42 U. S.C. § 263 a(j) and 42 C.F.R. § 493.1846, and pending a hearing on the preliminary injunction, defendant, its owners, operators, employees, agents, representatives, successors or assigns, and all persons in active concert or participation with them are hereby restrained from operating a clinical laboratory, or soliciting or accepting materials derived from the human body for laboratory examination or other procedure without certification pursuant to the requirements of the Clinical Laboratories Improvement Amendments of 1988 ("CLIA") (Public Law 100-578), and as set forth in 42 C.F.R. § 493, et seq.

3. The foregoing temporary restraints shall remain in force until the close of business on the **2nd** day of **July**, 2001, or at such later date as may be set by the Court or agreed upon by the parties.

4. Defendants she show cause before this Court on the **2nd** day of **July**, 2001 at **2:00p.m**. why an Order granting a preliminary injunction in the form annexed hereto should not be granted.

5. Written opposition by defendant, if any, to plaintiff's application shall be filed with this Court and received by the United States Attorney on or before the **25th** day of **June**, 2001.

6. The plaintiff may file, and serve upon defendant, a reply to any opposition filed by defendant no later than the **29th** day of **June**, 2001. *by 12:00 pm*

7. True copies of this Order to Show Cause with Temporary Restraining Order, together with the other papers filed with this application shall be served upon defendant or their attorney within **I** days of the date of this Order, Service of these documents may be effected by sending the same via next-day mail or by hand delivery. a*nd by fax.*

8. Pursuant to 42 U.S.C. § 263a(j), the plamff need not post a bond.

HON.

UNITED STATES DISTRICT JUDGE

ROBERT J. CLEARY
United States Attorney
STUART A. MINKOWITZ
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2925
SAM-2692

ORIGINAL FILED
JUL l 6 2001

WILLIAM T. WALSH, CLERK

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,
Plaintiff,

Hon. Katharine S. Hayden

Civil Action No. 01-2872 (KSH)

v.

EDISON MEDICAL
LABORATORY SERVICE
CORPORATION,
Defendant.

CONSENT DECREE

WHEREAS, Plaintiff, the United States of America, on behalf of its agencies the Department of Health and Human Services and Centers for Medicare and Medicaid Services ("CMS") (formerly the Health Care Financing Administration ("HCFA")) (collectively "the Government"), having filed its complaint against the defendant, Edison Medical Laboratory Service Corporation ("EMLS"); seeking to permanently enjoin defendant, owners, operators, employees, agents, assigns and/or successors from violating the Clinical Laboratories Improvement Act Of 1967; Clinical Laboratories Improvement Amendments of 1988 ("CLIA") (42 U.S.C. § 263a(b) and (j) and its associated regulations (42 C.F.R. 493.1846); and

WHEREAS, the parties have engaged in discussions in an effort to resolve all issues raised by the Complaint; and

WHEREAS, the defendant has consented to entry of this Decree without contest and the Government has consented to the entry of this Decree; therefore,.

NOW, it is hereby ORDERED, ADJUDGED AND DECREED as follows:

1. The Court has subject matter jurisdiction over this ation under 28 U.S.C. § 1345, 42 U.S.C. § 263a(j) and 42 C.F.R. § 493.1946, and its general equity and ancillary jurisdiction.

2. Venue lies in the District of New Jersey under 28 US.C. § 1391(b) and (c) and 42 U.S.C. § 2634a(j), as the place where the claims arose and where the defendant's laboratory is located.

3. The Complaint states a valid claim against the defendant under CLIA.

4. Defendant does not contest the allegations contained in the Complaint.

5. Defendant, EMLS, and its owners, operators, employees, agents. assigns and/or successors, are hereby permanently enjoined and restrained from soliciting or accepting materials derived from the human body for laboratory examination or other procedure unless and until there is in effect for the laboratory a valid certificate issued by the Secretary of HHS under 42 U.S.C. § 263a. The permanent restraint includes, but is not limited to, (1) the diagnosis, prevention or treatment of any human disease or impairment, or (2) the assessment of the of health of any person, (3) procedures to determine, measure, or otherwise describe the presence or absence of substances or organisms in the human body, or (4) the taking of specimens or samples derived from the human body.

6. Defendant, its owners, operators, employees., agents, assigns and/or successors agree that HHS, CMS or New Jersey Department of Health and Senior Services, or their agents, may periodically inspect EMLS, unannounced, at any time during regular business hours to verify that the laboratory has not resumed diagnostic testing without a valid CLIA certificate. Defendant, its owners, operators, employees., agents, assigns and/or successors consent to such periodic inspections and acknowledge that they may be required to bear the cost of each inspection, if the defendant is found to be in violation of this Consent Decree.

7. In the event EMLS, its owners, operators, employees., agents, assigns and/or successors, violate any provision of this Consent Decree, upon notice by HHS, CMS or the New Jersey Department of Health and Senior Services, EMLS, it owners, operators, employees., agents, assigns and/or successors shall, within 10 days of receipt of such

notice, pay a penalty of $5, 000.00 per violation. In addition, EMLS, it owners, operators, employees., agents, assigns and/or successors, shall pay $500.00 per day for each day the violation continues beyond the date of the receipt of the notice of a violation. The penalties shall be made payable to the United States Department of Justice. This remedy is not in lieu of, but in addition to any other remedy available to the Government by statute, regulation or the common law, including an order for contempt. If EMLS, it owners, operators, employees., agents, assigns and/or successors disagree with the findings of HHS, CMS, or the New Jersey Department of Health and Senior Services, that there has been a violation of this Consent Decree, it shall be entitled to challenge such findings in this Court, but solely on the grounds that the violation did not occur and by demonstrating the nonoccurrence by a preponderance of the evidence.

8. Without leave of Court, the Government may take discovery reasonably calculated to determine whether persons or entities bound by this Consent Decree are in full compliance with the provisions of this Consent Decree.

9. If any person or entity bound by this Consent Decree fails to comply with any provision of this Consent Decree or is found in civil or criminal contempt thereof, that defendant shall, in addition to other relief, reimburse the Govenment for its reasonable attorney's fees, investigational expenses and costs.

10. Nothing in this Consent Decree shall be deemed to excuse defendant, it owners, operators, employees., agents, assigns and/or successors , from hereinafter complying with CLIA and the regulations promulgated thereunder, or any other obligations under applicable law or regulation.

11. If the present owners or operators of EMLS become affiliated as an owner, operator or otherwise, with any laboratory other than EMLS, or applies for a CLIA certificate on behalf of any laboratory, they must notify the Government within seven days, identifying the name, address, owners, officers and nature of the laboratory.

12. All notices and corespondence required by this Consent Decree shall be sent by first class mail to the parties at the following addresses, and, if possible, by facsimile unless otherwise indicated:

To the Government

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Jacob K. Javits Federal Bldg.
26 Federal Pza., Rm. 3809
Now York, NY 10278

With a copy to:

U.S. Department of Health and Human Services
Office of the General Counsel, Region II
Jacob K. Javits Federal Bldg.
26 Federal Pza., Rm. 3908
New York, NY 10278
Fax: (212) 264-6364

Chief, Civil Division
United States Attorney's Office
970 Broad St., Ste. 700
Newark, NJ 07102
Fax: (973) 297-2010

To the-Defendant

Kenneth B. Falk, Esq.
Deutch & Falk, P.C.
843 Rahway Ave.
Woodbridge, NJ 07095-3699
Fax: (732) 636-3575

Edison Medical Laboratory Services Corporation
1692 Oak Tree Pza.
Edison, NJ 08820

The parties will notify each other promptly upon any change in the above information.

13. This Consent Decree shall be binding upon defendant, it owners, operators, officers, agents, employees, lessess, assigns, successors in interest, and those persons who are in acitive concert or participation with them directly or indirectly.

14. The individuals executing this Consent Decree on behalf of EMLS represent that they are duly authorized to execute this Consent Decree on EMLS's behalf.

15. Nothing herein shall be deemed to limit the Government's ability to enforce CLIA and its regulations.

16. This Court shall retain jurisdiction for the purpose of enforcing or modifying this Consent Decree, and for the purpose of granting such addiional relief as may hereafter appear neccessary or appropriate.

17. With the exception of inspection costs outlined in paragraph 6, above, each party shall bear its own costs, including attorney's fees.

18. The Government reserves the right to seek costs, investigation and attorney's fees against defendant, its owners, operators, employees, agents, assigns, and/or successors, should defendant violate the terms and conditions of this Consent Decree.

19. If any provision of this Consent Decree is declared invalid, such declaration shall not effect the validity of any other provision herein.

IT IS SO ORDERED,

Dated: *7/6/01*

HON. KATHARINE S. HAYDEN
United States District Judge

AGREED AND CONSENTED TO:

For the Plaintiff, United States of America

ROBERT J. CLEARY
United States Attorney
District of New Jersey

By: STUART A. MINKOWITZ
Assistant U.S. Attorney

Dated: *7/2/01*

For theDefendant, Edison Medical Laboratory Service Corporation

DEUTCH & FALK, P.C.

By: Kenneth B. Falk, Esq.
Attorney(s) for Edison Medical Laboratory Service Corporation

Dated: *6/28/01*

EDISON MEDICAL LABORATORY
SERVICE CORPORATION

By:
Name: Edison Medical Laboratory Services Corporation
Title: President

Dated: *6/26/2001*

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT Of MICHIGAN

SOUTHERN DIVISION

PREFERRED FAMILY MEDICINE, P.C.
A Michigan Professional Corporation,
MARC WEISMAN, D.O. and
JASON TALBERT, M.D.

Case No-. 01 -72447

v. Honorable Victoria A. Roberts

TOMMY G. THOMPSON, SECRETARY OF HEALTH
AND HUMAN SERVICES, and THOMAS SCULLY,
ADMINISTRATOR OF THE CENTERS FOR
MEDICARE AND MEDICAID SERVICES, formerly
known as the Health Care Financing Administration

OPINION & ORDER DENYING PLAI ITIFF'S MOTION FOR

INJUNCTIVE RELIEF AND REQUEST FOR DECLARATORY

JUDGMENT AND MANDAMUS, AND GRANTING

DEFENDANTS' MOTION TO DISMISS

I. Introduction

This matter is before the Court on Plaintiff s' Verified Complaint for Declaratory Judgment, Mandamus and Injunctive Relief, as well as their Motion for a Temporary Restraining Order and Preliminary Injunction pursuant to Fed. R. Civ. P. 65(a) and (b).

Plaintiffs contend that they are entitled to injunctive relief in order to prevent Defendants from canceling Preferred Family Medicine's ("PFM") approval to receive Medicare payments for its laboratory services. This cancellation went into effect or, July 2, 2001, pursuant to 42 C.F.R. § 493.1808(a), 493.1842(o) (1) and 493.1844(d) (3). Additionally, Plaintiffs are requesting injunctive relief to prevent the revocation of their CLIA ("Clinical Laboratory Improvement Amendment") Certificate of

Accreditation. Plaintiffs maintain that if either of these two events occur, it would effectively force the closure of PFM's laboratory and cause irreparable harrn to Plaintiffs and numerous Medicare and other patients. Plaintiffs also seek declaratory relief and relief in the form of a writ of mandamus.

Secondly, Plaintiffs argue that this Court has subject matter jurisdiction even though they have not exhausted their administrative remedies prior to judicial review, as required by 42 U.S.C. § 405(h). Plaintiffs state that the waiver exception under 42 U.S.C. § 405(g) applies to their factual circumstances, thus giving this Court jurisdiction.

Defendants' response is two-fold. First, they assert that this Court does not have subject matter jurisdiction, thereby requiring the dismissal of Plaintiffs' claim without reaching the merits. Defendants also maintain that Plaintiffs are not entitled to a writ of mandamus or declaratory relief because the facts and circumstances of this case do not warrant such extraordinary relief.

Second, if this Court reviews Plaintiffs' Motion on the merits. Defendants argue that Plaintiffs are not entitled to injunctive relief because this matter does not meet the requisite factors before injunctive relief con be granted.[1]

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(1) whether the movant has a "strong" likelihood of success on the merits;

(2) whether the movant would otherwise suffer irreparable injury; (3) whether

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Defendants claim that: (1) nonpayment of Medicare claims for laboratory services is not irreparable harm; (2) the public interest would be disserved by requiring the Secretary to continue Medicare payments to a laboratory that engaged in such serious misconduct with respect to the handling of proficiency testing samples; and, (3) the balance of the equities weighs against granting injunctive relief.

For the reasons set forth below, Plaintiffs' Motion for Injunctive Relief is **DENIED**, Plaintiffs' request for declaratory judgment and mandamus is **DENIED**; and, Defendants Motion to Dismiss is **GRANTED**.

II. Background

A. The Parties

PFM provides family/primary care physician services including laboratory testing. Plaintiffs, Drs. Weisman and Talbert, are practicing physicians with PFM and are also the President and Director,

respectively, of PFM. Defendant, Secretary Health and Human Services, through the Centers for Medicare and Medicaid Services (CMS - a component of the Department of Health and

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issuance of a preliminary injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of a preliminary injunction. *United Food & Commercial Workers Union,* Local *1099 v. Southwest Ohio Regional Transit Auth.,* 163 F.3d. 341, 347 (6th Cir. 1998)

Human Services)[2] is responsible for operating the Medicare Program and is statutorily empowered with enforcement authority for the regulations regarding clinical laboratories. Defendant, Administrator of CMS, is responsible for the administration of the Medicare Program and shares responsibility for the proposed actions by CMS against Plaintiffs which are at issue here.

B. PFM Accreditation

As a clinical laboratory, PFM is required to comply with the provisions of the Social Security Act and with CLIA regulations. PFM is entitled to payment from Medicare for medically necessary, covered laboratory services it renders to its Medicare patients so long as PFM is deemed to be compliant with the above referenced statutory law. In order to assist in the compliance with and enforcement of the CLIA requirements, CMS has approved COLA (formerly the Commission on Office Laboratory Accreditation) as an accreditation organization for laboratories under the CLIA program.

Prior to such approval, HCFA conducted a detailed and in-depth comparison on COLA's requirements[3] for its laboratories to those of CLIA and

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[2] CMS was formerly known as the Health Care Financing Administration (HFCA).

[3] The COLA Accreditation Manual was created to inform persons involved with laboratory medicine how COLA works. The Manual also includes the following references to the CLIA and HCFA: (1) "COLA has been approved by the federal government as a private non-profit accrediting organization for CLIA purposes;" (2) "COLA accreditation has been deemed by the federal government to be equivalent to the CLIA regulations. (3) 'Deeming authority' (i.e.,

dermined that it should grant approved status to COLA as a private nonprofit organization for accrediting laboratories under CLIA for specific specialty or subspecialty areas of human specimen testing.[4]

On July 31, 1992, HCFA issued a final rule (57 FR 33992). Under section 353(e)(2) of the Public Health Service Act (PHSA), HCFA may approve a private nonprofit organization to accredit clinical laboratories (an "approved accreditation organization") under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program if the organization meets certain requirements.

An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 Code of Federal Regulations (CFR), part 493 (Laboratory Requirements). Therefore, a laboratory accredited by an approved

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equivalent standard) is a COLA status recognized by HCFA; (3) Laboratories accredited by COLA are 'deemed' to meet the government standards; and COLA-accredited labs are not routinely inspected by the government; (4) "As a result of being granted deeming authority, some COLA criteria now mirror federal CLIA requirements;" (5) Once a laboratory applies to COLA for accreditation, HCFA recognizes the lab as a COLA-accredited laboratory; and (7) Although it's useful to see the relationship between the COLA and CLIA standards, COLA-accredited laboratories are quartered to meet COLA standards, not CLIA. *COLA* Accreditation *Manua[, §3*

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[4] Baciedology, mycobacteriology, mycology, parasitology, virology, syphilis serology, general immunology, routine chemistry, endocrinology, toxicology, urinalysis, and hematology, immunohematology.

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accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) of part 493 specify the requirements an accreditation organization must meet to by an approved accreditation organization. HCFA approves an accreditation organization for a period not exceed 6 years. 65 FR 64966.

In establishing laboratory compliance with CLIA requirements, COLA must, among other conditions and requirements (1) use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by CMS; (2) apply standards and criteria that are equal to or more stringent than CMS requirements; (3) provide reasonable assurance that these standards and

criteria are continually met by its accredited laboratories; (4) provide CMS with the name of any laboratory that had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action; (5) notify CMS in writing at least 30 days before the effective date of any proposed changes in its standards; and, (6) if CMS withdraws its approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal. *65 FR* 64966 (October *31, 2000).* COLA's requirements for PT are equivalent to those of CLIA. ld.

C. September 3,1999 COLA Letter to PFM

In a letter dated September 3, 1999 PFM was first notified by COLA of a pending denial of COLA accreditation due to PFM's complicity in proficiency test (PT) averaging, resulting in an improper referral, collaboration, and integration at PFM's laboratory in 1998 and 1999. (See September 3, 1999 Letter from COLA to Plaintiff Talbert attached to Plaintiffs' Verified Complaint as Exhibit B). Upon receipt of the Letter, Plaintiffs Weisman and Talbert contend that they conducted an immediate investigation into the allegations by COLA and learned that while PFM's laboratory technician, Marilyn Nichols, had properly tested the proficiency of PFM's laboratory as required by COLA and CLIA, she had averaged the test results with test results she had obtained at two other laboratories where she worked. She then reported the averaged test results to Medical Laboratory Evaluation (MLE), a COLA and CMS approved proficiency test program.

On or about October 19,1999, COLA denied PFM's COLA accreditation based upon "knowingly comparing results of proficiency test prior to the proficiency test program end-date for receipt of the results." (See October 19, 1999 letter from COLA to Plaintiff Talbert attached to Plaintiffs' Verified Complaint as Exhibit). At some point after the PT averaging discovery, Plaintiffs terminated Marilyn Nichols and hired Lawrence S. Michaelski, a certified chemist with over thirty years of clinical laboratory experience and the Chemistry Supervisor of Crittenton Hospital in Rochester, Michigan. After hiring Mr. Michaelski, Plaintiffs designed and implemented a Quality Assurance Program which has been in place at PFM since January 2000. Plaintiffs submitted proof of their remedial efforts to COLA and requested a reconsideration of the denial of COLA accreditation. Ultimately, after a hearing on February 19, 2000, the COLA Accreditation Committee voted to reverse the initial decision to deny accreditation (reversal "constitutes the final action of the Accreditation Committee") and notified Plaintiffs in a letter dated March 3, 2000. (See March 3, 2000 letter from COLA to Plaintiff Tolbert attached to Plaintiffs' Verified Complaint as Exhibit J). From early March 2000 until the present, Plaintiffs allege that PFM has been fully compliant with all applicable CLIA and COLA requirements.

Defendants have not presented any evidence to the contrary. Plaintiffs further allege that during an on-site survey at PFM in April 2001, no new deficiencies were noted[5]; only the violation of which PFM was notified by COLA in September of 1999, and determined by COLA in March 2000 not to warrant the revocation of the laboratory accreditation.

D. May 29, 2001 CMS Letter to PFM

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[5] On April 10, 2001, a complaint investigation survey was conducted by Lucy Estes, CLS, MSA, who is a laboratory evaluation specialist and employed by the Michigan Department of Consumer and industry Services (MDICS), Laboratory Improvement and Special Projects Section. (Declaration of *Lucy Estes, CLS, MSA)*

Despite this compliance, Quality Assurance Program and "final action of the Accreditation Committee" to not deny accreditation, based on the 1998 and 1999 testing events, Plaintiffs were informed in a letter dated May 29, 2001 from HCFA (CMS) that the Michigan Department of Consumer and Industry Services (MDCIS) conducted a complaint investigation survey at PFM on April 10, 2001 to determine whether "improper referral, collaboration, and integration occurred at PFM's laboratory during proficiency testing events of 1998 and 1999." (See May *29, 2001* letter from HCFA *to Plaintiff Talbert attached to Plaintiffs' Verified* Complaint *as Exhibit K).*

In the May 29, 2001 letter, HCFA (CMS) alleged that PFM'S laboratory was not in compliance with CLIA as a result of an "improper referral, collaboration, and non-integration [which] occurred during specific 1998-1999 testing events;" and, therefore, PFM was deemed non-compliant with 42 C.F.R. § 493.1441, 493.61 (b) (1); and 493.801 (b) (3) and 42U.S.C.§ 263a(d) (1) (E). Consequently, certain penalties were imposed: (1) cancelling PFM's laboratory's approval to receive Medicare payment for services effective July 2, 2001; and (2) the future revocation of PFM's CLIA Certificate of Accreditation.

E. Procedural Process Undertaken By Plaintiffs In Response To The May 29, 2001 Letter

On June 14, 2001, Plaintiffs presented their request to Defendant Secretary of Health and Human Services to reverse CMS' determination to impose these additional sanctions upon PFM. (See *Plaintiffs' Verified* Complaint, pg. 13, ¶*46).* Plaintiffs allege that they have no idea when the procedural process will get underway. Plaintiffs allege that they requested an expedited hearing with the Administrative Law Judge (ALJ) on June 18, 2001, and were told by Jacqueline Williams, Chief of the Civil Remedies Division at CMS, "it happens [the hearing] when it happens." Id. *at* ¶*47.* On June 27, 2001, Plaintiff filed a request for a hearing before an ALJ of the Department of Health and Human Services pursuant to 42 C.F.R. § 493.1844. Id. *at* ¶*48.*

F. Pendency ot ALJ Hearing

Plaintiffs acknowledge that revocation of PFM'S CLIA Certificate of Accreditation will not take effect until a decision is rendered by the ALJ of the Department of Health Services pursuant to 42 C.F.R. § 493.1844(d)(2). However, the effective date of the cancellation of PFM's approval to receive Medicare payment for its laboratory services, July 2, 2001, was prior to any opportunity for an ALJ decision. Moreover, Defendants are permitted to publish in a local newspaper and in the laboratory registry, information about PFM and its directors being sanctioned. 42 C. F. R. § 1844 (g) (1).

G. The CMS Complaint lnvestigation

CMS imposed its sanction determination based on a complaint investigation survey performed at Plaintiffs' laboratory by the MDCIS at CMS's request. CMS requested the survey of PFM after inspections by MDCIS of two

other Detroit-area laboratories employing the same laboratory technician for proficiency testing as PFM (Marilyn Nichols). This investigation uncovered the alleged prohibited referral and/or collaboration of PT results. PFM was identified as the third laboratory involved in this alleged unlawful conduct detailed above which occurred in 1998 and 1999. (See *Declaration of Richard J.* Benson ¶ 9-18 attached to Defendants' Memorandum of Low *in* Opposition *to Plaintiffs'* TRO *Motion as Exhibit 1).* It is important to point out that COLA had an obligation to notify CMS in September 1999 when it made the decision to deny accreditation to PFM. 65 *FR* 64966 (October 31, 2000). Plaintiffs have presented no evidence that COLA did that, and Defendants state that COLA did not notify CMS about its withdrawal of Plaintiff' accreditation status. (Defendants' Motion to *Dismiss, pp. 7-12).*

III. Standard of Review

A. Subject Matter Jurisdiction

Pursuant to Federal Rule of Civil Procedure 12(b) (1), when "considering a motion to dismiss for lack of subject matter jurisdiction, the person asserting jurisdiction bears the burden of showing that the case is properly before the court at all stages of the litigations." *Fed. Realty Inv. Trust v.* Juniper Props. *Group*, No. 99-3389, 2000 WL 45996, at 3 (E.D.Pa.2000) (citing Packard *v. Provident Nat'l Bank, 994* F.2d 1*039, 1045 (3d Cir. 1993), cert.* denied, 51 0 U.S. 964, 114 S.Ct. 440, 126 L.Ed.2d 373 (1993)). The district court, when reviewing a motion to dismiss for lack of subject matter jurisdiction, "must accept as true the allegations contained in the plaintiff's complaint, except to the extent federal jurisdiction is dependent on certain facts." Id. *(citing Hoydo v. Amerikohl Mining,* Inc., 830 F.2d 494, 496 (3d Cir. 1987)).

The district court is not confined to the face of the pleadings when deciding whether subject matter jurisdiction exists. Id. *(citing Armstrong World Indus.* v. *Adams,* 961 F.2d 405, 410, n. 10 (3d Cir.1 992)). "in assessing a Rule 12 (b) (1) motion, the parties may submit and the court may consider affidavits and other relevant evidence outside of the pleadings." *Id. (citing Berardi v.* Swanson Mem'l Lodge No. *48 of Fraternal Order* of Police, 920 F.2d 198, 200 (3d Cir. 1 990)). In the case where the defendant attacks jurisdiction with supporting affidavits, "the plaintiff has the burden of responding to the facts so stated." Id. "A conclusory response or a restatement of the allegations of the complaint is not sufficient." Id. *(citing lnt'i Ass'n* of Machinists & Aerospace Workers v. *Northwest Airlines,* Inc., 673 F.2d 700, 711 (3d Cir. 1982)).

IV. Finding of Fact

For purposes of resolving the issues before the Court, the following are accepted as fact:

1. While COLA is an approved accreditation organization for laboratories under the CLIA program, CMS reserves the right to conduct validation and complaint investigation surveys in order to ensure compliance with CLIA requirements. 65. *FR 64966.*

2. The language in the COLA Accreditation Manual conflicts with 65 FR 64966 (October 31, 2000) to the extent that in the COLA Manual, CMS appears to confer full authority upon COLA to work through noncompliance issues. However, in the Federal Register, it is recognized that although a COLA accreditation "provides reasonable assurance that the laboratories accredited by it meet the conditions required by CLIA law and regulations," these accredited laboratories remain subject to federal validation and complaint investigation surveys. Id.

3. COLA cited PFM for PT Violations and denied PFM an accreditation as a result. After reconsideration by COLA and implementation of a Plan of Correction which has been followed by PFM, CMS was never notified in accordance with 65 FR 64966 by COLA about PFM's alleged PT deficiencies and the process that followed.

4. If COLA had given CMS notice of its accreditation activity with PFM, CMS would have been able to begin its investigation sooner, especially since CMS was already investigating two other Detroit laboratories which also had PT deficiencies and which also employed Marilyn Nichols.[6]

[6] Accredited laboratories (i.e., COLA) are obligated pursuant to 65 FR 64966-01 to "[p]rovide HCFA with the name of any laboratory that has had its accreditation denied, suspended, withdrawn limited, or revoked within 30 days of the action taken.

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5. CMS and COLA View the issue of "intent" differently when determining whether a laboratory should be held responsible for "knowingly comparing results of proficiency tests prior to the PT program end-date for receipt of results."

6. In reversing itself, COLA did not impute the actions of PFM's laboratory technician to the laboratory director. On the other hand, CMS holds the laboratory and its director accountable for all business activity related to the functioning of the laboratory.

V. Conclusions of Law

A. Subject Matter Jurisdiction

The express language of 42 U.S.C. § 405(h) bars district court jurisdiction over an action to compel payment of Medicare reimbursement because the

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[7] During the COLA investigation process, it determined that "the knowledge of the lab technician should not be imputed to the laboratory itself," *(Exhibit* J of *Plaintiffs' Verified.Compliaint for* Declaratory *Judgment, Mcindamus and Injunctive Relief).* Conversely, CMS imputes the actions of a laboratory technician upon the laboratory director and the laboratory itself by indicating that "as laboratory director, [you] have not fulfilled your responsibility of assuring that PT samples are tested as required under 42 CFR 493, subpart H. The deficiencies noted in this letter and the HCFA-2567 demonstrate that you have failed to fulfill your responsibility for the overall operation and administration of your laboratory. Therefore, the *condition* level *requirement for* a laboratory director *is out* of compliance *at 42* CFR § 4930.1441." Exhibit K of Plaintiffs' Verified Complaint for Declaratory Judgment, Mandamus and Injunctive Relief).

Medicare Act requires exhaustion of administrative remedies before judicial review.

Since Plaintiffs' claim arises under the Medicare Act, the general rule is that this Court does not have subject matter jurisdiction. *Shalala V. Illinois Couvncil* on Long *Term* Care, Inc. 529 U.S. 1. 10 (2000); *Heckler v. Ringer, 466* U.S. 602 (1984); *Weinberger v. Salfi,* 422 U.S. 749 (1975); *Cathedral Rock of North* College *Hill v.* Shalala, 223 F.3d 354 (6th Cir. 2000); *Michigan Association of* Homes and

Services for *the Aging v. Shalala,* 127 F.3d 496, 500-01 (6th Cir. 199*7); Monakee* Professional Medical *Transfer* Service, Inc. v. *Shalala, 71* F.3d 574 (6th Cir. 1995); *Farkas v. Blue Cross & Blue* Shielct of *Michigan,* 24 F.3d 853 (6th Cir. *1994); Livingston* Care Center *v.* United States, 934 F.2d 719, 721 (6th Cir.), cert. denied., 502 U.S. 1003 (1991).

Having concluded that this Court lacks subject matter jurisdiction, it is unnecessary and inappropriate, for the Court to reach the other issues raised by Plaintiffs.

Conclusion

Even though this Court finds in favor of Defendants, the Court is troubled that the law allows COLA to make determinations concerning violations; communicate with PFM about the problem; and, work out a Corrective Plan, yet CMS can enter the picture over a year later and, in effect, vitiate COLA's entire investigation and efforts to reinstate accreditation for P FM, which has remained in compliance with CLIA requirements. There are several references in the Federal Register as to how comparable and "equivalent" COLA accreditation standards are to those of CLIA.[8]

However, the law also seems to allow CMS to completely ignore the COLA finding and the Corrective Plan that is in place, as well as impose stiffer sanctions for the some conduct in however long a time frame it desires.

This Court finds that PFM justifiably believed that it had resolved its accreditation problems based upon the fact that it had been in compliance with its Corrective Plan for over a year; and, because COLA represented its

actions to be final.

Therefore, it is unfortunate that PFM, must in effect, be subjected to the entire validation and complaint investigation all over again.

However, the Court finds that, despite the apparent inequity of the matter, the express language of 42 U.S.C. § 405(h) and the above cited case low bars

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[8] COLA has been approved as an accreditation organization for laboratories under the CLIA prograrm; COLA requirements for PT are equivalent to those of CLIA according to the Federal Register; accreditation and approval of a laboratory by COLA meets the applicable CLIA condition level requirements for laboratories as indicated in the Federal

Register; COLA has complied with the requirements under CLIA for approval as an accreditation organization according to the Federal Register; COLA's requirements are equal to the CLIA requirements; and COLA's laboratory enforcement and appeal policies are essentially equivalent to the requirements of the Federal Register as they apply to accreditation organizations.

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this Court from compelling payment of Medicare reimbursement, under either 28 U.S.C. § 1 331 or 28 U.S.C. § 1346. Therefore, upon consideration of the Verified Complaint and motions and briefs of the parties, it is hereby **ORDERED** that Plaintiffs' Motion for Temporary Restraining Order & Preliminary Injunction [**Doc. # 2-1**] is **DENIED**.

IT IS fURTHER ORDERED THAT this Court is without subject matter jurisdiction and that accordingly, Defendants' Motion to Dismiss [**Doc. #6-1**] is **GRANTED**.

IT IS FURTHER ORDERED THAT Plaintiffs' request for declaratory relief and request for a mandamus action in Plaintiffs' Verified Complaint [**Doc. #1 –1**] is **DENIED**.

IT IS SO ORDERED.

Victoria A. Roberts

United States District Judge

DATED: **JUL 31 2001**

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

PREFERRED FAMILY MEDICINE, P.C.,
a Michigan Professional Corporation,
MARC WEISMAN, D.O. and
JASON TALBERT, M D.,

Plaintiffs

vs

Case No: 01-72447

Honorable Victoria A. Roberts

TOMMY G. THOMSON, SECRETARY OF HEALTH AND HUMAN SERVI'CES and THOMAS SCULLY, ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, formerly known as HEALTH CARE FINANCING ADMINISTRATION.

Defendants.

SUPPLEMENTAL OPINION & ORDER DENYING PLAINTIFFS' MOTION FOR INJUNCTIVE RELIEF AND REQUEST FOR DECLARATORY JUDGMENT AND MANDAMUS, AND GRANTING DEFENDANS' MOTION TO DISMISS

1. Introduction

On July 31, 2001, this Court entered an Order denying Plaintiff s Motion for Temporary Restraining Order & Preliminary Injunction. The Court also denied Plaintiff's request for declaratory relief and request for a mandamus action. Accordingly, Defendant's Motion to Dismiss was granted. Upon review of the July 31, 2001 Opinion and Order, the Court finds that clarification is warranted concerning the issue of whether the factual circumstances of this case come within the exception to the general rule

that district courts do not have original subject matter jurisdiction over claims arising under the Medicare Act. The Court found that this matter did not fall within the exception, thus precluding this Court from having subject matter jurisdiction rule upon the issues presented by Plaintiff. The rationale of the Courts ruling on this issue is detailed below.

II. applicable Law & Analysis

A. Subject Matter Jurisdiction

Plaintiffs argue that this Court has subject matter jurisdiction of this matter, even though they admittedly have not exhausted their administrative remedies prior to judicial review as required by 42 U.S.C. § 405(h). Plaintiffs state that the waiver exception under 42 U.S.C. § 405(g) applies to their factual circumstances, thus giving this Court jurisdiction.

Defendants' response is that this Court does not have subject matter jurisdiction to hear this matter, thereby requiring the dismissal of Plaintiff s claim without reaching the merits.

The express language of 42 U.S.C. § 405(h) bars district court jurisdiction over an action to compel payment of Medicare reimbursement because the Medicare Act requires exhaustion of administrative remedies before judicial review. Since Plaintiff's claim arises under the Medicare Act, the general rule is that this Court does not have subject matter jurisdiction. *Shalala v. Illinois Council on Long Term Care, Inc*. 529 U.S. 1, (?)0 (2000); *Heckler v. Ringer*, 466 U.S. 602 (1984); *Weinberger v. Salfi*, 422 U.S. 749 (1975); *Cathedral Rock of North College Hill v. Shalala*, 223 F.3d 354 (6th Cir. 2000); *Michigan. 4ssociation of Homes* and *Services for* the Aging v. *Shalala*, 127 F.3d 496, 500-01 (6th Cir. 1997); Manakee *Professional Medical Transfer Service, Inc. v. Shalala,* 1 F 3d 574 (6th Cir. 1995); *Farkas v. Blue Cross & Blue Shield of Michigan*, 24 F.3d (?)53 (6th Cir. 1994); *Livingston Care Center* v. *United States,* 934 F.2d. 719, 721 ((?)th Cir.), *cert. denied*., 502 U.S. 1003 (1991).

Based upon the evidence presented, Plaintiffs have not met the waiver requirements set forth in *Matthews v. Eldridge*, 424 U.S. 319 (1976). Pursuant to *Matthews* and its progeny, the exhaustion of administrative remedies may be waived where the plaintiff: (1) raises a colorable constitutional claim collateral to the substantive claim of entitlement (2) shows that irreparable harm would result from exhaustion; and (3) shows that the purposes of exhaustion would not be served by requiring further administrative procedures, i.e., futility. *Matthews*, at 330-31.

First, this Court finds that Plaintiff s Verified Complaint does not raise any colorable constitutional claim, and especially not one “wholly collateral to a claim for benefits." *Id*. Plaintiffs' claim is squarely one for continued Medicare payments. It is well settled that procedures that provide for a hearing before an administrative law judge after the effective date of a determination which cancels Medicare payments, meet the requirements of due process. See *Cathedral Rock, supra* (termination of nursing home's provider agreement); Lavapies *v. Bowen*, 883 F.2d 465 (6th Cir. 1989) (exclusion of physician from Medicare participation); *Nothlake Community Hospital v. United States*, 654 F.2d 1234 (7th Cir. 1981) (termination of Hospital Medicare provider agreement).

Plaintiff’s attempt to rebut this by claiming that administrative res judicata applies in this case because COLA already conducted an investigation, instituted discipline and assisted in implementing a Corrective Plan. Therefore, Plaintiffs contend that to repeat this process with CMS for the same alleged wrongful conduct. would in effect be res judicata. Since this Court finds as a matter of fact that COLA is not an administrative arm of CMS and has no authority over CMS. COLA’s findings are immaterial to CMS' present complaint investigation.

Since this Court finds that there is no colorable constitutional claim, Plaintiffs' ability to come within the *Matthews* exhaustion exception and 42 U.S.C. § 405(g) is not possible. However, this Court further finds, addressing the second prong of the waiver exhaustion requirement, that Plaintiffs have not shown that they will be irreparably harmed if a temporary restraining order is not put into place. Plaintiffs claim that their business will likely fold; and, as a result their patients will be harmed due to the potential severance of the physician/patient relationship. Moreover, Plaintiffs allege that they will lose a significant amount of money if they do not receive Medicare payments. Finally, Plaintiffs maintain that they will suffer irreparable harm in the form of damage to their reputation, based upon the publication of the sanctions.

The Sixth Circuit has concluded that injuries stemming from stoppage of Medicare payments are avoidable, and thus not irreparable. *Livingston*, 934 F.2d at 721. Subsequently, thie Sixth Circuit stated that such injuries are not necessarily irreparable even if they force a health care provider out of business. *Manakee*, 71 F.3d at 581. Regarding the physician/patient relationship harm, this Court agrees with Defendants in that such a claim is speculative and such claims do not constitute irreparable harm.

War(ner?) v. *Central Trust Co.*, 715 F.2d 1121, 1123 (6th Cir. 1983). Finally, regarding the harm to Plaintiffs' reputation, courts have recognized that Plaintiffs have an opportunity to clear their names through the administrative appeal process. *A(?)nett v. Kennedy*, 416 U.S. 134, 157 (1974).

Thus, the Court finds that Plaintiffs have not shown that exhausting administrative remedies would be futile or that it would not serve the purpose of the exhaustion requirement.

As a result of the foregoing, this Court finds that it is bound by 42 U.S.C. § 405(h) and that Plaintiffs do not come within the exception under 42 U.S.C. § 405(g). Consequently, this Court does not have subject matter jurisdiction. The Court's July 31, 2001 Order is affirmed as clarified.

IT IS SO ORDERED.

Victoria A. Roberts
United States District Judge

Dated: **AUG 2 8 2001**

Bethesda PDF – Page 1 Only

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Departmental Appeals Board

Civil Remedies Division

In the Case of:	)	
	)	
Bethesda Pathology Clinical, Inc.,	)	Date: FEB - 3 2004
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-03-566
	)	
Centers for Medicare & Medicaid Services.	)	
	)	

DISMISSAL

Petitioner's request for hearing dated May 22, 2003, is dismissed pursuant to 42 C.F.R. § 70(b). The hearing scheduled to take place January 29 -30, 2004, in Los Angeles, California is cancelled.

I. PROCEDURAL HISTORY

On June 12, 2003, a dismissal for untimely filing of the request for hearing was issued in a case entitled *Roy Hollins/Western Reference Laboratory*, DAB CR1055. As a result of that dismissal, the Centers for Medicare & Medicaid Services' (CMS) determination that the Western Reference Laboratory (WRL) was not in compliance with CLIA requirements to the extent of immediate jeopardy to laboratory customers remained in place. Accordingly, CMS's proposed sanctions against WRL were imposed. These sanctions included a civil money penalty, a directed plan of correction, cancellation of Medicare payments, and suspension and revocation of WRL's CLIA certificate. *Roy Hollins/Western Reference Laboratory*, DAB CR1055 (2003).

CMS had determined previously that Roy Hollins was an owner of WRL at the time its CLIA certificate was revoked. On September 17, 2002, CMS notified Mr. Hollins that, as a result of the action taken against WRL, Mr. Hollins could not own, operate or direct any laboratory until at least August 6, 2004. CMS Ex. 1. CMS also asked Mr. Hollins to

FILED

United States Court of Appeals

Tenth Circuit

June 2, 2009

Elisabeth A. Shumaker

Clerk of Court

PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

WADE PEDIATRICS,

Petitioner,

v.

DEPARTMENT OF HEALTH AND

HUMAN SERVICES, CENTERS FOR

MEDICARE AND MEDICAID

SERVICES,

Respondent.

No. 08-9529

Petition for Review from the Departmental Appeals Board

of the Department of Health and Human Services

App. Div. Docket No. A-08-06

Decision No. 2153

Sarah J. Glick, Scoggins & Cross, PLLC, Oklahoma City, OK (Linda G. Scoggins with her on the briefs), for Petitioner.

G. Dirk Rozendale, Assistant Regional Counsel, Department of Health and Human Services, Dallas, Texas (Thomas R. Barker, Acting General Counsel, and Katherine W. Brown, Acting Chief Counsel, with him on the brief), for Respondent.

Before **LUCERO, O'BRIEN,** and **GORSUCH**, Circuit Judges.

GORSUCH, Circuit Judge.

From time to time, labs federally certified to analyze human specimens must take proficiency tests to ensure their reliability and accuracy. On two such tests, Wade Pediatrics checked its answers with those of another lab before submitting its results to the government. The problem is that the government's proficiency testing program seeks to assess the competency of each lab's independent work. Sharing answers defeats the purpose of the exercise. Even more pointedly, sharing answers violates the clear and unambiguous terms of a federal statute. In response to Wade's statutory violation, the government suspended its certificate for one year. We deny Wade's petition for review of that decision.

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Labs like Wade must meet certain federal standards in order to be certified

to conduct diagnostic tests on human specimens (blood, tissue, and the like), and to receive Medicare or Medicaid reimbursement for their services. These standards are embodied in the Clinical Laboratory Improvement Amendments of 1988 ("CLIA" or "the Act") and its implementing regulations. *See* 42 U.S.C. § 263(a); 42 C.F.R. Part 493. Among other things, certified labs must participate in periodic quality control proficiency tests.

Wade's troubles began in 2005 when it flunked portions of two proficiency tests. In response, a field investigator for the Centers for Medicare and Medicaid Services ("CMS") advised Wade "that it would be beneficial" for the lab "to

receive training and comparison testing of the[ir] equipment from another" certified lab, such as the nearby Muskogee Regional Medical Center. Wade followed up on this recommendation, arranging to receive training and technical support from Muskogee.

In February 2006, Wade took another proficiency test. This time, instead of testing the proficiency testing samples in Wade's own lab, a technician first took the samples to Muskogee and tested them on Muskogee's equipment. Only then did the technician return the samples to Wade's lab and run tests on them there. The purpose of all this was apparently to double-check Wade's results to ensure their accuracy before submitting anything to the government.

As yet unaware of Wade's conduct in connection with the February 2006

proficiency test, in March 2006 the government notified Wade that it was temporarily restricting the scope of its certificate based on its 2005 problems. In due course, Wade submitted a remedial plan to CMS promising to correct its errors and adding that, toward this end, it was already engaging in training and consultation with Muskogee's staff. Wade added that it would "continue internal proficiency testing with assistance and support/guidance" from Muskogee. When CMS sent Wade yet another set of proficiency testing samples in May 2006, Wade again checked its test results against results achieved in Muskogee's lab before submitting its answers to the government.

Eventually, CMS got wind that Wade had twice tested its proficiency testing samples at another lab before submitting its results. CMS responded by revoking Wade's certificate for one year, citing as authority for its actions 42 U.S.C. § 263a(i)(4), which provides that "[a]ny laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year. . . ." Wade unsuccessfully challenged the revocation of its certificate before an ALJ, and then before the Departmental Appeals Board ("DAB") of the Department of Health and Human Services.

Failing to obtain relief in the administrative context, Wade petitions to us. *See* 42 U.S.C. § 263a(k)(1). Wade asserts that its actions did not violate the

CLIA, and, alternatively, that CMS should be estopped from revoking its certificate because it induced Wade into sharing its proficiency test results with Muskogee. We address each argument in turn.

II

Wade argues first that it did not "refer" its proficiency testing samples "for analysis" to Muskogee in violation of § 263a(i)(4) of the CLIA. In Wade's view, the Act prohibits a lab only from passing off another lab's results as its own work; it does not prohibit a lab from double-checking its own results with another lab. And, Wade stresses, it corresponded with Muskogee not out of any design to

cheat the proficiency testing program but simply as part of a training program, undertaken in good faith, to confirm the accuracy of its own work.

Even accepting Wade's description of its actions, they still violated the plain and unambiguous terms of the statute. To "refer" means "to commit, submit, hand over (a question, cause, or matter) to some special or ultimate authority for consideration, decision, execution. . . ." Oxford English Dictionary, Vol. XIII at 463 (2d. ed. 1989). "Analysis," in turn, means "[t]he resolution or breaking up of anything complex into its various simple elements . . .; the exact determination of the elements or components of anything complex (with or without their physical separation)." *Id.* Vol. I at 433. Without doubt, Wade committed, submitted, or handed over for consideration its proficiency testing

samples to Muskogee for analysis – that is, for Muskogee's resolution or breaking up of those samples into their various simple elements. Of course, as it contends, Wade did not simply pass off Muskogee's results as its own. But nothing in the text of § 263a(i)(4) suggests that a test-taker must pass off another lab's results before a violation has occurred. Under the statute's plain terms, *any* intentional "referral" of a proficiency testing sample "for analysis" in another lab is forbidden. And that indubitably occurred here.

Wade is like the student who protests that he did not cheat on his exam because he did not hand in someone else's work but merely checked his answers against those of another student. But peering over the shoulder of another student

in the middle of an exam to check one's answers is as much cheating as handing in someone else's work. While consultation between labs may be permissible in other circumstances, before or after a proficiency test, asking an outsider for help during a test corrupts the process and defeats its purpose. Indeed, this type of double-checking is exactly what Congress sought to prevent in the CLIA. It is not just passing off another's work as one's own that concerned Congress: "Run[ning] repeated tests on the sample, us[ing] more highly qualified personnel than are routinely used for testing, or send[ing] the sample out to another laboratory" are all among the many practices that "obviously undermine the purpose of proficiency testing." H.R. Rep. No. 100-899, at 16, 24 (1988), *as*

reprinted in 1988 U.S.C.C.A.N. 3828.

Even if it did "refer" its test samples "for analysis" to Muskogee, Wade replies that it did not do so "intentionally," as the statute requires before CMS may impose a one-year suspension. Although Wade agrees with CMS that the statutory term "intentional" connotes "knowing and willful," Aplt. Br. at 10, Wade stresses that it had no wish to violate the law, and in fact was seeking to do just the opposite – to improve its testing standards by reaching out to another lab for guidance.

This line of argument will not work either. Even assuming Wade's *ultimate* or *end* intent was to improve its work product, as a *means* of effecting that intent Wade surely referred its proficiency test results "knowingly and willfully" to

Muskogee. Wade does not suggest, for example, that its technician negligently left the lab's proficiency testing samples at Muskogee and Muskogee went ahead, without Wade's knowledge, to analyze them. Instead, it is undisputed that Wade's technician took the lab's proficiency testing samples to Muskogee with the express purpose of testing them there – that is, with the express purpose of referring them for analysis. There was no mistake, accident, negligence or recklessness about it. And under the statute's plain language, such a "knowing and willful" action is sufficient to trigger liability, even if it was undertaken only in service of some further and ultimate intent. Simply put, Wade is responsible

for its intended *means*, whatever its intended *ends* might have been.

CMS makes much the same point when it maintains that Wade's "motive" in asking Muskogee to analyze its test samples is "irrelevant." Appellee Br. at 17. While Wade might well have acted with the benign motive of seeking to improve its testing standards, CMS argues, that is neither here nor there; the statute asks only whether a lab has acted intentionally. CMS's argument recalls the oft-repeated maxim every law student hears that the law cares about intent, not motive. But like many maxims, this one obscures difficult analytical questions – in this case, the longstanding question what qualifies as a motive rather than an intention. *See, e.g.*, Wayne LaFave, Substantive Criminal Law § 5.3(a) (2008) ("[W]hat is meant by the word 'motive' and how it differs from 'intention,' [is] a matter which has caused the theorists considerable difficulty for

years."); Walter Cook, Act, Intention and Motive in the Criminal Law, 26 Yale L. J. 624 (1917); Walter Hitchler, Motive as an Essential Element of Crime, 35 Dick. L. Rev. 105 (1931). But whether Wade's state of mind is characterized as a motive, as the government would have it, or as a further intent, as Wade would have it, makes no difference to the outcome of this case. However characterized, the fact that Wade acted with the earnest desire to improve its testing standards does not negate the fact that the company *did* intentionally refer its proficiency testing samples to another lab for analysis.

III

Perhaps seeing the writing on the wall, Wade supplements its statutory argument with another approach. Even if it violated the statute, Wade submits, it did so only at the direction and with the approval of CMS. Wade points to the 2005 statement by the CMS field investigator urging Wade to seek out opportunities for "training and comparison testing of the[ir] equipment" with other certified labs. Wade also points to the remedial plan it submitted to CMS where it made mention of its correspondence with Muskogee. Because CMS urged or at least tacitly approved its cooperation with other labs, Wade maintains, the government should be estopped from complaining that it did just that. The DAB of course disagreed with this line of argument, and we cannot say that its factual findings lack substantial evidence or that its legal rulings were erroneous.

To the contrary, winning an equitable estoppel argument against the government is a tough business. Courts generally invoke estoppel against the government "only when it does not frustrate the purpose of the statutes expressing the will of Congress or unduly undermine the enforcement of the public laws." *FDIC v. Hulsey*, 22 F.3d 1472, 1489 (10th Cir. 1994). In addition to requiring the traditional elements of estoppel, we require the party claiming estoppel to show "affirmative misconduct on the part of the government"; mere "erroneous advice" will not do. *Id.* at 1489-90 (noting that traditional elements of estoppel are (1)

the party to be estopped must have known the facts; (2) that party must have intended that its conduct would be acted on or must have acted such that the party asserting estoppel had a right to believe it was so intended; (3) the asserting party must have been ignorant of the true facts; and (4) the asserting party must have relied on the other party's conduct to his injury); *see also INS v. Miranda*, 459 U.S. 14, 17–19 (1982); *Board of County Comm'rs of County of Adams v. Isaac*, 18 F.3d 1492, 1499 (10th Cir. 1994). Courts are parsimonious about estoppel claims against the government for good reason: "When the government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined." *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 60 (1984). The public should not have to suffer, the reasoning goes, because of a bureaucratic bungle. *See Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414,

422 (1990) (noting that the Supreme Court had, to date, "reversed every finding of estoppel that [it had] reviewed").

Wade does not come even close to meeting its burden under this standard. Wade stresses that a CMS representative suggested the lab work with another certified lab to train its employees and confirm the reliability of its equipment. But there's no hint in the record that CMS erroneously advised Wade that it could or should share proficiency testing samples with another lab prior to handing in

its own proficiency test results (let alone that CMS engaged in any affirmative act of misconduct). Teachers often allow students to work collaboratively to prepare for an exam or to discuss answers after an exam, but that is no license for students to share thoughts and answers during the exam. Under the statute, Wade might have been free to work with another lab to train its personnel and to fix its equipment, but it's a very different thing to compare results during the testing process.

Wade replies by pointing to its remedial plan. There, Wade told CMS that it intended to "continue internal proficiency testing with assistance and support/guidance" from Muskogee. Even if one could read this statement as clearly notifying CMS of Wade's intent to break the law – a debatable enough proposition – CMS said nothing in response. CMS did not condone or applaud Wade's plan. Silence, of course, does not rise to the level of giving erroneous advice – which is still insufficient to warrant estoppel against the government –

let alone to the level of "affirmative misconduct" required to warrant estoppel against the government.

The petition for review is denied.

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