

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 12/31/2018. 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](#), [2010](#), [2011](#), [2012](#), [2013](#), [2014](#), [2015](#), [2016](#), [2017](#), [2018](#), [2019](#), [2020](#), [2021](#), [2022](#), [2023](#).

Decision Date and Case Name	Issues	Outcome	Regulatory References
9/23/1994 [CR334] Long Medical Laboratory v. HCFA	<ul style="list-style-type: none"> - Improper PT - Intentional PT referral - State laws vs. CLIA 	For HCFA	<p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>42 C.F.R. § 493.1840(b) Adverse action based on improper referrals in proficiency testing.</p>
9/28/1994 [CR335] Central Valley Medical Laboratory v. HCFA	<ul style="list-style-type: none"> - Client list - Directed Plan of Correction - Immediate Jeopardy - Pattern of deficiencies 	For HCFA	<p>42 C.F.R. § 493.1832 Directed plan of correction and directed portion of a plan of correction.</p> <p>42 C.F.R. § 493.1840(a)(7) Failed to comply with an alternative sanction imposed.</p> <p>42 C.F.R. § 493.1804(d) Choice of sanction [relationship of deficiencies]</p> <p>42 C.F.R. § 493.1844(c)(6) The determination that a laboratory’s deficiencies pose immediate jeopardy.</p>
2/15/1995 [CR358] Center Clinical Laboratory v. HCFA	<ul style="list-style-type: none"> - Effective date - Immediate Jeopardy 	For Petitioner	<p>42 C.F.R. § 493.1810(c)(2)(i) HCFA provides notice at least 5 days before the effective date of alternative sanctions.</p> <p>42 C.F.R. § 493.1844(c)(6) The determination that a laboratory’s deficiencies pose immediate jeopardy.</p>
7/31/1995 [DAB1526] Center Clinical Laboratory v. HCFA	<ul style="list-style-type: none"> - Effective date 	For HCFA	<p>42 C.F.R. § 493.1844(h)(1) Effective date of adverse action (5 days after notice).</p>

Decision Date and Case Name	Issues	Outcome	Regulatory References
2/15/1996 [CR411] Center Clinical Laboratory v. HCFA	<ul style="list-style-type: none"> - Immediate Jeopardy (not subject to appeal) 	For HCFA	42 C.F.R. § 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy. 42 C.F.R. § 493 Subpart H (Participation in Proficiency Testing) 42 C.F.R. § 493 Subpart J (Patient Test Management) 42 C.F.R. § 493 Subpart K (Quality Control) 42 C.F.R. § 493 Subpart P (Quality Assurance) 42 C.F.R. 493 Subpart M (Personnel)
9/30/1996 [CR438] Blanding Urgent Care Center Laboratory v. HCFA	<ul style="list-style-type: none"> - Improper PT - Intentional PT referral - Motive - Physical transport 	For HCFA	42 C.F.R. § 493.2 Intentional violation. 42 C.F.R. § 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 C.F.R. § 493.1840(b) Adverse action based on improper referrals in proficiency testing.
10/9/1996 [CR439] Primary Care Medical Group v. HCFA	<ul style="list-style-type: none"> - Improper PT - Intentional PT referral - Lab Director 	For HCFA	42 C.F.R. § 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 C.F.R. § 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	<ul style="list-style-type: none"> - Acceptable Plan of Correction - Certificate change - Immediate jeopardy 	For HCFA	42 C.F.R. § 493.1800 Basis and scope of enforcement procedures. 42 C.F.R. § 493.1806(a) Applicability. HCFA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions. 42 C.F.R. § 493.1806(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions.

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5/30/1997 [CR476] California Medical Associates Laboratory v. HCFA	<ul style="list-style-type: none"> - Choice of sanctions - Lab closure - Voluntary cessation 	For HCFA	42 C.F.R. § 493.1800 Basis and scope of enforcement procedures. 42 C.F.R. § 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 C.F.R. § 493.1806(b) Principal sanction. HCFA may impose any of the three principal CLIA sanctions. 42 C.F.R. § 493.1804(d) Choice of sanction: Factors considered.
7/24/1997 [DAB1624] Ward General Practice Clinic v. HCFA	<ul style="list-style-type: none"> - Certificate change - History of non-compliance 	For HCFA	42 C.F.R. § 493.1800 Basis and scope of enforcement procedures. 42 C.F.R. § 493.1804 General considerations of enforcement.
8/5/1997 [CR487] Williams Bio Medical Laboratory v. HCFA	<ul style="list-style-type: none"> - Burden of proof - Directed Plan of Correction - Standard deficiencies 	For HCFA	42 C.F.R. § 493.1816(b) Action when deficiencies are not at the condition level. Failure to correct deficiencies. 42 C.F.R. § 493.1820 Ensuring timely correction of deficiencies. 42 C.F.R. § 493.1832(c) Duration of a directed plan of correction. 42 C.F.R. § 493.1840(a)(7) Failed to comply with an alternative sanction imposed under this subpart.
10/21/1997 [CR501] Thyroid Specialty Laboratory v. HCFA	<ul style="list-style-type: none"> - Intentional PT referral - Lab Director - Motive 	For HCFA	42 C.F.R. § 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 C.F.R. § 493.1840(b) Adverse action based on improper referrals in proficiency testing.

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3/31/1998 [CR527] Eugene R. Pocock, M.D. v. HCFA	<ul style="list-style-type: none"> - Affected party (right to hearing) - Lab Director - Operator 	For HCFA	42 C.F.R. § 493.2 Definitions. Operator. 42 C.F.R. § 498.2 Definitions. [Affected party]. 42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. 42 C.F.R. § 498.40 Request for Hearing. An affected party entitled to a hearing.
2/16/1999 [CR576] BAN Laboratories v. HCFA	<ul style="list-style-type: none"> - Due process - Exit Conference - Immediate Jeopardy - Re-survey 	For HCFA	42 C.F.R. § 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate. 42 C.F.R. § 493.1806 Available sanctions. 42 C.F.R. § 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	<ul style="list-style-type: none"> - Director/Owner responsibilities - Intentional PT referral - State Law vs CLIA 	For HCFA	42 C.F.R. § 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results. 42 C.F.R. § 493.1840(b) Adverse action based on improper referrals in proficiency testing.
5/27/1999 [CR597] Eugene A. Shaneyfelt, M.D. v. HCFA	<ul style="list-style-type: none"> - Certificate of Waiver - Director/Operator - Operator 	For HCFA	42 C.F.R. § 493.2 Definitions: operator. 42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

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6/7/1999 [CR599] Edison Medical Laboratories, Inc. v. HCFA	- Accreditation - Immediate Jeopardy	For HCFA	42 C.F.R. § 493.1780(a) Validation inspection. 42 C.F.R. § 493.1800 Basis and scope of enforcement procedures. 42 C.F.R. § 493.1806 Available sanctions. 42 C.F.R. § 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 C.F.R. § 493.1804(d) Choice of sanction: Factors considered. 42 C.F.R. § 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 C.F.R. § 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 C.F.R. § 493.1771 Condition: Inspection requirements applicable to all CLIA-certified laboratories. 42 C.F.R. § 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 C.F.R. § 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 C.F.R. § 493.1804(a) Purpose. The enforcement mechanisms. 42 C.F.R. § 493.1806 Available sanctions. 42 C.F.R. § 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.

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1/21/2000 [CR642] Kaulson Labs v. HCFA	- Clerical errors	For HCFA	42 C.F.R. § 493.1806(a) Applicability. HCFA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions. 42 C.F.R. § 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 C.F.R. § 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 C.F.R. § 493.803 Condition: Successful participation.
6/21/2000 [DAB1731] US Bio-Chem Medical Laboratories v. HCFA	- Complainant disclosure - Right to inspect	For HCFA	42 C.F.R. § 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 C.F.R. § 493.3 Applicability. 42 C.F.R. § 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 C.F.R. § 498.2 Definitions. [Affected party]. 42 C.F.R. § 493.49(e) In the event of a noncompliance determination resulting in an HHS action. 42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. 42 C.F.R. § 493.1884(d)(2) Suspension, limitation, or revocation of a laboratory's CLIA certificate.

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<p>7/18/2000 [CR688] Oakland Medical Group, P.C. v. HCFA</p>	<ul style="list-style-type: none"> - Accreditation - Independent contractor - Intentional PT referral - Owner/Operator - PT collaboration 	<p>For HCFA</p>	<p>42 C.F.R. § 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples.</p> <p>42 C.F.R. § 493.6(c)(3) A laboratory failing to meet the requirements of this section may be subject to suspension, revocation.</p> <p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform.</p> <p>42 C.F.R. § 493.1441 The laboratory director must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>42 C.F.R. § 493.1840(a) Adverse action based on actions of the laboratory's owner, operator or employees.</p> <p>42 C.F.R. § 493.1840(b) Adverse action based on improper referrals in proficiency testing.</p>
<p>7/28/2000 [CR690] Stanley Boykansky, M.D. v. HCFA</p>	<ul style="list-style-type: none"> - Acceptable Plan of Correction - CMS modifying state agency findings - Intentional PT referral 	<p>For HCFA</p>	<p>42 C.F.R. § 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload.</p> <p>42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 C.F.R. § 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results.</p> <p>42 C.F.R. § 493.1806(a) Applicability. HFCA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p>

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9/11/2000 [CR698] Garden City Medical Clinic v. HCFA	<ul style="list-style-type: none"> - Employee termination - Intentional PT referral - PT collaboration - Statistics 	For HCFA	42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 C.F.R. § 493.1840(a) Adverse action based on actions of the laboratory's owner, operator or employees.
9/20/2000 [DAB1747] Kaulson Labs v. HCFA	<ul style="list-style-type: none"> - Remand 	For Petitioner	42 C.F.R. § 493.1844 Appeals procedures.
12/5/2000 [DAB1755] Oakland Medical Group, P.C. v. HCFA	<ul style="list-style-type: none"> - Accreditation - Improper PT - Physical transfer - Standard/Condition level Deficiencies 	For HCFA	42 C.F.R. § 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	<ul style="list-style-type: none"> - Intentional PT referral - Physical transfer - Single condition out 	For HCFA	42 C.F.R. § 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload. 42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 C.F.R. § 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 C.F.R. § 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results. 42 C.F.R. § 493.1806(a) Applicability. HCFA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

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1/24/2001 [CV 00-12209 SVW (CWx)] Physicians Independent Laboratory Inc. v. Donna Shalala, DHHS, [et.al.]	<ul style="list-style-type: none"> - Administrative remedies - Suspension before hearing - TRO 	For DHHS	42 C.F.R. § 493.1840(d) Procedures for suspension or limitation.
1/26/2001 [DAB1762] Sentinel Medical Laboratories, Inc. v. HCFA	<ul style="list-style-type: none"> - Administrative remedies - Constitutionality - Director responsibilities - 2-year prohibition 	For HCFA	<p>42 C.F.R. § 493.49(e) In the event of a noncompliance determination resulting in an HHS action.</p> <p>42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p> <p>42 C.F.R. § 493.1844(d)(2) Suspension, limitation, or revocation of a laboratory's CLIA certificate.</p>
1/30/2001 [DAB1763] Garden City Medical Clinic v. HCFA	<ul style="list-style-type: none"> - Accreditation - Remand - Summary Judgment - Witness cross-examination 	For Petitioner	<p>42 C.F.R. § 493.1844(a) Appeals procedures. General rules.</p> <p>42 C.F.R. § 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples.</p>
2/15/2001 [No. 00-3138] Edison Medical Lab. Inc. v. HCFA	<ul style="list-style-type: none"> - Accreditation 	For HCFA	
3/6/2001 [CR749] Union City Diagnostic Laboratory v. HCFA	<ul style="list-style-type: none"> - Immediate Jeopardy - Quality Control - Single condition out 	For HCFA	<p>42 C.F.R. § 493.1701 Condition: Quality assurance. The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures.</p> <p>42 C.F.R. § 493.1806(a) Applicability. HFCA may impose one or more sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.</p> <p>42 C.F.R. § 493.1844(c)(6) The determination that a laboratory's deficiencies pose immediate jeopardy.</p>

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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 C.F.R. § 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 C.F.R. § 493.1810 Imposition and lifting of alternative sanctions. Notice of noncompliance and of proposed sanction. 42 C.F.R. § 493.1812(b) Opportunity to respond. 42 C.F.R. § 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 C.F.R. § 493.61(b)(1) Laboratories issued a certificate of accreditation must treat proficiency testing samples in the same manner as patient samples. 42 C.F.R. § 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory. 42 C.F.R. § 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.

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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 C.F.R. § 493.1773 Dismissal for cause. (No right to hearing) 42 C.F.R. § 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 C.F.R. § 498.2 Definitions. [Affected party.] 42 C.F.R. § 493.801(b)(5) The laboratory must document and maintain a copy of all proficiency testing results. 42 C.F.R. § 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 C.F.R. § 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 C.F.R. § 493.801 Enrollment and testing of samples
12/17/2001 [CR848] Edward Ming-Che Lai, M.D. v. CMS	- Lab Director	For Petitioner	42 C.F.R. § 493.51 Notification requirements for laboratories issued a certificate of compliance. 42 C.F.R. § 493.1773 Basic inspection requirements for all laboratories issued a CLIA certificate.

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01/28/2002 [CR863] Sol Teitelbaum, M.D. v. CMS	<ul style="list-style-type: none"> - Effective date of prohibition - Lab Director - Operator - Right to hearing - 2-year prohibition 	For CMS	<p>42 C.F.R. § 493.2 Definitions. (Operator).</p> <p>42 CRF § 493.1407 Laboratory Director responsibilities.</p> <p>42 C.F.R. § 493.1806 Available sanctions.</p> <p>57 Fed. Reg. 7226 (1992) (Lab director is an operator; legislative purpose of CLIA.)</p>
02/25/2002 [CR875] Millenium Medical Group v. CMS	<ul style="list-style-type: none"> - Affected party - Ownership - 2-year prohibition 	For CMS	<p>42 C.F.R. § 498.40(c)(1) Affected party.</p> <p>42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
03/12/2002 [CR879] Caroline D. Zohoury, D.O. v. CMS	<ul style="list-style-type: none"> - Denial CLIA application - Owner/Operator - 2-year prohibition 	For CMS	<p>42 C.F.R. § 493.2 Definitions (owner/operator)</p> <p>42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>
03/18/2002 [DAB1820] RNA Laboratories, Inc., and Ter-Zakarin Medical Clinic v. CMS	<ul style="list-style-type: none"> - Improper PT referral - Lab Director 	For CMS	<p>42 C.F.R. § 493.801(a) Enrollment and testing of samples.</p> <p>42 C.F.R. § 493.1403 Laboratory Director condition of participation.</p>
04/15/2002 [CR889] Gen Sys Incorporated v. CMS	<ul style="list-style-type: none"> - Immediate Jeopardy - Lab Director qualifications - Summary Judgment - Technical Supervisor qualifications 	For CMS	<p>42 C.F.R. § 493.2 Definitions (Immediate Jeopardy).</p> <p>42 C.F.R. § 493.1441 Laboratory Director.</p> <p>42 C.F.R. § 493.1447 Technical Supervisor.</p>

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06/19/2002 [CR919] Dearborn Family Clinic v. CMS	<ul style="list-style-type: none"> - Improper PT referral - Lab Director responsibilities - Technical Supervisor qualifications 	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples. 42 C.F.R. § 493.1441 Laboratory Director. 42 C.F.R. § 493.1447 Technical Supervisor. 42 C.F.R. § 493.1806(a) Available sanctions (Applicability).
07/29/2002 [CR935] Emil S. Sitto, M.D., & Associates, PLLC v. CMS	<ul style="list-style-type: none"> - Improper PT referral - Lab Director responsibilities - Technical Supervisor qualifications 	For CMS	42 C.F.R. § 493.61 Requirements for a certificate of accreditation. 42 C.F.R. § 493.801 Enrollment and testing of samples. 42 C.F.R. § 493.1441 Laboratory Director. 42 C.F.R. § 493.1447 Technical Supervisor.
07/30/2002 [CR936] Medical Service Laboratories v. CMS	<ul style="list-style-type: none"> - Immediate Jeopardy - PT enrollment 	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples. 42 C.F.R. § 493.1844(c)(6) Appeals procedures (Immediate jeopardy not subject to appeal). 42 C.F.R. § 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	<ul style="list-style-type: none"> - Constitutional issue - Lab Director - Misrepresentation on CLIA application - 2-year prohibition 	For CMS	42 C.F.R. § 493.2 Definitions (owner/operator). 42 C.F.R. § 493.643 Fee for determination of program compliance. 42 C.F.R. § 493.1840(a)(1) Misrepresentation in obtaining certificate. 42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

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08/30/2002 [CR946] Alaa Ahmed, M.Sc., Ph.D., (Global Esoteric Reference Labs, Inc.) v. CMS	<ul style="list-style-type: none"> - Improper proficiency testing - Laboratory Director - 2-year prohibition 	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples. 42 C.F.R. § 493.1205(e)(1) Supplies exceeding expiration date. 42 C.F.R. § 493.1441 Laboratory Director. 42 C.F.R. § 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	<ul style="list-style-type: none"> - Improper proficiency testing - 2-year prohibition 	For CMS	42 C.F.R. § 493.801(b)(4) Intentional referral of proficiency testing samples. 42 C.F.R. § 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	<ul style="list-style-type: none"> - Deficiencies during a Lab Director's tenure - Lab Director - Summary Judgment - 2-year prohibition 	For CMS	42 C.F.R. § 493.2 Definitions (owner/operator). 42 C.F.R. § 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	<ul style="list-style-type: none"> - Improper PT - Lab Director 	For CMS	42 C.F.R. § 493.801(b) Testing of proficiency testing samples. 42 C.F.R. § 493.1441 Laboratory Director. 42 C.F.R. § 493.1806(a),(b) Available sanctions (applicability, principal sanctions).

Decision Date and Case Name	Issues	Outcome	Regulatory References
11/27/2002 [CR981] St. Charles Health Care v. CMS	<ul style="list-style-type: none"> - Standard-level deficiencies not corrected in 12 months - Unacceptable AOC - Unsuccessful PT 	For CMS	42 C.F.R. § 493.2 Definitions (credible allegation of compliance; unsuccessful proficiency testing performance). 42 C.F.R. § 493.1816(b) Failure to correct standard-level deficiencies within 12 months. 42 C.F.R. § 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	<ul style="list-style-type: none"> - Improper PT - Physical transport - PT collaboration 	For CMS	42 C.F.R. § 493.563 Validation inspections - basis and focus. 42 C.F.R. § 493.569(a) Validation inspection of an accredited laboratory out of compliance with Condition-level requirements. 42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 C.F.R. § 493.801(b)(4) Intentional referral of proficiency testing samples. 42 C.F.R. § 493.1804(d) Choice of sanction: Factors considered.
03/21/2003 [DAB1870] Lackawanna Medcial Group Laboratory v. CMS	<ul style="list-style-type: none"> - Improper PT - Relationship of 42 C.F.R. 493.801(b)(1) and 42 C.F.R. 493.801(b)(4) - Summary Judgment 	For CMS	42 C.F.R. § 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload. 42 C.F.R. § 493.801(b)(4) Intentional referral of proficiency testing samples.
04/14/2003 [CR1025] Medimex Clinical Laboratory v. CMS	<ul style="list-style-type: none"> - Doctrine of Laches - Immediate Jeopardy - Lab Director responsibilities 	For CMS	42 C.F.R. §§ 493.1403 and 493.1441 Laboratory Director provides overall management and direction.

Decision Date and Case Name	Issues	Outcome	Regulatory References
05/01/2003 [DAB1878] Alaa Ahmed, M.Sc., Ph.D. (Global Esoteric Reference Labs, Inc.) v. CMS	<ul style="list-style-type: none"> - Improper PT - Lab Director responsibilities - State licensure issue (lab name) 	For CMS	<p>42 C.F.R. § 493.801 Enrollment and testing of samples.</p> <p>42 C.F.R. § 493.1441 Lab Director.</p>
06/12/2003 [CR1055] Roy Hollins/Western Reference Laboratory v. CMS	<ul style="list-style-type: none"> - Due process - Owner - Untimely filing of request for hearing - 2-year prohibition 	For CMS	<p>42 C.F.R. § 498.70(c) Dismissal of a late filed request.</p> <p>42 C.F.R. § 493.1844(b) Hearings are conducted in accordance with procedures set forth at 42 C.F.R. Part 498.</p> <p>42 C.F.R. § 493.1844(d)(4) Effect of ALJ decision.</p>
06/16/2003 [Docket No. C-03-203] Alani Medical Management Corp., d.b.a. Advanced Diagnostic Services Laboratory v. CMS	<ul style="list-style-type: none"> - Affected party (right to hearing) - Alternative sanction (civil money penalties) 	Denial of CMS' motion to dismiss and Petitioner's motion for summary judgment	<p>42 C.F.R. § 493.1806 Available sanctions.</p>
08/26/2003 [CR1079] Bolsa Medical Group Laboratory, Sheldon Barasch, M.D. v. CMS	<ul style="list-style-type: none"> - Delegation of responsibilities - Intentional PT referral - Physical transport of PT sample - Relationship of 42 C.F.R. 493.801(b)(3) and 42 C.F.R. 	For CMS	<p>42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>42 C.F.R. § 493.1840(a)(8) Adverse action.</p>
08/28/2003 [CR1080] James Bryant, M.D. v. CMS	<ul style="list-style-type: none"> - Affected party (right to hearing) - Owner/operator - 2-year prohibition 	Dismissal	<p>42 C.F.R. § 493.1844 Appeals procedures.</p> <p>42 C.F.R. § 493.2 Definitions (owner/operator)</p> <p>42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>

Decision Date and Case Name	Issues	Outcome	Regulatory References
09/17/2003 [CR1083] Immuno Biogene, Inc., Charles T. Black, M.D. v. CMS	<ul style="list-style-type: none"> - Improper PT - Immediate Jeopardy - Failure to notify CMS of receipt of PT samples from another laboratory - Lab Director responsibilities 	For CMS	42 C.F.R. § 493.801(b) Testing of proficiency testing samples. 42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 C.F.R. § 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 C.F.R. § 493.1407 Laboratory director responsibilities.
11/14/2003 [CR1109] White Lake Family Medicine, P.C. v. CMS	<ul style="list-style-type: none"> - Intentional PT referral - Physical transport 	For CMS	42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications. 42 C.F.R. § 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	<ul style="list-style-type: none"> - Affected party (right to hearing) - Owner/operator - 2-year prohibition 	Dismissal	42 C.F.R. § 493.1844 Appeals procedures. 42 C.F.R. § 493.2 Definitions (owner/operator) 42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

Decision Date and Case Name	Issues	Outcome	Regulatory References
02/03/2004 [Docket No. C-03-566] Bethesda Pathology Clinic, Inc. v. CMS	<ul style="list-style-type: none"> - Affected party (right to hearing) - Owner/Operator - Transfer of ownership - 2-year prohibition 	Dismissal	<p>42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p> <p>42 C.F.R. § 493.1844 Appeals procedures.</p> <p>42 C.F.R. § 498.70(b) The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.</p>
04/19/2004 [CR1167] Vijay Sakhuja, M.D. v. CMS	<ul style="list-style-type: none"> - CMS access to laboratory records - Condition Level Non-compliance - Immediate Jeopardy - Plan of Correction 	For CMS	<p>42 C.F.R. §§ 493.1771 & 1773 Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.</p> <p>42 C.F.R. § 493.1844(c)(6) Actions that are not initial determinations -- The determination that a laboratory's deficiencies pose immediate jeopardy.</p>
06/09/2004 [CR1189] American Diagnostic Labs (by Ayazar Rahman, Owner, & Charles Panchari, M.D., Director), v. CMS	<ul style="list-style-type: none"> - 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	<p>42 C.F.R. § 493.1804(b)(2) CMS may impose principal or alternative sanctions when it finds that a laboratory has a "condition-level" deficiency.</p> <p>42 C.F.R. § 493.1844(b)(3) The imposition of an alternative sanction is subject to ALJ review as an initial determination.</p> <p>42 C.F.R. § 493.1804(a) Civil Money Penalty.</p> <p>42 C.F.R. § 493.1423(a) Testing personnel. State license.</p> <p>42 C.F.R. § 493.1840(a)(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.</p>

Decision Date and Case Name	Issues	Outcome	Regulatory References
<p>09/13/2004 [CR1212] Millennium Clinical Laboratories, Inc., v. CMS</p>	<ul style="list-style-type: none"> - Condition Level Non-compliance - Civil Money Penalty - Immediate Jeopardy (when declared) - State Operations Manual (guidance) 	<p>For CMS</p>	<p>42 C.F.R. § 493.1804(b)(2) CMS may impose principal or alternative sanctions when it find that a laboratory has a "condition-level" deficiency</p> <p>42 C.F.R. § 493.1834 Civil Money Penalty.</p> <p>42 C.F.R. § 493.2 Definition of Immediate Jeopardy.</p> <p>SOM Appendix C, Section 6100 (non-regulatory)</p>
<p>10/06/2004 [DAB1946] Immuno Biogene, Inc., v. CMS</p>	<ul style="list-style-type: none"> - Appeal of ALJ decision [CR1083] - Civil Money Penalty - Condition Level Non-compliance with Immediate Jeopardy - Improper PT (inter-laboratory communications) - Failure to notify CMS of receipt of PT samples from another laboratory - Lab Director responsibilities 	<p>For CMS</p>	<p>42 C.F.R. § 493.801(b) Testing of proficiency testing samples.</p> <p>42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.</p> <p>42 C.F.R. § 493.1407 Laboratory director responsibilities.</p>
<p>11/09/2004 [DAB1951] White Family Medicine, P.C., v. CMS</p>	<ul style="list-style-type: none"> - Appeal of ALJ decision [CR1109] - Improper PT - Summary judgment 	<p>For CMS</p>	<p>42 C.F.R. § 493.801(b) Testing of proficiency testing samples.</p> <p>42 C.F.R. § 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications.</p> <p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p>

Decision Date and Case Name	Issues	Outcome	Regulatory References
1/11/05 [DAB 1958] Vijay Sakhuja, M.D., v. CMS	<ul style="list-style-type: none"> - Acceptable Plan of Correction - Appeal of ALJ decision [CR 1167] - Condition Level Non-compliance - State Agency Procedures 	For CMS	42 C.F.R. § 493.1806 Available sanctions.
1/13/05 [CR1267] Sonali Diagnostic Laboratory v. CMS	<ul style="list-style-type: none"> - 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 C.F.R. § 493.49 Requirements for a certificate of compliance. 42 C.F.R. § 493.1101 Facility administration for nonwaived testing. 42 C.F.R. § 493.1449(c)(5) Technical supervisor qualifications. 42 C.F.R. § 493.1804(b) Basis for decision to impose sanctions.
2/18/05 [CR1280] Rustom Ali, Ph.D., Operator of Scottsdale Medical Laboratory v. CMS	<ul style="list-style-type: none"> - 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 C.F.R. § 493.1804(a)(3) Purpose [of sanctions].
3/18/05 [CR1283] Clinical Immuno Diagnostic Lab, Inc., v. CMS	<ul style="list-style-type: none"> - ALJ Jurisdiction to Review Imposition of Civil Money Penalty - Misrepresentation 	For CMS	42 U.S.C. Section 263a(i)(1) 42 C.F.R. § 493.1840(a)(1) Guilty of misrepresentation in obtaining a CLIA certificate.

Decision Date and Case Name	Issues	Outcome	Regulatory References
4/21/05 [CR1295] Open Faith Medical Laboratory, v. CMS	<ul style="list-style-type: none"> - Condition Level Non-compliance with Immediate Jeopardy - Certificate of Registration - Denial of Accreditation - Laboratory Director Qualifications - Summary Judgment 	For CMS	42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. 42 C.F.R. § 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	<ul style="list-style-type: none"> - Definition of owner - Owner/operator - Ownership of laboratory - 2-year prohibition 	For CMS	42 C.F.R. § 493.2 Definitions (owner/operator) 42 C.F.R. § 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	<ul style="list-style-type: none"> - 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 C.F.R. § 493.1236(b)(2) Evaluation of proficiency testing performance. 42 C.F.R. § 493.803(a) Successful Participation [in proficiency testing]. 42 C.F.R. § 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 42 C.F.R. § 493.1407(e)(4)(iii) Laboratory director responsibilities.
1/13/2006 [CR1390] Dimensions Medical Laboratory, Inc. v. CMS	<ul style="list-style-type: none"> - Administrative finality - Plan of correction - Res judicata 	For CMS	42 C.F.R. § 493.1844(b) Initial determinations.

Decision Date and Case Name	Issues	Outcome	Regulatory References
1/17/06 [CR1267] [DAB 2008] Rustom Ali, Ph.D., Sonali Diagnostic Laboratory v. CMS	- Appeal of ALJ Decision CR1267	For CMS	42 C.F.R. § 493.45, 42 C.F.R. § 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 C.F.R. § 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 C.F.R. § 493.2 Definitions (owner/operator) 42 C.F.R. § 493.1701 Quality assurance. 42 C.F.R. § 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 C.F.R. § 493.2 Definitions (owner/operator). 42 C.F.R. § 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 C.F.R. § 493.1804(b) Imposition of sanctions. 42 C.F.R. § 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 C.F.R. § 498.40(b) Basis for appeal. 42 C.F.R. § 493.1804(b) Imposition of sanctions.

Decision Date and Case Name	Issues	Outcome	Regulatory References
6/13/07 [CR1607] Physician Laboratory Technology, Inc., v. CMS	<ul style="list-style-type: none"> - Condition-level noncompliance - CMP - 2-year prohibition 	For CMS	<p>42 C.F.R. § 493.2 Definition of owner/operator.</p> <p>42 C.F.R. § 493.1804(b) Imposition of sanctions.</p> <p>42 C.F.R. § 493.1840(a)(8) 2-year prohibition.</p>
8/01/07 [CR1630] Wade Pediatrics v. CMS	<ul style="list-style-type: none"> - Estoppel - Improper PT referral (“intentional”) - Summary judgment 	For CMS	<p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p>
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	<ul style="list-style-type: none"> - Appeal of DAB - Simultaneous imposition of intermediate and principal sanctions - Stop testing prior to hearing due to immediate jeopardy 	For DHHS	<p>42 C.F.R. § 493.1806(c) Impose one or more intermediate sanctions in lieu of or in addition to principal sanctions.</p>
10/03/07 [DAB2118] [CR1497] HRT Laboratory, Inc., v. CMS	<ul style="list-style-type: none"> - Appeal of DAB - Lab closure in face of sanctions - Initial determinations subject to appeal - Unacceptable Plan of Correction not appealable 	For CMS	<p>42 C.F.R. § 498.40(b) Basis for appeal.</p> <p>42 C.F.R. § 493.1804(b) Imposition of sanctions.</p> <p>42 C.F.R. § 493.1844(ff.) Initial determinations.</p>
11/08/07 [CR1688] Wade Borg, M.D., v. CMS	<ul style="list-style-type: none"> - Condition-level noncompliance - State requirements - Summary judgment 	For CMS	<p>42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures; laboratory director.</p> <p>42 C.F.R. § 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.</p>

Decision Date and Case Name	Issues	Outcome	Regulatory References
01/09/08 [CR1723] Daniel M. Stewart, v. CMS	<ul style="list-style-type: none"> - Intentional PT referral - Laboratory director requirements - Proficiency testing - Summary judgment 	For CMS	<p>42 C.F.R. § 493.801 Condition: Enrollment and testing of samples.</p> <p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>42 CRF § 493.803 Condition: Successful participation.</p> <p>42 C.F.R. §403.1403 Condition: Laboratory Director.</p>
02/11/08 [CR1630] [Decision No. 2153] Wade Pediatrics, v. CMS	<ul style="list-style-type: none"> - Appeal of ALJ Decision - Intentional PT referral 	For CMS	<p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p>
02/27/08 [CR1743] Stat Lab I, Inc., v. CMS	<ul style="list-style-type: none"> - Condition-level noncompliance: analytical systems - Immediate jeopardy - Laboratory director requirements - Technical consultant requirements - Summary judgment - 2 year prohibition 	For CMS	<p>42 C.F.R. § 493.1250 Condition: Analytic systems.</p> <p>42 C.F.R. § 493.1403 Condition: Laboratory director.</p> <p>42 C.F.R. § 493.1409 Condition: Technical Consultant.</p>
03/18/08 [CR1754-1758] Hematology & Oncology Services, LLC, v. CMS	<ul style="list-style-type: none"> - Administrative finality - Hearing requests - Summary judgment - 2 year prohibition 	For CMS	<p>42 C.F.R. § 493.1840(a)(8) 2 year prohibition.</p> <p>42 C.F.R. § 493.1844(a)(2) Appeals procedures.</p> <p>42 C.F.R. § 498.40 Request for hearing.</p>
06/23/08 [CR1807] Mahmoud H. Aly, M.D., v. CMS	<ul style="list-style-type: none"> - Abandonment - Dismissal - Proficiency testing requirements 	For CMS	<p>42 C.F.R. § 493.69(a)(b) Dismissal for Abandonment</p>

Decision Date and Case Name	Issues	Outcome	Regulatory References
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, 10 th Circuit] Wade Pediatrics v. CMS	- Appeal of ALJ Decision - Intentional PT referral	For CMS	42 C.F.R. § 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.
01/21/2010 [CR2060] CARI Reproductive Services v. CMS	- Laboratory Director responsibilities - Technical Supervisor responsibilities - Revocation - 2 year prohibition	For CMS	42 CRF § 493.1840(e) CLIA certificate revoked after ALJ hearing upholds revocation. 42 C.F.R. § 493.1844(d)(2) Effective date of sanction is not delayed because the laboratory has appealed and the hearing is pending. 42 C.F.R. § 493.1441 Condition: Laboratory Director 42 C.F.R. § 493.1447 Condition: Technical Supervisor
01/27/2010 [CR2005] [DAB2298] Associated Internists, P.C. v. CMS	- Appeal of ALJ - DecisionContent of request for hearing	For CMS	42 C.F.R. § 493.1844(b) Initial determinations as defined in the regulation above are subject to appeal. 42 C.F.R. § 493.1844(c) Actions that are not initial determinations are not subject to appeal. 42 C.F.R. § 493.1230 Condition: General Lab Systems 42 C.F.R. § 493.1250 Condition: Analytic Systems 42 C.F.R. § 493.1441 Condition: Laboratory Director

Decision Date and Case Name	Issues	Outcome	Regulatory References
06/15/2010 [CR2156] Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D. v. CMS	<ul style="list-style-type: none"> - Intentional PT referral - Immediate Jeopardy - Laboratory Director - 1 year prohibition (PT referral) - 2 year prohibition (Owner, Operator, Director) 	For CMS	<p>42 C.F.R. § 493.801(b)(4) Condition: The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>42 C.F.R. § 493.1441 Condition: Laboratory Director</p>
06/17/2010 [CR2159] St. Elizabeth's Medical Center v. CMS	<ul style="list-style-type: none"> - Appeal of ALJ Decision - Intentional PT referral - Summary Judgement 	For CMS	42 C.F.R. § 493.801(b)(4) Condition: The laboratory must not send PT samples or portions of samples to another laboratory
10/22/2010 [Decision No. 2340] Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D. v. CMS	<ul style="list-style-type: none"> - Appeal of ALJ decision - Intentional PT referral 	For CMS	42 C.F.R. § 493.801(b)(4) Condition: The laboratory must not send PT samples or portions of samples to another laboratory
1/10/2011 [CR2300] Southlake Emergency Care Center v. CMS	<ul style="list-style-type: none"> - Owner Prohibition of Another CLIA Certificate - Revocation 	For CMS	42 C.F.R. § 493.1840(a)(8) Adverse action based on owning/operating a laboratory within preceding two-year period that has had its CLIA certificate revoked
7/27/2011 [CR2402] Family Medical Center v. CMS	<ul style="list-style-type: none"> - Intentional PT referral - Owner/Operator Prohibition 	For CMS	<p>42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.</p> <p>42 C.F.R. § 493.1840(e) Procedures for Revocation</p> <p>42 C.F.R. § 493.1844(d)(2) Suspension, Limitation, or revocation of a laboratory's CLIA certificate</p>

Decision Date and Case Name	Issues	Outcome	Regulatory References
8/2/2011 [DAB2402] Southlake Emergency Care Center v. CMS	- Owner Prohibition of Another CLIA Certificate - Revocation	For CMS	42 C.F.R. § 493.1840(a)(8) Adverse action based on owning/operating a laboratory within preceding two-year period that has had its CLIA certificate revoked
9/21/2011 [CR2436] J.B. and Greeta B. Arthur Comprehensive Cancer Center Laboratory v. CMS	- Intentional PT referral - Owner/Operator Prohibition	For Petitioner	42 C.F.R. § 493.801(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory.
1/17/2012 [CR2490] Huntington Beach Clinical Laboratory, Inc. vs. CMS	- Misrepresentation of Test Volume - Testing Outside CLIA Certificate - Laboratory Director Responsibilities - 2 year Prohibition	For CMS	42 C.F.R. § 493.1840(a)(8) Adverse action based on owning/operating a laboratory within preceding two-year period that has had its CLIA certificate revoked
1/24/2012 [CR2492] Kids Med (Delta Medical Branch) v. CMS	- Timely filing of an appeal - Request for a hearing must comply with 42 C.F.R. § 498.40	For CMS	42 C.F.R. § 493.1844(f) Appeal rights of laboratories 42 C.F.R. § 498.40 Request for hearing
8/14/2012 [DAB 2471] Kids Med (Delta Medical Branch) v. CMS	- Timely filing of an appeal - Request for a hearing must comply with 42 C.F.R. § 498.40	For CMS	42 C.F.R. § 493.1844(f) Appeal rights of laboratories 42 C.F.R. § 498.40 Request for hearing
9/18/2012 [CR2614] Mercedes Children's Clinic/Mercedes Kids Medical v. CMS	- Owner Prohibition of Another CLIA Certificate - Revocation	For CMS	42 C.F.R. § 493.1840(a)(8) Adverse action based on owning/operating a laboratory within preceding two-year period that has had its CLIA certificate revoked

Decision Date and Case Name	Issues	Outcome	Regulatory References
7/12/2013 [CR2854] Planned Parenthood Choice of Abilene, Texas v. CMS	- Improper PT (Collusion) - Moderate Complexity Laboratory Director - Revocation	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples 42 C.F.R. § 493.1403 Laboratories performing moderate complexity testing; laboratory director
9/18/2013 [Docket No. C-12-1225] Xuan Q. Zhang, MD Laboratory and Robert Ireland, PhD, Lab Director v. CMS	- Right to a hearing	For CMS	42 C.F.R. § 498.40(c)(2) For good cause, the ALJ may extend the time for filing the request for hearing. 42 C.F.R. § 498.70(b) No right to hearing. The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.
11/14/2013 [CR2995] Liberty Laboratory, Inc. v. CMS	- Unsuccessful PT - Moderate Complexity Laboratory Director - Analytic Systems	For CMS	42 C.F.R. § 493.803 Successful Participation 42 C.F.R. § 493.1250 Analytic Systems 42 C.F.R. § 493.1403 Laboratories performing moderate complexity testing; laboratory director
3/24/2014 [DAB 2562] Liberty Laboratory, Inc. v. CMS	- Unsuccessful PT - Moderate Complexity Laboratory Director - Analytic Systems	For CMS	42 C.F.R. § 493.803 Successful Participation 42 C.F.R. § 493.1250 Analytic Systems 42 C.F.R. § 493.1403 Laboratories performing moderate complexity testing; laboratory director
04/22/2015 [CR3808] Academic Institute of Pathology v. CMS	-revocation/suspension - American Society of Cytotechnologists and Texas Department of State Health Services -PT referral	For CMS	42 C.F.R. § 493.803, Successful participation; 42 C.F.R. § 493.1221, Cytology; 42 C.F.R. § 493.1441, Laboratories performing high complexity testing, laboratory director 42 C.F.R. § 493.1447, Laboratories performing high complexity testing, technical supervisor 42 C.F.R. § 493.801, Enrollment and testing of samples; 42

Decision Date and Case Name	Issues	Outcome	Regulatory References
5/29/2015 [CR3919] Adeona Clinical Laboratory, LLC, v. CMS	Intentional PT Referral	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples
8/30/2016 [CR 4694] Fullerton-Kimball Medical & Surgical Center Laboratory v. CMS	- Toxicology - Analytic Systems - Laboratory Director Responsibilities - Technical Supervisor - Qualifications - General Supervisor Qualifications - Testing Personnel Qualifications	For CMS	42 C.F.R. § 493.1213 Toxicology 42 C.F.R. § 493.1250 Analytic Systems 42 C.F.R. § 493.1441 High complexity laboratory director 42 C.F.R. § 493.1447 Technical supervisor 42 C.F.R. § 493.1459 General Supervisor 42 C.F.R. § 493.1487 High complexity testing personnel
12/20/2016 [Ruling No. 2017-5] Shadow Creek Medical Clinic v. CMS Fairway Medical Clinic vs. CMS	- Timing of hearing request - Mode of notification of hearing rights	For CMS	42 C.F.R. § 498.40(a)(2), (c) Request for a hearing
8/14/2017 [CR4918] The Malaria & Rheumatic Disease Research Institute, Inc. (MARDRI) v. CMS	- Refusal to allow survey - Imposing immediate suspension of CLIA certificate	For CMS	42 C.F.R. § 493.1777 Inspection requirements
8/18/2017 [DAB 2811] Shadow Creek Medical Clinic v. CMS Fairway Medical Clinic vs. CMS	- Timing of hearing request - Mode of notification of hearing rights	For CMS	42 C.F.R. § 498.40(a)(2), (c) Request for a hearing
5/28/2018 [DAB 2872] The Malaria & Rheumatic Disease Research Institute, Inc. (MARDRI) v. CMS	- Refusal to allow survey - Imposing immediate suspension of CLIA certificate	For CMS	42 C.F.R. § 493.1777 Inspection requirements
7/23/2018 [US Court of Appeals, DAB 2811] Murtaza Mussaji v. US Dept. HHS	- Extension for filing an appeal - Mode of transmittal for enforcement notices	Petition Denied	n/a
8/5/2019 [CR5385] Kensington Diagnostics LLC vs. CMS	- Condition-Level Noncompliance - Revocation of CLIA certificate - Two year prohibition for owners/operators	For CMS	42 C.F.R. § 493.1230 General Laboratory Systems 42 C.F.R. § 493.1250 Analytic Systems 42 C.F.R. § 493.1441 Laboratory Director

Decision Date and Case Name	Issues	Outcome	Regulatory References
8/21/2019 [CR5400] Medicos Para La Familia vs. CMS	- Intentional PT Referral - Laboratory Director Responsibilities	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples 42 C.F.R. § 493.1403 Laboratory Director
12/23/2019 [CR5494] Dr. Kenneth U. Ihenetu, Ph.D., DABCC, FACB, Laboratory Director of EMS Toxicology, LLC vs. CMS	- Revocation of CLIA certificate - Two-year laboratory director prohibition - Condition-level noncompliance	For CMS	42 C.F.R. § 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate 42 C.F.R. § 493.1441 High Complexity, Laboratory Director
1/31/2020 [CR5523] LabCorp vs. CMS	- Intentional PT Referral - Laboratory Director Responsibilities	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples 42 C.F.R. § 493.1445 Laboratory Director
2/14/2020 [ALJ Ruling No. 2020-6] Charles S. Pewitt, D.O., d/b/a Jackson Medical Center vs. CMS	- Timely request for hearing	For CMS	42 C.F.R. § 493.1844(f) Appeal procedures 42 C.F.R. §§ 498.40(a)(2), (c) Request for hearing
3/16/2020 [DAB2992] Kensington Diagnostics LLC vs. CMS	- Condition-Level Noncompliance - Revocation of CLIA certificate - Two year prohibition for owners/operators	For CMS	42 C.F.R. § 493.1230 General Laboratory Systems 42 C.F.R. § 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate
4/16/2020 [CR5589] Laboratorio Concordia Lugaro vs. CMS	- Intentional PT Referral	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples
5/21/2020 [CR5616] Albert Cohen, M.D. vs. CMS	- Intentional PT Referral - Two-year prohibition of Laboratory Director - Testing of PT samples for which a laboratory is certified to perform	For CMS	42 C.F.R. § 493.801 Enrollment and testing of samples 42 C.F.R. § 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate
7/31/2020 [3009] Charles S. Pewitt, D.O., d/b/a Jackson Medical Center vs. CMS	- Timely request for hearing	For CMS	42 C.F.R. § 493.1844(f) Appeal procedures 42 C.F.R. §§ 498.40(a)(2), (c) Request for hearing
9/29/2020 [CR5723] UNEVX, Inc. d/b/a R.E.D. Laboratories vs. CMS	- Condition-Level Noncompliance - Technical Supervisor	For CMS	42 C.F.R. § 493.1447 Laboratories performing high complexity testing; technical supervisor
10/16/2020 [CR5736] Calvin S. Rosenfeld, M.D., P.A. vs. CMS	- Unsuccessful Participation in Proficiency Testing - Laboratory Director Responsibilities	For CMS	42 C.F.R. § 493.803 Successful participation 42 C.F.R. § 493.1403 Laboratories performing moderate complexity testing; laboratory director

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Decision Date and Case Name	Issues	Outcome	Regulatory References
10/28/2020 [Case No. 6:20-CV-033337-MDH] Gamma Healthcare, Inc (GHC) vs. HHS (United States District Court For the Western District of Missouri)	- IJ - Suspension of a certificate prior to hearing	For CMS	42 C.F.R. § 493.1840(d)(2) Suspension, limitation, or revocation of any type of CLIA certificate
4/29/2021 [CR5861] Justin Camillo and ACN Medical Labs vs. CMS	- Laboratory Director, Other Personnel - Proficiency Testing - Analytic Systems	For CMS	42 C.F.R. § 493.801 (Enrollment and Testing of PT Samples) 42 C.F.R. § 493.1250 (Analytic Systems) 42 C.F.R. § 493.1403 (Moderate Complexity; Laboratory Director) 42 C.F.R. § 493.1409 (Moderate Complexity; Technical Consultant) 42 C.F.R. § 493.1421 (Moderate Complexity; Testing Personnel) 42 C.F.R. § 493.1441 (High Complexity; Laboratory Director) 42 C.F.R. § 493.1447 (High Complexity; Technical Supervisor, 42 C.F.R. § 493.1459 (High Complexity; General Supervisor 42 C.F.R. § 493.1487 (High Complexity; Testing Personnel)
11/9/2021 [CR5976] Laboratorio Concordia Lugaro vs. CMS	- Intentional Proficiency Testing Referral	For CMS	42 C.F.R. § 493.801; Enrollment and testing of samples 42 C.F.R. § 493.1100; Facility Administration 42 C.F.R. § 493.1403; Moderate Complexity, Laboratory Director
2/23/2022 [CR6031] Ellington Behavioral Health vs CMS	- Analytic Systems - Laboratory Director	For CMS	42 C.F.R. § 493.1250 Analytic Systems 42 C.F.R. § 493.1441 High Complexity; Laboratory Director
07/06/2022 [DC 4:22CV399 HEA] David L. Smalley, Ph.D. Vs Xavier Becerra, Secretary of HHS	- Laboratory Director Prohibition - Appeal process	For CMS	42 C.F.R. §493.1844 Appeals procedures

Decision Date and Case Name	Issues	Outcome	Regulatory References
8/22/2022 [CR6135] Vitas Laboratory, LLC vs. CMS	<ul style="list-style-type: none"> - Revocation of Vitas' CLIA certificate - Two-year prohibition for the Laboratory Director 	For CMS	42 C.F.R. § 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate
8/22/2022 [CR6142] Vitas Laboratory, LLC and Chenbo Dong, Ph.D. vs. CMS	<ul style="list-style-type: none"> - Misrepresentation - Revocation - Two-year prohibition 	For CMS, Dong	42 C.F.R. § 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate
11/14/2022 [ALJ Ruling No. 2023-3] David L. Smalley, Ph.D. vs CMS	<ul style="list-style-type: none"> - Suspension and revocation of CLIA certificate - Two-year prohibition for the Laboratory Director 	For CMS	42 C.F.R. § 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate
3/31/2023 Quantum Laboratory, LLC vs CMS	<ul style="list-style-type: none"> - Order of Dismissal 	For CMS	42 C.F.R. § 498.69 Dismissal for abandonment
6/2/2023 [CR6293] Quantox Lab, LLC vs CMS	<ul style="list-style-type: none"> - Laboratory Director - Analytic Systems 	For CMS	42 C.F.R. § 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate

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. Shanevfelt, 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* [\[DAB1747\]](#) (DABaffirmation)

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* [\[DAB1762\]](#) (DABaffirmation)

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 [\[DAB17551\]](#) (DAB affirmation)

Stanley Boykanskv, 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 not 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 Elsenetv, 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 Garv 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 Elsenetv, 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(l)(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 apprise 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 C.F.R. § 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 (Disclosure 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 [\[CR334\]](#) 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 Brvant, 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 deficiencies 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 statute requires no action by the Secretary to be 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 C.F.R. 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 Avazar 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) and 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 [DAB1951]

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 [\[DAB1763\]](#)

Vijav 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 of 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]
Sonal 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 issues 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 matter 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 to 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 within 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
[\[DAB 1820\]](#)
Hrt
cr1497.pd
f

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.

Petitioner 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 C.F.R. 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 C.F.R. 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 conformance 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 C.F.R. 493.1355), and the condition for inspection requirements (42 C.F.R. 493.1771). The laboratory was conducting testing for specimens outside the scope of its CLIA microscopy certificate, testing was being performed in the absence of appropriate supervision, and the testing was done by 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 C.F.R. 493.1355 and 1771. CMS is, therefore, justified in imposing sanctions for noncompliance with condition-level deficiencies.

The existence 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 because 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 failed 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 laboratory 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 any reason 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 laboratory for 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 that it was certified to perform. Under the regulations, CMS may revoke a certificate where the referral was non-intentional, but only 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 C.F.R. 493.1250 (conditions for a laboratory to monitor and evaluate the overall quality of the analytic systems it employs), 42 C.F.R. 493.1403 (conditions to be met by the individual holding the laboratory director position), and 42 C.F.R. 493.1409 (conditions that must be met by 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 certificate 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 substitute 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 C.F.R. 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 certificate 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 than 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 determination 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 if 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. "Abandonment" 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 C.F.R. 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 C.F.R. § 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 C.F.R. § 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 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 answer is as much cheating as handing in someone else's.

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 C.F.R. 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

**CARI Reproductive Services
v. CMS Docket No: C-09-407
Decision No. CR2060**

CLIA #: 14D1056871
State: Illinois
Type of Certificate: Registration
ALJ: Keith W. Sickendick

Basis for Sanction(s):

CMS based its determination to revoke on the provisions under 42 CFR § 493.1840(e) and 42 C.F.R. § 493.1844(d)(2). Condition-level deficiencies included failure of the laboratory director (42 C.F.R. § 493.1441) and the technical supervisor (42 C.F.R. § 493.1447) to provide overall management and direction of the laboratory, and overall technical oversight of the laboratory, respectively. CMS maintained that the Petitioner attempted to avoid the penalty of revocation by withdrawing from CLIA certification after receiving unfavorable survey results.

Argument(s):

The Petitioner argued that it applied for a CLIA certificate in error based on information provided by the state agency. The Petitioner contended that the testing performed at the facility was research and development, not clinical; therefore, the CLIA certificate should have been terminated not suspended and revoked. The Petitioner also argued that the state agency employees should have known that the Petitioner was not subject to CLIA and terminated the CLIA certificate.

Ruling Excerpt(s):

The Petitioner did not represent itself as a research laboratory rather it represented itself as a diagnostic laboratory performing general immunology testing during the application process. In fact, the laboratory did perform clinical diagnostic testing. A CLIA certificate was issued to the Petitioner based on the Petitioner's application, and as such, the Petitioner was subject to inspection to assess compliance. The Petitioner does not dispute that it was not in compliance with conditions of participation 42 C.F.R. § 493.1441 and 42 C.F.R. § 493.1447. Inconsistent information provided by the state agency employees as to the applicability of CLIA was not a defense for the Petitioner as the information was available with "reasonable diligence." The Petitioner cannot avoid revocation of its CLIA certificate by withdrawal of its application or voluntary termination of its participation in CLIA.

Other Case(s) Referenced:

Edison Medical Laboratories, Inc, DAB
1713 Ward General Practice Clinic,
DAB No. 1624

Associated Internists, P.C. v.
CMS Docket No: A-10-10
Decision No. 2298
DAB CR2005

CLIA #: 23D0983891
State: Michigan
Type of Certificate: Compliance
DAB: Judith A. Ballard, Constance B. Tobias, Leslie A. Sussan

Basis for Sanction(s):

CMS determined that the Petitioner was out of compliance with three conditions of participation (42 C.F.R. § 493.1230, 42 C.F.R. § 493.1250, and 42 C.F.R. § 493.1441) at the immediate jeopardy level. CMS determined that the Petitioner removed the immediate jeopardy; however, the Petitioner did not submit a “credible Allegation of Compliance and evidence of correction of the deficiencies”. CMS imposed sanctions against the Petition which included revocation. CMS filed a motion to dismiss the hearing requested based on the argument that the Petitioner did not “specify issues, and the findings of fact and conclusions of law” (42 C.F.R. § 498.40(b)). In addition, CMS argued that that the Petitioner had no right to appeal the rejection of the plan of correction (POC) (42 C.F.R. § 493.1844).

Argument(s):

The Petitioner asserted that it had “regained compliance with CLIA requirements”.

Ruling Excerpt(s):

The Petitioner did not dispute that it was not in compliance with the three conditions of participation, and did not challenge CMS’ imposition of principal sanctions. Associated’s hearing request appeared to be “yet another attempt to assert that it has regained compliance with CLIA requirements”. In addition, the hearing request reflected the Petitioner’s continued misunderstanding about laboratory appeal rights under CLIA. Rejection of a POC is not an initial determination and is, therefore, not subject to appeal under 42 C.F.R. § 493.1844(b). The DAB upheld the ALJ’s decision.

Other Case(s) Referenced:

HRT Laboratory, Inc., DAB No. 2118

Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D. vs.
CMS Docket No: C-07-715, C-07-721
Decision No. CR2156

CLIA #: 05D0663016
State: California
Type of Certificate: Accreditation
ALJ: Alfonso J. Montaña

Basis for Sanction(s):

CMS determined that the Petitioners intentionally referred proficiency testing specimens (42 C.F.R. § 493.801(b)(4)) for subspecialty of bacteriology. CMS also determined that the laboratory director did not provide overall management and direction of the laboratory (42 C.F.R. § 493.1441). CMS further asserted that either condition-level non-compliance citation can stand alone as a reason for revocation.

Argument(s):

The Petitioner (Victor Valley) maintained that the PT was intentionally referred; however a “mistake” by an employee is not an intentional act by the hospital. The Petitioner argued that the referral did not violate CLIA because: (1) the employee was not able to complete the PT testing at the Petitioner’s lab and, therefore, had no choice but to refer the samples to Quest, (2) the improper referral was the mistake of an employee rather than intentional referral by the hospital, (3) the employee did not intend to violate the CLIA statute and regulations, (4) the employee followed the laboratory’s usual procedure for testing patient samples, and (5) the PT results reported to CAP were only those results performed by the employee. The Petitioner further asserted that in order to have “intentionally” referred its PT samples, it must have the intent of reporting these results as its own which it did not. Finally, the Petitioner argued that sections of the State Operations Manual (SOM) and Interpretive Guidelines (IG) should be used to support their assertion(s) regarding PT referral. The Laboratory Director asserted that the referral was an accident or mistake.

Ruling Excerpt(s):

The Petitioner filed a Motion for Preliminary Injunction against the Secretary on September 20, 2007 (Docket No. C-07-715) which was issued on January 10, 2008. The injunction prohibited the cancellation of the Petitioner’s approval to receive Medicare and Medicaid payments pending the resolution of this matter. The Laboratory Director filed a separate request for a hearing (Docket No. C-07-721) which was consolidated with Docket No. C-07-0715.

The determination as to which alternative sanction(s) to impose and/or the amount of the CMP is not subject to appeal (42 C.F.R. § 493.1844(b)(3)(c)(4)). No delay exists in the suspension or limitation of the laboratory’s CLIA certificate if the laboratory refuses a reasonable request for information.

The statute and regulations do not allow for exceptions to revocation if laboratories send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform (42 C.F.R. § 493.1840(b)). Moreover, the motives are irrelevant. Victor Valley was certified to perform the tests on the two PT samples, therefore, mistakenly sending the PT samples out is not a defense.

The evidence does not support the assertion that the employee had no choice but to send the PT samples to Quest. The Petitioner’s laboratory technician’s intentions at the time of referral are irrelevant. A laboratory does not need to report PT results from the lab to which it referred

samples for it to be considered improper or intentional PT referral. It is irrelevant.

Victor Valley was misguided in its interpretation of the statute. The statute does not intend to only address referrals in the case that the laboratory both sent samples to another laboratory for analysis and also reported the results of the analysis as its own. The ALJ clarified that the SOM and IG do not have “the force and effect of the law”.

Both Petitioners had the duty to familiarize themselves with applicable standards prior to seeking certification under those standards. Victor Valley and the Laboratory Director were responsible for the actions of their staff, and in this case, for the intentional referral of PT samples. The Petitioners had the opportunity to present testimony from the laboratory technician, the Laboratory Director and any experts, but the Petitioners chose not to present this testimony.

The Laboratory Director offered no evidence throughout the proceedings to support his contention that the referral was inadvertent or a mistake. In fact, the laboratory technician labeled the specimens as PT specimens prior to referring them to Quest. The Laboratory Director bore the ultimate responsibility for ensuring that PT was performed as required by 42 C.F.R. § 493.801. In addition, he had a duty to be kept apprised of the day-to-day operations of his laboratory and to exercise supervision of his employees in order to assure the quality of laboratory services provided and to identify failures as they occur (42 C.F.R. § 493.1445(e)(5)).

42 C.F.R. § 493.1840(b) requires that if CMS determines that a laboratory has intentionally referred PT samples, the CLIA certificate is required to be revoked for at least one year.

Other Case(s) Referenced:

Wade Pediatrics, CR 1630, DAB
No. 2153 Edison Medical Labs,
Inc., DAB No. 1713 Ward General
Practice Clinic, DAB No. 1624
Emerald Oaks, DAB No. 1800
Lackawanna Medical Group Laboratory, DAB CR957,
DAB No. 1879 White Lake Family Medicine, PC, DAB No.
1951
Primary Care Medical Group, DAB No. CR439
Rustom Ali, Jahan Fedours & Scottsdale Medical Lab, Dab No. 2016

**St. Elizabeth's Medical
Center v. CMS Docket No:**
C-09-399
Decision No. CR2159

CLIA #: 24D0404612
State: Minnesota
Type of Certificate: Accreditation
ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

Intentional proficiency testing (PT) referral (42 C.F.R. § 493.801(b)(4)).

Argument(s):

The Petitioner argued that the employee who performed the proficiency testing (PT) had never participated in PT before, did not realize that she was violating any statute or regulation, and did not intend to "cheat" on the testing process. In addition, the Petitioner argued that CMS's position is overly harsh because an inexperienced employee performed the PT.

Ruling Excerpt(s):

CMS's motion for summary judgment was granted based on the fact that the Petitioner did not present factual evidence to support its dispute with CMS's facts. The motives of a laboratory which 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. §193.801(b)(4).

Other Case(s) Referenced:

White Lake Family Medicine, DAB
No. 1951 RNA Laboratories, DAB No.
1820
Wade Pediatrics, DAB No. 2153
Lackawanna Med. Group Lab, DAB No. 1870

Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D. vs.
CMS Docket No: A-10-74
Decision No. 2340

CLIA #: 05D0663016

State: California

Type of Certificate: Accreditation

DAB: Judith A. Ballard, Constance B. Tobias, Leslie A. Sussan

Basis for Sanction(s):

CMS determined that the Petitioners intentionally referred proficiency testing specimens (42 C.F.R. § 493.801(b)(4)) for subspecialty of bacteriology. CMS disputed the ALJ's finding of fact 10 which spoke to the Petitioner (Victor Valley) treating PT samples the same as patient samples. CMS also argued that the revocation must be upheld regardless of whether the referral was intentional as Victor Valley did not deny facts that established condition-level deficiencies.

Argument(s):

The laboratory director did not appeal the ALJ decision. Victor Valley did not challenge the ALJ's conclusions related to the laboratory director requirements.

Victor Valley asserted that PT referral can only be intentional if CMS proved that the laboratory knew that it was violating the applicable statute and regulation. Victor Valley contended that it meant to seek comparison test results to improve its testing standards. Victor Valley further argued that by clearly marking the PT samples as PT samples the laboratory demonstrated that it did not intend to "trick" Quest or to hide the referral. The Petitioner suggested that a different standard should be adopted for finding a laboratory's referral is knowing and willful. The Petitioner also argued that complying with the introductory language of 42 C.F.R. § 493.801 requiring PT samples to be treated the same as patient samples results in the inability to comply with 42 C.F.R. § 493.801(b)(4) which prohibits PT samples from being referred out for analysis. Finally, the Petitioner continued to assert that PT referral cannot be intentional if the results reported to the PT provider are their own and not from the referred laboratory.

Ruling Excerpt(s):

The ALJ was correct in concluding that Victor Valley's referral of PT samples to Quest was intentional within the meaning of the statute and regulations. The DAB noted that the CLIA regulations do not specifically define "intentional" referral; however "intentional violation" in general means "knowing and willful" non-compliance with any CLIA condition. The DAB concluded that clearly marking the PT samples sent to Quest indicated that there "was no mistake, accident, negligence or recklessness" about the PT referral. Victor Valley did not identify any evidence on which to conclude that intentional referral can only be deceptive or secret. The Petitioner was aware that it was referring out PT samples and, based on the requisition, that the PT samples would be subjected to analysis. CMS was not required to wait to see if the Petitioner used the results as a comparison of their own results or submitted Quest's results as their own prior to reasonably acting once notified by Quest of the PT referral. The regulatory requirement is not that the treatment of the PT sample must be in all respects identical to the handling of a patient sample, but rather that "the laboratory must test the samples in the same manner as patients' specimens".

Finding of Fact 10 was stricken from the ALJ's decision based on the fact that the DAB concluded that no substantial evidence relied on by the ALJ and cited by Victor Valley supported any affirmative finding about why Victor Valley or its laboratory technician referred out these PT samples.

The ALJ's decision was upheld, modifying it only to remove Finding of Fact 10.

Other Case(s) Referenced:

Associated Internists, PC, DAB No.
2298 Edison Medical Laboratories,
DAB No. 1713 Ward General
Practice Clinic, DAB No. 1624
Wade Pediatrics, DAB No. 2153
Mark Gary Hertzberg, DAB No. 1805
US Bio-Chem Medical Laboratories, Inc., DAB No.
1731 Lackawanna Medical Group Laboratory, DAB
No. 1870

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.

For 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.

Background

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

Addressees:

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and

Brenda F. Kohn, Esq. Assistant Regional Counsel DHHS - Region IX
50 United Nations Plaza, Room 420 San Francisco, California 94102

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**. I will set up a prehearing conference in this matter during the week of **January 24, 2000**.

It is so ordered.
March

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n

Administrative Law Judge

Addressees:

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UNITED STATES DISTRICT COURT CENTRAL DISTRICT OF CALIFORNIA

Physicians Independent CV 00-12209 SVW (CWx)

Laboratory, Inc., a California corporation; Sahibzada A. Akhtar, an individual, ORDER

DENYING PLAINTIFFS' MOTION

FOR PRELIMINARY INJUNCTION

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.

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 Administrative 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 Jersey, 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 Regulation 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

¹. At oral argument, the Secretary stated that 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.

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 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

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 (2d 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 it 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

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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 came 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

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No. 00-3138

EDISON MEDICAL LAB., INC.,

Petitioner

V.

HEALTH CARE FINANCING ADMINISTRATION,
Respondent

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.

(Opinion Filed: February 15, 2001)

MEMORANDUM OPINION OF THE COURT

92

Kenneth B. Falk (Argued)
Deutch & Falk
843 Rahway Avenue
Woodbridge, NJ 07095

Counsel for Petitioner

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 CV 00-12209 SVW (CWx)
Laboratory, Inc., a California
corporation; Sahibzada A.
Akhtar, an individual, ORDER GRANTING DEFENDANTS, MOTION
TO DISMISS

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.

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 its principal 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 expertise 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 ORDERED.

DATED: 5/9/2001

STEPHEN V. WILSON

UNITED STATES DISTRICT JUDGE

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United States Attorney
STUART A. MINKOWITZ
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ORIGINAL FILED
JUN 18 2001

WILLIAM T. WALSH, CLERK

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,
Plaintiff,

Hon.

Civil Action No. 01-2872 [(k?)sh]

v.

EDISON MEDICAL TEMPORARY RESTRAINING
LABORATORY SERVICE CORPORATION, 42 U.S.C. § 263a(j) and 42 C.F.R. §
Defendant. ORDER TO SHOW CAUSE AND
ORDER (Fed. R. Civ. P. 65(a), (b);
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:

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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 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. *and by fax.*

8. Pursuant to 42 U.S.C. § 263a(j), the plaintiff 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 16 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:

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1. The Court has subject matter jurisdiction over this action 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 U.S.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 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, its 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, its 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, its 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 Government for its reasonable attorney's fees, investigational expenses and costs.

10. Nothing in this Consent Decree shall be deemed to excuse defendant, its 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 correspondence 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
New 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, its owners, operators, officers, agents, employees, lessors, assigns, successors in interest, and those persons who are in active 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 additional relief as may hereafter appear necessary 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 the Defendant, 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 PLAINTIFF'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 on 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 harm 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 can be granted.¹

-
- (1) whether the movant has a "strong" likelihood of success on the merits;
 - (2) whether the movant would otherwise suffer irreparable injury; (3) whether

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

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 requirements³ for its laboratories to those of CLIA and

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.,

determined 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 (C.F.R.), part 493 (Laboratory Requirements). Therefore, a laboratory accredited by an approved

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 Manual*, §3

⁴ Bacteriology, mycobacteriology, mycology, parasitology, virology, syphilis serology, general immunology, routine chemistry, endocrinology, toxicology, urinalysis, and hematology, immunohematology.

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 be 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. *Id.*

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 noted⁵; 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

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 of 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 Investigation

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 Law *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 1039, 1045 (3d Cir. 1993), cert. denied, 510 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.1992)). "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. 1990)). 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 *Int'l 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.

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

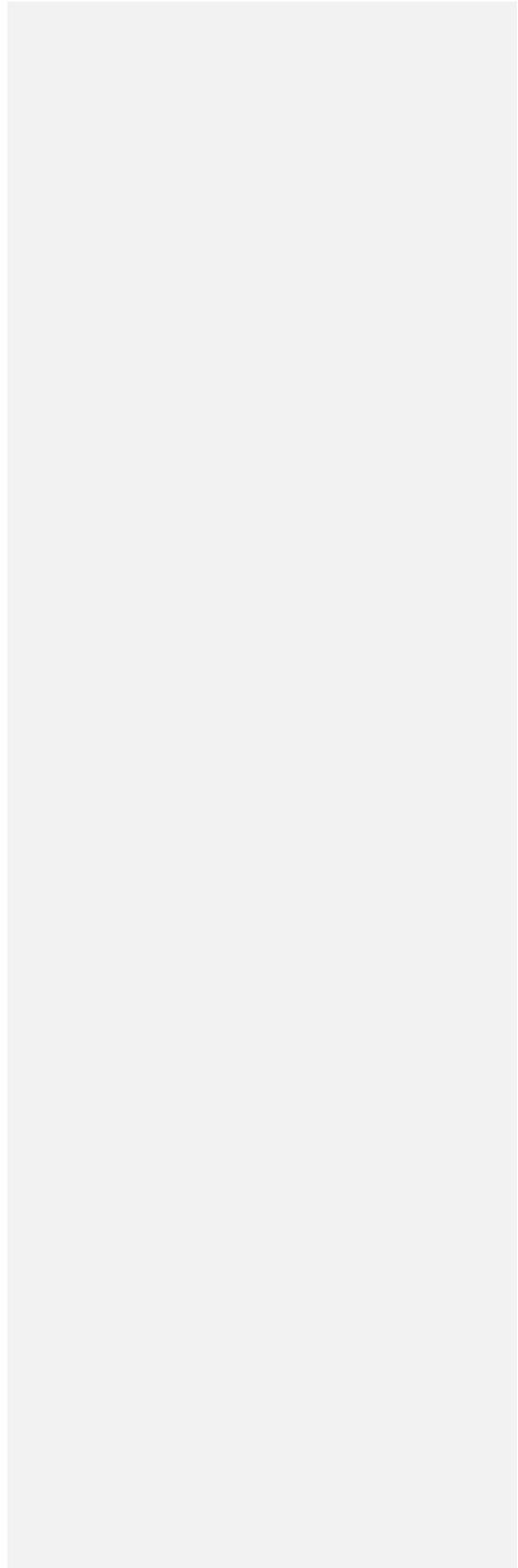
⁷ During the COLA investigation process, it determined that "the knowledge of the lab technician should not be imputed to the laboratory itself," (*Exhibit J of Plaintiffs' Verified Complaint for Declaratory Judgment, Mandamus and Injunctive Relief*). Conversely, CMS imputes the actions of a laboratory 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 C.F.R. 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 C.F.R. § 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 Council 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*

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Services for *the Aging v. Shalala*, 127 F.3d 496, 500-01 (6th Cir. 1997); *Monakee Professional Medical Transfer Service, Inc. v. Shalala*, 71 F.3d 574 (6th Cir. 1995); *Farkas v. Blue Cross & Blue Shield 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 PFM, 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 law bars

⁸ COLA has been approved as an accreditation organization for laboratories under the CLIA program; 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.

this Court from compelling payment of Medicare reimbursement, under either 28 U.S.C. § 1331 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 SERVICES 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, (?)(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. 1997); *Manatee 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 *Mathews v. Eldridge*, 424 U.S. 319 (1976). Pursuant to *Mathews* 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. *Mathews*, 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 *Mathews* 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, the 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 28 2001**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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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.

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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.

I

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

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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.

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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

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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

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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

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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 LaFare, *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 Case: 08-9529 Document: 01018075294 Date Filed: 06/02/2009 Page: 7

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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.

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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. Hulse*, 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, Case: 08-9529 Document: 01018075294 Date Filed: 06/02/2009 Page: 9

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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 –

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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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Southlake Emergency Care Center vs. CMS
Docket No: C-10-877
Decision No. CR2300
Date: January 10, 2011

CLIA #: 45D1021990
State: TX
Type of Certificate: Compliance
ALJ: Joseph Grow

Basis for Sanction(s):

- Undisputed evidence established that that owner of Southlake Emergency Care Center (Southlake Lab) was also the owner of Coppell Minor Emergency Center, LLC (Coppell Laboratory).
- CMS had previously revoked the CLIA certificate of Coppell Laboratory; therefore, had the authority to revoke the CLIA certificate of Southlake Emergency Care Center, pursuant to 42 C.F.R. § 493.1840(a)(8).

Argument(s):

- The Petitioner asserted that CMS informed the laboratory that if they surrendered the CLIA certificate for Coppell Laboratory (due to closure) rather than have the certificate revoked, then the CLIA certificate for Southlake Lab would be unaffected.
- The Petitioner never acted upon the purported bad advice to give notice to CMS that it would surrender Coppell Labs CLIA certificate.
- The Petitioner also asserted that CMS should not have revoked Coppell Lab's CLIA certificate since the laboratory closed prior to the revocation date.

Ruling Excerpt(s):

- The motion for summary judgment upheld in favor of CMS. After the CLIA certificate for Coppell Labs was revoked, the owner of Southlake Lab was banned from owning or operating a laboratory for a period of two-year period.
- The regulatory language is plain, and there is no genuine issue of material fact. CMS acted within its regulatory authority to revoke the Petitioner's CLIA certificate.

Issues:

- Whether Petitioner may contest CMS's revocation of its CLIA certificate
- Whether further discovery shall be permitted regarding the revocation of a CLIA certificate with common ownership
- Whether CMS is entitled to summary judgement

Statutory/Regulatory References:

- 42 U.S.C. § 263a
- 42 U.S.C. § 263a(f)(i)

- 42 U.S.C. § 263a(i)(3)
- 42 U.S.C. § 263a(f)(1)(E)
- 42 C.F.R. § 493.1, Basis and scope
- 42 C.F.R. § 493.1806, Sanctions available to all laboratories
- 42 C.F.R. § 493.1840(a)(8), Suspension, limitation, or revocation of any types of CLIA certificate
- 42 C.F.R. § 493.1844(a), (b)(1), Appeals procedures
- 42 C.F.R. § 498.60

Family Medical Center v. CMS
Docket No: C-11-129
Decision No. CR2402
Date: July 27, 2011

CLIA #: 24D0405950
State: Minnesota
Type of Certificate: Accreditation
ALJ: Richard J. Smith

Basis for Sanction(s):

- Based on a complaint survey, CMS determined that the Petitioner was out of compliance with two CLIA conditions of participation: 42 C.F.R. § 493.801 (enrollment and testing of samples) and 42 C.F.R. § 493.1403 (laboratories performing moderate complexity testing; laboratory director) and intentionally referred proficiency testing (PT) samples to another laboratory.
- CMS imposed sanctions which included revocation of the Petitioner's CLIA certificate and cancellation of the laboratory's approval to receive Medicare payments for its services.

Argument(s):

- Both parties agreed that the Petitioner referred the PT sample to another laboratory for analysis; however, the Petitioner argued that the referral was not intentional, but rather in order to comply with its policy and CLIA requirements to treat PT samples in the same manner it treats patient samples.
- The Petitioner also asserts that CMS failed to present evidence that the Petitioner "willfully" referred the PT sample.
- The Petitioner also argues that the referral was "accidental" because they performed the wrong test on the PT sample, thus creating a sequence of events leading to the referral.

Ruling Excerpt(s):

- Petitioner did intend to send and did send the PT sample to another laboratory to perform a hemoglobin A1C test (which it was certified to perform).
- Therefore, CMS must revoke the Petitioner's CLIA certificate for at least one year. The Board found that the argument that PT samples which are referred out to in order to "treat the same as patient samples" do not demonstrate that the referral was unintentional within the meaning of CLIA.
- In fact, the historical legal position is that intentional referral means the general act of referring, regardless of the motivation. The action alone is sufficient to trigger liability.

Issues:

- Intentional PT Referral
- 1 year prohibition (PT referral)
- 2 year prohibition (Owner, Operator, Director)

Statutory/Regulatory References:

- 42 U.S.C § 263a(i)(4)
- 42 C.F.R. § 493.2, Definitions
- 42 C.F.R. § 493.801(b), Enrollment and testing of samples
- 42 C.F.R. § 493.801(b)(1), Enrollment and testing of samples
- 42 C.F.R. § 493.801(b)(4), Enrollment and testing of samples
- 42 C.F.R. § 493.1777, Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance
- 42 C.F.R. § 493.1806, Available sanctions for laboratories
- 42 C.F.R. § 493.1840(b), Suspension, limitation, or revocation of any types of CLIA certificate
- 42 C.F.R. § 493.1840(e), Suspension, limitation, or revocation of any types of CLIA certificate
- 42 C.F.R. § 493.1844(a), Appeal procedures
- 42 C.F.R. § 493.1844(d)(2), Appeal procedures

Southlake Emergency Care Center vs. CMS

Docket No: A-11-56

Decision No. 2402

Date: August 2, 2011

CLIA #: 45D1021990

State: TX

Type of Certificate: Compliance

DAB: Judith A. Ballard, Constance B. Tobias, Stephen M. Godek

Basis for Sanction(s):

- CMS asserted that they had the authority to revoke Southlake Laboratory's CLIA certificate based on the fact that Coppell Laboratory's CLIA certificate had been revoked. Undisputed evidence showed that both Southlake and Coppell had the same owner.

Argument(s):

- The Petitioner argued that the revocation of the CLIA certificate was invalid even if Coppell did not appeal the revocation of its CLIA certificate.

Ruling Excerpt(s):

- The Petitioner raised no dispute of material fact and showed no basis in law for invalidating the revocation of Coppell Laboratory's CLIA certificate.
- ALJ did not err in concluding that CMS was authorized to revoke Southlake Emergency Care Center's CLIA certificate.
- CMS was not estopped from revoking Southlake's CLIA certificate by any advice Dr. O'Hearn received from a CMS employee that he could avoid revocation of Southlake's CLIA certificate by surrendering Coppell's CLIA certificate.
- Coppell's CLIA certificate was not revoked without due process.
- The DAB sustained the ALJ's decision upholding the revocation of Southlake's CLIA certificate.

Issues:

- Revocation of CLIA certificate based on revocation of another CLIA certificate with the same owner

Statutory/Regulatory References:

- 42 U.S.C. § 263a
- 42 U.S.C. § 263a(f)(i)
- 42 U.S.C. § 263a(i)(3)
- 42 U.S.C. § 263a(f)(1)(E)
- 42 C.F.R. § 493.1, Basis and scope
- 42 C.F.R. § 493.1806, Available sanctions for all laboratories

- 42 C.F.R. § 493.1840(a)(8), Suspension, limitation, or revocation of any types of CLIA certificate
- 42 C.F.R. § 493.1844(a), (b)(1), Appeal procedures
- 42 C.F.R. § 498.60

J.B. and Greeta B. Arthur Comprehensive Cancer Center Laboratory v. CMS
Docket No: C-10-543
Decision No. CR2436
Date: September 21, 2011

CLIA #: 26D1047130
State: Missouri
Type of Certificate: Accreditation
DAB/ALJ: Richard J. Smith

Basis for Sanction(s):

- Based on a complaint survey, CMS determined that the Petitioner had intentionally referred proficiency testing (PT) samples to another laboratory for testing.
- The Petitioner tested PT samples, and prior to the PT provider's cut-off date, also sent the PT samples to another laboratory for testing.
- Both laboratories are operated by the same entity.

Argument(s):

- The Petitioner asserted that the unused portions of the PT samples were brought to the second laboratory for storage and eventual disposal only which does not constitute intentional referral.
- In addition, the Petitioner stated that they never requested that the PT samples be tested at the second laboratory. The laboratory personnel brought the Petitioner's results and unused portion of the PT samples to the second laboratory so that the results could be submitted to the PT provider by personnel at the second laboratory and the samples could be stored until after the PT provider cut-off date.

Ruling Excerpt(s):

- Based on the documentary evidence and testimony, it was determined that the Petitioner did not intentionally refer the PT samples by bringing the PT samples to the second laboratory for storage and disposal after completion of the PT testing.
- It was not a referral for purposes of analysis since the Petitioner never requested that the second laboratory do testing of any sort.

Issues:

- Intentional PT Referral
- 1 year prohibition (PT referral)
- 2 year prohibition (Owner, Operator, Director)

Statutory/Regulatory References:

- 42 U.S.C. § 263a
- 42 C.F.R. 493.801, Condition: Enrollment and testing of samples
- 42 C.F.R. 493.801(b)(1)(4), Condition: Enrollment and testing of samples

- 42 C.F.R. 493.803, Condition: Successful participation
- 42 C.F.R. 493.1840(b), Suspension, limitation, or revocation of any types of CLIA certificate
- 42 C.F.R. 493.1844, Appeal procedures

Huntington Beach Clinical Laboratory, Inc. vs. CMS
Docket No: C-11-192
Decision No. CR2490
Date: January 17, 2012

CLIA #: 05D1080532
State: California
Type of Certificate: Compliance
ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

- The laboratory misrepresented its annual testing volume, performed and represented that it was authorized to perform tests that its CLIA certificate did not authorize, and employed a director who was prohibited from owning, operating or directing any laboratory.

Argument(s):

- The Petitioner argued that he should not be sanctioned because he resigned from his position as director before the lab lost its certification.
- The Petitioner stated that he had not abandoned his appeal, but needed an additional, indefinite amount of time in which to seek counsel and prepare his defense.

Ruling Excerpt(s):

- There is no dispute that Huntington violated CLIA rules and is subject to sanctions, including a two-year owner or operator (which includes the director) ban when a laboratory's CLIA certificate is revoked. (42 U.S.C. § 263a(i)(3), 42 C.F.R. § 493.(a)(8)). The lab's CLIA application, signed by the Director, said that its annual test volume would be 8,500. The laboratory was assessed a compliance fee which is based on the annual test volume and a certificate fee. However, Medicare billing data showed that the laboratory billed Medicare for 120,782 tests (14 times the reported volume) which would have significantly increased the laboratory's fees. Huntington did not report the increased volume.
- In addition, Huntington billed Medicare for many tests outside of three subspecialties (urinalysis, toxicology, endocrinology). In fact, the lab was not authorized to perform 92% of the tests for which it billed Medicare. Petitioner has not challenged the misrepresentation of total test volume or that the laboratory performed testing and billed Medicare for tests outside of its CLIA certificate.
- The laboratory director is responsible for the "operation and administration" of the laboratory. 42 C.F.R. § 493.1407. Dr. Pfu-pajena "well understood his responsibilities". He signed an attestation in which he agreed to assume "all directorship responsibilities" and confirmed that he understood that, with the lab owner, he would be held responsible for any violations, including prohibition from owning, operating, or directing a laboratory for 2 years from the date of revocation if the CLIA certificate was revoked during his tenure.

- The ALJ ruled during Dr. Pfulpajena's tenure as Huntington's laboratory director, the laboratory failed to comply with CLIA requirements, so CMS has revoked its CLIA certificate and cancelled its approval to bill Medicare. Pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), CMS may prohibit Dr. Pfulpajena from owning, operating or directing a laboratory for two years.

Issues

- 2 year mandatory prohibition (Owner, Operator, Director)
- Misrepresentation of test volume
- Testing outside of CLIA certificate
- Laboratory Director responsibilities

Statutory/Regulatory References:

- 42 U.S.C. § 263a(i)(3)
- 42 U.S.C. § 263a(f)(1)(E)
- 42 C.F.R. § 493.51(b)
- 42 C.F.R. § 493.649(a)
- 42 C.F.R. § 493.69(b)(2)
- 42 C.F.R. § 493.1407
- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1808(a)
- 42 C.F.R. § 493.1840(a)(1-3)(8)
- 42 C.F.R. § 493.1842(a)(1)

Kids Med (Delta Medical Branch) vs. CMS
Docket No: C-11-749
Decision No. CR2492
Date: January 24, 2012

CLIA #: 45D0925763
State: Texas
Type of Certificate: Compliance
DAB/ALJ: Richard J. Smith

Basis for Sanction(s):

- Both the Statute at 42 U.S.C. § 263(a)(i)(3) and the regulations at 42 C.F.R. § 493.1840(a)(8) prohibit the owner of a laboratory with a revoked CLIA certificate from owning, operating, or directing another CLIA laboratory for a period of two years.
- Dr. Aviles requested to continue performing waived testing; CMS' responded that the laboratory must cease all testing. Based on the fact that Dr. Aviles did not file an appeal, the revocation became final.
- CMS notified three other laboratories (MVP, DMC, MCC) that were owned by Dr. Aviles that their CLIA certificates would be revoked based on the revocation of Kids Med unless they filed an appeal.
- CMS further noted that once the revocation of Kids Med (KMDMB) became final, the revocation of the other three labs' CLIA certificates was a matter of law. CMS argued that Dr. Aviles' letter of March 14 did not constitute a request for a hearing, and that KMDMB had not shown good cause for extending the deadline to file such a request. CMS filed a motion for summary judgment.

Argument(s):

- The Petitioner stated that "a timely and complete request for a hearing was filed on March 9, 2011", and that the letter sent on March 14, 2011 was, in fact, a request for a hearing. KMDMB, "argued that good cause exists for extending the time for filing so as to allow its August 31 letter to serve as a timely request". KMDMB further asserted that because it had filed its March 14 letter and its August 31 letter, the revocation of KMDMB's CLIA certificate was not administratively final.

Ruling Excerpt(s) [from ALJ/DAB]:

- The ALJ consolidated the three cases (MVP, DMC, MCC) since all had common, identical issues of fact and law, and all three depended on the outcome of this appeal. CMS's March 9 letter clearly outlined and advised Dr. Aviles of his appeal rights and the procedures that must be followed as well as the serious consequences to which MVP, DMC, and MCC were exposed if KMDMB's sanction became final.
- Dr. Aviles' March 14 letter clearly was not intended to be a request for a hearing rather Dr. Aviles accepts the results of the survey and CMS' determination. However, putting this issue aside, a request for a hearing must be filed using the appropriate process and timeframe.

- The record does not show “good cause” to allow KMDMB to amend the August 31, 2011 letter to comply with 42 C.F.R. § 498.40 or to extend the deadline for filing a request for a hearing so that its August 31, 2011 request can be considered timely.
- The ALJ granted CMS’ motion for summary judgment.

Issues:

- Timely filing of an appeal
- Request for a hearing must comply with 42 C.F.R. § 498.40

Statutory/Regulatory References:

- 42 U.S.C. § 263a
- 42 U.S.C. § 263a(i)(3)
- 42 C.F.R. § 498.40
- 42 C.F.R. § 498.40(a)(1-2)
- 42 C.F.R. § 498.40(b)(1-2)
- 42 C.F.R. § 498.40(c)(1-2)
- 42 C.F.R. § 498.70(c)
- 42 C.F.R. § 493.1840(a)(8)
- 42 C.F.R. § 493.1844(f)

Kids Med (Delta Medical Branch) vs. CMS
Docket No: A-12-53
Decision No. DAB2471
Date: August 14, 2012

CLIA #: 45D0925763
State: Texas
Type of Certificate: Compliance
DAB/ALJ: Sheila Ann Hagy, Leslie A. Sussan, Stephen M. Godek

Basis for Sanction(s):

- Based on the revocation of Kids Med's (KMDMB) CLIA certificate, the owner, Dr. Aviles, was notified that the CLIA certificate for three additional labs (MVP, DMS, MCC) also owned by Dr. Aviles would be revoked unless an appeal was filed.

Argument(s):

- KMDMB argued that the ALJ incorrectly disregarded specific language in the March 14 letter which indicated Dr. Aviles' intention to appeal CMS' determination.
- In addition, KMDMB asserted that the March 14 letter should be broadly interpreted as a hearing request because Dr. Aviles is not an attorney and did not have legal assistance at the time he authored the letter.
- Further, KMDMB contended that the ALJ incorrectly overlooked language in MVP, DMS, MCC's hearing requests that supports the interpretation of Dr. Aviles March 14 letter as a request for a hearing.
- KMDMB also challenged the ALJ's determination that it failed to establish "good cause" for either amending Dr. Aviles' letter or extending the deadline for filing an appeal.
- Finally, KMDMB claimed that the ALJ improperly attributed Dr. Aviles' deliberate inaction as a strategic choice.

Ruling Excerpt(s):

- The ALJ did not err in concluding that Dr. Aviles' March 14 letter was not a request for a hearing. KMDMB cannot use the hearing requests filed for MVP, DMS, and MCC to fix problems with Dr. Aviles' March 14 letter.
- These filings, made by separate entities long after the period for appealing KMDMB's revocation had expires, are not relevant to demonstrating a disagreement with survey findings about KMDMB which Dr. Aviles did not express during the appeal period for KMDMB.
- The ALJ 's determination that KMDMB failed to establish "good cause" for allowing it to a mend the letter or extending the deadline to file an appeal was upheld.
- ALJ decision to dismiss is affirmed.

Issues:

- Timely filing of an appeal

- Request for a hearing must comply with 42 C.F.R. § 498.40

Statutory/Regulatory References:

- 42 U.S.C. § 263a
- 42 U.S.C. § 263a(i)(3)
- 42 C.F.R. § 498.20(c)(2)
- 42 C.F.R. § 498.40(a)
- 42 C.F.R. § 498.40(b)
- 42 C.F.R. § 498.40(c)(2)
- 42 C.F.R. § 493.1840(a)(8)
- 42 C.F.R. § 493.1844(a)(b)

Mid Valley Pediatrics (MVP), Donna Medical Clinic (DMC), Mercedes Children's Clinic/Mercedes Kids Med (MCC) (Consolidated) vs. CMS

Docket No: C-11-619

Decision No. CR2614

Date: September 18, 2012

State: Texas

Type of Certificate:

DAB/ALJ: Richard J. Smith

Refer to CR2492 and DAB 2471

Ruling Excerpt(s):

- Kids Med (KMDMB) was owned by Dr. Aviles and until May 10, 2011 participated in Medicare and Texas Medicaid programs. KMDMB's CLIA certificate was properly revoked by CMS effective May 10, 2011. Dr. Aviles, also at that time, owned MVP, DMC, and MCC. 42 U.S.C. § 263a(i)(3) mandate that CMS revoke CLIA certificate of MVP, DMC, and MCC.

Planned Parenthood Choice of Abilene, Texas vs. CMS
Docket No: C-12-1229
Decision No. CR2854
Date: July, 12, 2013

CLIA #: 45D2019250
State: Texas
Type of Certificate: Compliance
DAB/ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

- A survey performed by the Texas State Agency discovered, in addition to additional findings, that an employee who performed testing on proficiency testing (PT) samples during the first quarter of 2011 called a second lab to compare results prior to submitting Planned Parenthood's PT results.
- In addition, CMS's position also asserted that laboratory did not test PT samples in the same manner as patient specimens, the laboratory director did not attest for two testing events that the PT samples were incorporated into the regular patient workload, and that the lab was not in substantial compliance with testing of PT samples and moderate complexity laboratory director.

Argument(s):

- The Petitioner opposes, but "does not dispute the underlying conduct alleged in the statement of deficiencies"; however, the Petitioner argued that CMS "is not entitled to judgment as a matter of law on its imposition of sanctions".
- The Petitioner also asserted that they did not intend to violate the CLIA regulations.
- In addition, the Petitioner claimed that CMS failed to take into consideration all of the regulatory factors (42 C.F.R. § 493.1804(d)) when choosing sanction(s). Finally, the Petitioner argued that, because of a December 2012 amendment to CLIA due to the TEST Act, CMS may no longer impose the mandatory sanctions of suspension and revocation for collusion for PT samples.

Ruling Excerpt(s):

- The parties agreed on all material facts.
- The regulations only require that CMS take into account "one or more" of the listed factors. The mandatory revocation for PT referral still applies in this case because: 1) the survey and imposition of sanctions took place prior to the statutory change which is not retroactively applied, 2) the mandatory provision did not apply in this case as it involved collusion not referral, and 3) the statutory change increases CMS' discretion, but does not prevent it from revoking a laboratory's CLIA certificate if it finds that the cited deficiencies warrant the sanction.
- The Petitioner violated two CLIA conditions (Enrollment and testing of PT samples and moderate complexity laboratory director). CMS's motion for summary judgment is granted and the revocation of the laboratory's CLIA certificate was upheld.

Issues:

- Testing of PT samples (i.e., collusion)
- Moderate complexity laboratory director

Statutory/Regulatory References:

- 42 U.S.C. § 263a *et seq.*
- 42 U.S.C. § 263a(d)(3)
- 42 U.S.C. § 263a(d)(1)(E)
- 42 U.S.C. § 263a(f)(1)(E)
- 42 U.S.C. § 263a(i)(4)
- 42 C.F.R. § 493.61(b)(1)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.801
- 42 C.F.R. § 493.801(b)(1, 3)
- 42 C.F.R. § 493.803(a)
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1777
- 42 C.F.R. § 493.1804(d)
- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1800(a)(2)(iii)

Xuan Q. Zhang, MD Laboratory and Robert Ireland, Ph.D., Laboratory Director vs. CMS
Docket No: C-12-1225
Decision No. N/A
Date: September 18, 2013

CLIA #: 22D2026613
State: Massachusetts
Type of Certificate: Registration
DAB/ALJ: Richard J. Smith

Basis for Sanction(s):

- The Petitioner was not in compliance with five condition-level deficiencies: 42 C.F.R. § 493.1240 (preanalytic systems), 42 C.F.R. § 493.1250 (analytic systems), 42 C.F.R. § 493.1290 (post analytic systems), 42 C.F.R. § 493.1441 (high complexity laboratory director), and 42 C.F.R. § 493.1447 (high complexity technical supervisor). These deficiencies rose to the level of immediate jeopardy.
- The laboratory was notified of the findings and subsequently was notified of CMS' intention to impose principal and alternative sanctions.
- CMS determined the notified the laboratory's that the allegation of compliance (AOC) was incomplete and, therefore, not credible, as well as the reasons for their determination.

Argument(s):

- The Petitioner filed a hearing request which clearly based their appeal on the following: 1) Petitioner disagreed with CMS' assessment that the AOC was not credible and 2) Petitioner was continuing to work with CMS to come into compliance so the Petitioner believed that sanctions should not be imposed

Ruling Excerpt(s):

- A *sua sponte* Order noted Dr. Ireland's objection to counsel's being permitted to withdraw and overruled his objection, It also noted Dr. Zhang's request to be dropped as a nominal Petitioner and granted that request.
- The Order, most importantly, notified all parties that record of pleadings and evidence in this case was closed, and put the parties "on notice that the case stood submitted for decision on the pending CMS Motion to Dismiss for Summary Judgment".
- The ALJ determined that the reasons stated by the Petitioner in order to justify an appeal did not challenge the survey findings and did not challenge the existence of the deficiencies found by CMS or explained to the Petitioner. The Petitioner's hearing request can only be understood as a "an objection to CMS's rejection of the CAP and a plea for more time to return to full CLIA compliance".
- CMS' motion argues convincingly that this case must be dismissed per 42 C.F.R. § 498.70(b) and for that reason the Petitioner's request for a hearing is dismissed.

Issues:

- Right to a hearing

Statutory/Regulatory References:

- 42 C.F.R. § 493.1240
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1290
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1447
- 42 C.F.R. § 493.1844
- 42 C.F.R. § 498.40(b)
- 42 C.F.R. § 498.70(b)

Liberty Laboratory, Inc. vs. CMS
Docket No: C-13-237
Decision No.: CR2995
Date: November 14, 2013

CLIA #: 15D1019268
State: Indiana
Type of Certificate: Accreditation
ALJ: Keith W. Sickendick

Basis for Sanction(s):

- The laboratory was not in compliance with the condition-level requirements for successful PT participation, moderate complexity laboratory director, and analytic systems.
- CMS notified the laboratory notified by letter that it was imposing sanctions including revocation unless a hearing was requested.

Argument(s):

- The Petitioner did not dispute the accuracy of CMS' findings related to PT failures. In fact, the Petitioner acknowledges that PT failures occurred.
- The laboratory director (LD) asserted: 1) two employees left the company and too items needed for inspection however does not assert any connection with PT failures, 2) the survey team was let by an individual who she had previously filed sexual harassment charges against, but does not assert the survey team composition had any impact on unsatisfactory PT scores, 3) remedial action was implemented for the PT failures subsequent to the survey and the scores were satisfactory for two events in a row how this does not preclude CMS' authority to impose a principal sanction, 4) CMS requested corrective action related to unsatisfactory PT scores, even though the LD stated that she was previously advised that no corrective action was necessary however this is not a reviewable initial determination and this does not excuse unsuccessful PT participation, and finally, 5) extreme circumstances occurred during the period of unsatisfactory PT participation and she trusted an unreliable individual to oversee the laboratory but cites no legal authority to excuse the condition-level noncompliance because she was unable to perform her duties as the LD.

Ruling Excerpt(s):

- The Petitioner offered no affidavit or declaration in support of its response to CMS' motion for summary judgment. It is not disputed that the Petitioner failed to successfully participate in a PT program.
- As a matter of law, failing to successfully participate in PT is a condition-level violation and a basis for revocation of the CLIA certificate. CMS's determination as to which principal and alternative sanctions to impose and the determination of immediate jeopardy are not initial determinations subject to being reviewed. Summary judgment is granted.
- The laboratory's CLIA certificate is revoked as of the date of the ALJ decision.

Issues:

- Unsuccessful participation in PT

Statutory/Regulatory References:

- 42 U. S. C. § 263a *et seq.*
- 42 U. S. C. § 263a(f)(1)(E)
- 42 U. S. C. § 263a(i)(1,3), (k)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.801
- 42 C.F.R. § 493.803
- 42 C.F.R. §§ 493.823-.831, .835-.837, .841-.845, .851, .859-.865
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1806-.1844
- 42 C.F.R. § 493.1842(a)
- 42 C.F.R. §§ 493.1844(a-c), (d)(4)(ii)

Liberty Laboratory, Inc. vs. CMS
Docket No: A-14-23
Decision No.: DAB 2562
Date: March 24, 2014

CLIA #: 15D1019268
State: Indiana
Type of Certificate: Accreditation
DAB: Sheila Ann Hegy, Constance B. Tobias, Leslie A. Sussan

Basis for Sanction(s):

- The laboratory was not in compliance with the condition-level requirements for successful PT participation, moderate complexity laboratory director, and analytic systems.
- CMS notified the laboratory notified by letter that it was imposing sanctions including revocation unless a hearing was requested.

Argument(s):

- Liberty merely reiterates some of its arguments below, which the ALJ found lacked merit.
- Liberty alleges that the “lead inspector on the day of inspection” was a man against whom the laboratory director had previously filed sexual harassment charges and who the state agency had agreed would not have further contact with the laboratory director.
- In addition, Liberty alleges that the “other 2 inspectors were still in training.”
- Liberty also alleges that police reports showed that former employees of Liberty “removed key information before leaving employment at” Liberty.
- Liberty alleges further that due to “extreme” events in the personal life of the laboratory director, she relied on a laboratory employee “to help with the review of all aspects of the laboratory.”
- Finally, Liberty asserts that the state survey agency did not follow “[n]ormal procedures” to “immediately notify the laboratory” that the laboratory does not have a passing score on two PT events in a row and provide “a short time frame in order to get the laboratory back in compliance.”

Ruling Excerpt(s):

- The ALJ determined that “there are no genuine disputes as to the material facts that establish a prima facie showing of noncompliance with” successful PT participation and Liberty did not dispute it “failed to successfully participate in approved PT for routine chemistry”.
- The ALJ also determined that Liberty “can establish no defense to excuse it noncompliance with the condition-level requirement for successful PT participation.
- The decision of summary judgment is upheld. See CR2995.

Issues:

➤ Unsuccessful PT participation

Regulatory References:

- 42 U. S. C. § 263a *et seq.*
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.803
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1407
- 42 C.F.R. § 493.1800
- 42 C.F.R. § 493.1804(b)
- 42 C.F.R. § 493.1840(e)(1)

Adeona Clinical Laboratory, LLC vs. CMS
Docket No: C-14-1133
Decision No.: CR3919
Date: May 29, 2015

CLIA #: 14D1051026
State: Illinois
Type of Certificate: Compliance
ALJ: Joseph Grow

Basis for Sanction(s):

- The laboratory was not in compliance with the following CLIA conditions: Enrollment and testing of samples (42 C.F.R. § 493.801), laboratories performing high complexity testing, laboratory director (42 C.F.R. § 493.1441), and analytic systems (42 C.F.R. § 493.1250).
- In addition, CMS found that the laboratory's noncompliance rose to the level of immediate jeopardy. Specifically, the laboratory intentionally sent PT samples to another laboratory for testing and reported the results as their own.

Argument(s):

- The Petition argued that CMS failed to follow the required procedures and that CMS cannot impose principal sanctions until it first imposes alternative sanctions.
- The Petitioner stated that it is an undisputed fact that "Adeona sent proficiency samples and human specimens" to another laboratory for testing.
- The Petitioner further asserted that ALJ should grant a summary judgment in favor of the Petitioner because CMS allegedly failed to give it prior notice that CMS based its revocation action on the intentional referral of PT samples.

Ruling Excerpt(s):

- Undisputed evidence shows that the Petitioner intentionally sent PT samples to another laboratory for testing and reported the results as their own. In fact, the Petitioner did not produce evidence to dispute the material facts – that is it intentionally sent PT samples to another laboratory for testing and reported the results as their own.
- The relevant documents clearly demonstrate that the Petitioner received clear, proper and ample notice both in the Statement of Deficiencies and correspondence from CMS.
- The case is appropriate for summary judgment because there is not dispute of material facts. Failure to comply with even a single condition is sufficient to impose principal sanctions.
- The amendments to the CLIA regulations went into effect July 11, 2014, and, therefore, do not apply to the January 2014 survey and March 24, 2014 letter. The revocation of the CLIA certificate and the laboratory's approval to receive Medicare payments became effective as of the date of the ALJ decision.

Issues:

- Intention PT referral
- High complexity laboratory director
- Analytic systems

Regulatory References:

- 42 U. S. C. § 263a *et seq.*
- 42 C.F.R. § 493.801
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1804(b)
- 42 C.F.R. §§ 493.1806-1807
- 42 C.F.R. § 493.1812
- 42 C.F.R. §§ 493.1832-1836
- 42 C.F.R. § 493.1840(b)

Fullerton-Kimball Medical & Surgical Center Laboratory vs. CMS
Docket No: C-16-326
Decision No. CR 4694
Date: 8/30/2016

CLIA #: 14D1047993
State: Illinois
Type of Certificate: Certificate of Registration
ALJ: Steven T. Kessel

Basis for Sanction(s):

- CMS premises its case on the assertion that, as of a survey conducted on November 18, 2015, Petitioner was not compliant with six CLIA conditions: Toxicology (42 C.F.R. § 493.1213), Analytic Systems (42 C.F.R. § 493.1250), Laboratory Director (42 C.F.R. § 493.1441), Technical Supervisor (42 C.F.R. § 493.1447), General Supervisor (42 C.F.R. § 493.1459), Testing Personnel (42 C.F.R. § 493.1487).
- CMS also found the Petitioner's Allegation of Compliance incomplete and not credible. CMS contends the Petitioner failed as of November 18, 2015 to comply with Toxicology and Analytic Systems conditions for the following three reasons: the laboratory did not have a comprehensive procedure manual available that addressed corrective action and life threatening results, the laboratory could not demonstrate that it performed control materials on each day patient specimens were tested, and the laboratory failed to document date and time that it received specimens.
- CMS contends that the conditions for personnel were not met for the following reasons: the laboratory director did not fulfill regulatory responsibilities, the technical supervisor, general supervisor and testing personnel were not qualified for the level of testing performed.

Argument(s):

- Petitioner asserts that it always has been and remains in full compliance with all CLIA requirements.
- Petitioner conceded that it was unable to produce the requested manual, but the staff was unable to find the manuals.
- Petitioner stated flatly that it "is, and always has been, compliant with all...[quality control] requirements and performs...[quality control] testing as required." Petitioner denies CMS's personnel allegations as "wholly inaccurate."

Ruling Excerpt(s):

- Summary judgment granted in favor of CMS for five of the six conditions. The condition of technical supervisor was excluded from the summary judgment. On close analysis, the Petitioner does not actually rebut the facts offered by CMS. In fact, the Petitioner does not challenge the fact findings made by the surveyor nor does it deny the incompleteness or inadequacy of its plan of correction.
- It is irrelevant that the Petitioner asserted that the manuals existed – if they even existed – as they could not be located on that date rendered them useless to the staff. For

compliance purposes, it was as if the manuals did not exist. Petitioner did not offer evidence that quality control had been tested on the days in question or that it failed to document date and time of specimen receipt.

- The Petitioner continues to assert its compliance in the present tense, but it is irrelevant as they do not address their compliance as of the November 18th survey date and in January 2016 when it submitted both of its Allegations of Compliance. Throughout its argument Petitioner repeatedly offers to provide more evidence in the event that what it has provided is inadequate. Evidently, it labors under the misperception that the hearing in this case is open ended and that it has infinite opportunity and time to amend its submission. That is absolutely contrary to what I ordered the parties to do by way of pre-hearing exchanges. Petitioner was obligated to produce all of the evidence on which it intended to rely by a date certain. It cannot hold back evidence and offer vaguely, to provide more if requested to do so.
- The revocation of the CLIA certificate and the cancellation of the laboratory's approval to receive Medicare payments became effective as of the date of the ALJ decision. In addition, the civil money penalty of \$7500 per day for three days that CMS determined to impose were appropriate.

Issues:

- Toxicology
- Analytic Systems
- Laboratory Director Responsibilities
- Technical Supervisor Qualifications
- General Supervisor Qualifications
- Testing Personnel Qualifications

Statutory/Regulatory References:

- 42 U. S. C. § 263a
- 42 C.F.R. § 493.1213
- 42 C.F.R. §§ 493.1242(a), (b)
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1251(b)
- 42 C.F.R. § 493.1253(b)(2)
- 42 C.F.R. §§ 493.1256(d)(3)(i), (g)
- 42 C.F.R. § 493.1291(c)
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1447
- 42 C.F.R. § 493.1459
- 42 C.F.R. § 493.1261(b)
- 42 C.F.R. § 493.1487
- 42 C.F.R. § 493.1804(b)(2)
- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1806(c)(3)
- 42 C.F.R. § 493.1807
- 42 C.F.R. § 493.1808(a)
- 42 C.F.R. § 493.1834(d)(1-2)

➤ 42 C.F.R. § 493.1842(a)
Shadow Creek Medical Clinic vs. CMS
Docket No: C-17-41
Decision No. 2017-5
Date: 12/20/2016

CLIA #: 45D2050056
State: Texas
Type of Certificate: Certificate of Registration
ALJ: Steven T. Kessel

Ruling Excerpt(s):

➤ Hearing dismissed because Petitioners (Shadow Creek Medical Clinic, Fairway Medical Clinic) filed untimely hearing requests and they have not demonstrated good cause to extend their respective deadlines for filing a hearing request. A party loses its right to a hearing if it does not file its request timely and an ALJ does not find good cause for the party's late filing. CMS gave Petitioner sufficient notice of its intent to impose sanctions. The term "mail" does not suggest that the only form of "mail" is United States mail, especially when read in the context of all of the forms of reliable electronic communications available to CMS and to private parties. Faxing and email are acceptable forms of "mail".

Issues:

- Timing of hearing request
- Mode of notification of hearing rights

Regulatory References:

- 42 C.F.R. §§ 498.40(a)(2), (c)
- 42 C.F.R. § 498.70(c)

The Malaria & Rheumatic Disease Research Institute, Inc. (MARDRI) vs. CMS
Docket No: C-16-200
Decision No. CR4918
Date: 8/14/2017

CLIA #: 21D2065315
State: Maryland
Type of Certificate: Certificate of Registration
ALJ: Scott Anderson

Basis for Sanction(s):

- CMS alleged that the laboratory refused to allow state surveyors to inspect its laboratory for a revisit in order to verify compliance with condition-level deficiencies as well as engaged in a pattern of conduct over an extended period of time that obstructed state surveyors from completing an inspection of Petitioner's laboratory. Initially, CMS imposed a directed Plan of Correction on the laboratory's CLIA certificate for continuing to remain out of compliance with condition-level deficiencies related to the Laboratory Director responsibilities.
- CMS determined that the submission did "not constitute a credible allegation of compliance and [did] not comply with the requirements of the directed plan of correction." Principal sanctions (i.e., suspension of Petitioner's CLIA certificate and cancellation of Petitioner's approval to receive Medicare payments).
- Subsequently, CMS received another submission from Petitioner which was determined to be a credible allegation of compliance. The State Agency made multiple attempts to schedule the revisit which was ultimately scheduled for through Petitioner's counsel, that the laboratory director would be present for a survey on August 25, 2015. Surveyors arrived at Petitioner's laboratory and nobody was present.

Argument(s):

- Petitioner's main argument was that it made a good faith effort to demonstrate substantial compliance. Further, Petitioner claims that since it "has made a credible allegation of compliance on all tags" it "should have its CLIA certificate and Medicare payments reinstated."
- The Petitioner argued that she was not available as she was in the Emergency Room the previous evening and therefore unavailable for the prescheduled and confirmed survey on August 25, 2015.

Ruling Excerpt(s):

- CMS presented sufficient evidence supporting Petitioner's condition-level deficiency for failure to meet the Laboratory Director condition, including failing to fulfill regulatory responsibilities.
- Petitioner presented little to no evidence to rebut CMS' case. ALJ concluded that CMS has a basis for immediate suspension and subsequent revocation of Petitioner's CLIA certificate, and affirmed CMS's suspension and revocation of Petitioner's CLIA

certificate, as well as cancellation of Petitioner's approval to receive Medicare reimbursements for its services.

- CMS had a basis for imposing an immediate suspension and subsequent revocation because Petitioner refused a request to inspect its laboratory.

Issues:

- Refusal to allow survey
- Imposing immediate suspension of CLIA certificate

Statutory/Regulatory References:

- 21 U. S. C. §331(f)
- 42 U. S. C. § 263a *et seq.*
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.803(a)
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1253
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1445(e)(1), (3)(ii), (4), (15)
- 42 C.F.R. § 493.1777
- 42 C.F.R. §§ 493.1804(a), (b)(1), (c), (d)
- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1808(a)
- 42 C.F.R. § 493.1810(e)
- 42 C.F.R. § 493.1814(a)(2)
- 42 C.F.R. § 493.1840
- 42 C.F.R. §§ 493.1844(a)(2), (b)(1)

Fairway Medical Clinic & Shadow Creek Medical Clinic vs. CMS
Docket Nos: A-17-48 & A-17-49
Decision No.: DAB 2811
Date: 8/18/2017

CLIA #: 45D2050056

State: TX

Type of Certificate: Fairway Medical Clinic (CoC), Shadow Creek Medical Clinic (CoR)

DAB: Leslie A. Sussan, Constance B. Tobias, Susan S. Yim

Basis for Sanction(s):

- CMS finalized the revocation of Shadow Creek' CLIA certificate based on the fact that the laboratory did not submit and acceptable POC and AOC nor did they file an appeal during the time frame stated in the notification.
- CMS subsequently, revoked Fairway's certificate based on a prohibited owner/operator.
- CMS filed a motion to dismiss, which was granted, asserting that Petitioners filed their requests for appeal late despite actual notice of enforcement action and appeal rights to both Petitioners by fax, as evidenced by successful fax transmission confirmations, and despite Petitioners' acknowledgement of receipt of the notices.

Argument(s):

- Petitioner asserted the following: the only valid method of notice recognized by 42 C.F.R. § 498.20(a) is U.S. mail, and that CMS's fax notices are without legal significance for purposes of establishing the appeal due dates.
- Secondly, Petitioners maintained that they did not receive CMS's notices of right to appeal.
- Finally, Petitioners argued that, because they were not afforded due process inasmuch as CMS did not use a legally valid method of notice, they have shown good cause for filing their request for appeal late, and that the ALJ should have extended the filing dates in both cases.

Ruling Excerpt(s):

- The DAB sustained the Ruling (Ruling No 2017-5, 12/20/2016, ALJ granted CMS' motion to dismiss requests for a hearing to challenge revocation) by the ALJ for the following reasons:
 - The Petitioners were made aware of CMS's revocation action, but did not then take action until many months later.
 - The Board expressly commented that notice of appeal rights could be served by fax alone, so long as the document served is clearly the notice document.
 - Actual notice that Shadow Creek and Fairway's certificates had been revoked months before he requested a hearing is supported by substantial evidence, including Dr. Mussaaji's actual acknowledgement of the notices.
 - The ALJ did not abuse his discretion in determining that Petitioners did not show good cause to extend the filing due dates.

Issues:

- Mode of transmittal for enforcement notices

Regulatory References:

- 42 U. S. C. § 263a *et seq.*
- 42 U. S. C. § 263a(i)(1,3)
- 42 C.F.R. § 493.1215
- 42 C.F.R. § 493.1840(a)(8)
- 42 C.F.R. §§ 493.1844(a)(1-2), (b)(1), (f)(1)
- 42 C.F.R. § 498.20(a)
- 42 C.F.R. § 498.22(b)(3)
- 42 C.F.R. § 498.40(a)(c)
- 42 C.F.R. § 498.70(c)
- 42 C.F.R. § 498.78
- 42 C.F.R. § 498.82(a)

The Malaria & Rheumatic Disease Research Institute, Inc. (MARDRI) vs. CMS
Docket Nos: A-18-6
Decision No.: DAB 2872
Date: 5/28/2018

CLIA #: 21D2065315
State: Maryland
Type of Certificate: Certificate of Registration
DAB: Leslie A. Sussan, Constance B. Tobias, Christopher S. Randolph

Basis for Sanction(s):

- Petitioner failed allow a survey, and filed to provide a credible allegation of compliance (AOC) and failed to provide an AOC in a timely manner; therefore, the case would be sent to CMS with a recommendation for enforcement.
- The Petition failed to comply with an alternative sanction (directed plan of correction) or come into condition-level compliance so CMS moved to suspend the CLIA certificate and cancel MARDRI's ability to receive Medicare payment for tests it performed.
- The Petitioner appealed the suspension; however, they also provided additional documentation related to the condition-level noncompliance. Based on this information, the State Agency attempted to schedule a revisit to verify compliance; however, the laboratory director failed to appear, and did not have someone present, at the predetermined date and time.
- CMS determined that this equated to refusal to allow an inspection.

Argument(s):

- Petitioner argues that substantial evidence in the record does not support the conclusion that Petitioner failed to ensure quality laboratory services because the AOC confirmed that it had furnished evidence of compliance.
- Second, Petitioner argues that the ALJ erred when he upheld CMS's principal sanction of suspension of the CLIA certificate and cancellation of its approve to receive Medicare payments on the grounds that Petitioner's refusal to permit inspection was a reasonable basis for CMS to impose immediate suspension.

Ruling Excerpt(s):

- The DAB sustained the ALJ decision (CR 4918) for the following reasons:
- The ALJ Decision is supported by substantial evidence in the record and is free from legal error.
- CMS made a prima facie case for Petitioner's CLIA non-compliance.
- A good faith effort to comply with regulations established to ensure public safety is not the appropriate standard to apply. Petitioner did not cite any law that establishes a good faith effort compliance standard.
- Petitioner offered no evidence to rebut the evidence of its deficiencies.

- Petitioner misunderstands the meaning of a “credible AOC”; it is not a determination confirming that the information provided by the Petitioner provided evidence of compliance.
- The regulations require a laboratory issued a certificate to allow CMs or its agent to conduct an inspection to verify compliance.
- Petitioner’s refusal is evidenced by the laboratory director’s conduct throughout the pendency of the survey.

Issues:

- Refusal to allow survey
- Imposing immediate suspension of CLIA certificate

Statutory/Regulatory References:

- § 353(g)1), (i)(1)(E) of the Public Health Service Act
- 42 C.F.R. § 493.3
- 42 C.F.R. § 493.45
- 42 C.F.R. § 493.5(c)
- 42 C.F.R. § 493.57
- 42 C.F.R. §§ 493.1200(a)-(c)
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1445
- 42 C.F.R. § 493.1771
- 42 C.F.R. §§ 493.1773(d), (f)
- 42 C.F.R. § 493.1800(a)(2)(iii)
- 42 C.F.R. § 493.1804(b)(2)
- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1807
- 42 C.F.R. § 493.1810
- 42 C.F.R. § 493.1812-16
- 42 C.F.R. § 493.1814
- 42 C.F.R. § 493.1820(a)
- 42 C.F.R. § 493.1832(a)
- 42 C.F.R. § 493.1840
- 42 C.F.R. § 493.1844

Murtaza Mussaji, DO, PA vs. HHS
Petition for Review of a DAB Decision (Decision No. 2811)
Date: 7/13/2018

CLIA #: Fairway Medical Clinic (45D1087988), Shadow Creek Medical Clinic (45D2050056)

State: TX

Type of Certificate: Fairway Medical Clinic (CoC), Shadow Creek Medical Clinic (CoR)
U.S Court of Appeals for the Fifth Circuit: Stephen A. Higginson, Circuit Judge

Ruling Excerpt(s) from U.S Court of Appeals for the Fifth Circuit:

- The petition is denied.
- The ALJs finding that Mussaaji had actual notice that Shadow Creek and Fairway's certificates had been revoked months before he requested a hearing is supported by substantial evidence.
- Dr. Mussaji's actual knowledge of the revocation, the ALJ's finding that Mussaji failed to show good cause for his delay is supported by substantial evidence.

Issues

- Extension for filing an appeal
- Mode of transmittal for enforcement notices

Kensington Diagnostics LLC vs CMS
Docket No: C-17-289
Decision No. CR 5385
Date: 8/5/2019

CLIA #: 05D2087480
State: California
Type of Certificate: Certificate of Registration
DAB/ALJ: Keith W. Sickendick

Basis for Sanction(s):

- The Petitioner was in violation of three condition required for CLIA certification.
- The Petitioner violated the requirement to follow its written policies and procedures to assess competency of its employee who conducted high complexity testing by failing to follow the competency policy and procedure.
- The Petitioner failed to verify the accuracy of its testing of the carisoprodol analyte at least twice each year.
- The Petitioner failed to follow its established written policies and procedures for General Laboratory Systems quality assessment. For example:
 - Failure to assess employee competency
 - Failure to verify the accuracy of carisoprodol
- CMS explained that condition-level violations were had to likelihood to “together presented a serious problem that had the potential to adversely affect patient test results”.
- CMS further stated in their declaration that the Petitioner’s failure to maintain adequate documentation of testing person training and competency “called into question whether [Petitioner’s] laboratory technician had received proper training” as evidenced by competency evaluation and “could lead to the reporting of inaccurate test results” in the event the technician did not receive such training.
- CMS further indicated that Petitioner’s failure to verify the accuracy of its carisoprodol testing twice annually and its further failure to detect and correct this failure could lead Petitioner to “return test results that are inaccurate for the analytes no so verified.”

Argument(s):

- Banerjee asserted that the testing person (T. Nguyen) was competent and her competency has been assessed by Le and W. Nguyen before she was permitted to test.
- Banerjee stated that T. Nguyen conducted testing on PT samples and scored 100 percent as well as performing precision studies, accuracy studies, carry-over studies, and patient correlation studies supports her competency.
- The Petitioner contended that no split sample testing was done because, while Petitioner tested for carisoprodol, it reported no results. Banerjee stated that tests for carisoprodol were run for research only and no results were reported. He further indicated in his declaration that the Petitioner was just doing confirmation testing of samples that it compared with results obtained by another laboratory, that is, the laboratory used to confirm its test results.

- Petitioner asserted that it “had no obligation to enroll in any proficiency testing or [conduct] split sample testing” for carisoprodol because “it did not report Carisoprodol at the time of inspection” and the requirement for split sample testing “is only for reported analytes.”
- Petitioner argued that there was no noncompliance under D-5209 and D5217 to correct and, therefore, its policy required by the regulations was simply not triggered.
- Petitioner attacked the surveyor’s credibility in a variety of ways.
- Petitioner argued that there was no harm or potential for harm.
 - Petitioner contended that its deficiencies could not have harmed posed a risk of harm to patients because its test results were “merely used for initial screening purposes” and that an independent laboratory “always verified” its test results; and
 - Petitioner argued that no patients were at risk because it consistently received 100% scores in proficiency testing (PT) for the analytes that Petitioner actually sent for PT; and
 - Petitioner stated that no patients were at risk because if they were, CMS would have ordered Petitioner to stop testing but CMS did not do so.

Ruling Excerpt(s):

- Petitioner’s owners and operators are prohibited from owning, operating, or directing a laboratory subject to CLIA for two years.
- The CMS choice of alternative sanctions to impose, including the amount of a CMP to impose per day or per violation, is not subject to ALJ review.
- The “stated criteria” for a laboratory director to be considered an operator are those criteria described in the introductory sentence of the definition of “operator”, *i.e.*, whether a person oversaw all facets of the operation of the laboratory and bore primary responsibility for the safety and reliability of the results of specimen testing performed in the laboratory.
- CMS has the burden of coming forward with sufficient evidence prove a *prima facie* (*i.e.*, clear) case of noncompliance with one or more CLIA conditions.
- A single violation of a CLIA condition is an adequate basis for the imposition of sanctions.
- Whether a testing person can demonstrate competence is not the focus; the focus is whether the Petitioner adopted and implemented policies and procedures to ensure its testing personnel were competent. ALJ found that Petitioner violated the regulatory standard because Petitioner adopted policies and procedures for assessing competency but then failed to follow its policies and procedures.
- Petitioner’s argument ignores the plain language of the regulation, which requires laboratories like Petitioner to twice annually “verify the accuracy...[a]ny test or procedure it performs that is not included in subpart I...” No exception exists for tests a laboratory conducts but for which the laboratory does not report results.
- Petitioner’s failure to identify and correct two violations of CLIA standards clearly violated Petitioner’s QA policy. Such failures plainly pose at least a risk of potential error in all phases of laboratory testing, both generally as the failures related to testing personnel and specifically as the failures related to carisoprodol testing.
- Petitioner’s cavalier attitude toward its regulatory obligations, evidenced by its denial that certain clearly-applicable obligations actually apply to it, is especially concerning

because it shows why Petitioner continued to fail to achieve compliance with CLIA requirements.

- Even though no actual harm occurred in this case based on the regulatory violations I have found, that fact is no defense for Petitioner. Whether or not actual harm occurred is not recognized as a basis for the imposition of principal or alternative sanctions under the regulations. Whether or not a deficiency poses immediate jeopardy is a factor in the choice of sanctions, but not whether or not actual harm occurred.
- Under the SOM, Appendix C, the key distinction between condition-level and standards-level deficiencies is that a condition-level deficiency represents a “significant or serious problem.” The SOM instructs surveyors that “[w]hen [a laboratory’s] deficient practice is of such a serious nature that correction is a condition for allowing the laboratory to continue patient testing, cite the most appropriate condition...” *Id.* The SOM leaves to the surveyor’s judgment the determination of whether one or more deficiencies are significant or serious enough to cite as a condition-level deficiency.
- A CMP becomes effective 15 days (non-IJ) after CMS notifies the laboratory of CMS’s intent to impose the CMP; however, CMS will not attempt to enforce or collect the CMP until after the hearing decision is issued. Although the CMP would potentially continue to accrue while the laboratory’s appeal is pending, CMS cannot demand payment of the CMP until after the CMP is upheld by an ALJ decision.

Issues:

- Condition-Level Noncompliance
- Revocation of CLIA certificate
- Two year prohibition for owners/operators

Statutory/Regulatory References:

- 8 U.S.C. § 1746
- 42 U.S.C. § 263a(i)
- 42 U.S.C. § 263a(i)(3)
- 42 U.S.C. §§ 263a(d), (f)
- 42 U.S.C. §§ 263a(h)-(i)
- 42 U.S.C. § 263a(b)
- 42 C.F.R. § 493.1
- 42 C.F.R. § 493.2
- 42 C.F.R. §§ 493.3(a), (b)(2)
- 42 C.F.R. § 493.17(a)
- 42 C.F.R. §§ 493.25(a)-(b)
- 42 C.F.R. § 493, subpart I
- 42 C.F.R. § 493.1230
- 42 C.F.R. §§ 493.1231 through 493.1236
- 42 C.F.R. § 493.1235
- 42 C.F.R. § 493.1236(c)(1)
- 42 C.F.R. § 493.1239(a)
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1405
- 42 C.F.R. § 493.1407

- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1443
- 42 C.F.R. § 493.1445
- 42 C.F.R. § 493.1487
- 42 C.F.R. § 493.1489
- 42 C.F.R. § 493.1495
- 42 C.F.R. §§ 493.1806-1844
- 42 C.F.R. § 493.1807(a)
- 42 C.F.R. § 493.1816(b)
- 42 C.F.R. § 493.1840
- 42 C.F.R. § 493.1842(a)(1) and (2)
- 42 C.F.R. § 493.1844
- 42 C.F.R. § 498.62

Medicos Para La Familia vs CMS
Docket No: C-17-250
Decision No. CR5400
Date: 8/21/2019

CLIA #: 44D0964458
State/Territory: Tennessee
Type of Certificate: Certificate of Accreditation
DAB/ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

- CMS determined that Petitioner violated two CLIA conditions of certification: enrollment and testing of PT samples and complexity testing laboratory director responsibilities.

Argument(s):

- Petitioner has admitted that it “referred” the samples, but denies “intentionally” referring.
- The laboratory director conceded that all of the testing was performed on the same instrument at a different laboratory, but argued that “the submission of the PT sample to our sister lab was not deliberate or intentional.”
- Petitioner now denies that all tests were performed on the same instrument, claiming that Lab Director Rodney’s response was “based on limited information.”
- Petitioner maintains that the laboratory supervisor who performed the proficiency testing “honestly and legitimately believed that he was testing PT samples on behalf of Medicos on a machine owned and operated by Medicos.”

Ruling Excerpt(s):

- The parties agree that this matter should be decided based on the written record, without an in-person hearing.
- As lab director, his “information” should not have been so “limited.” His admitted ignorance supports CMS’s finding that the facility violated section 493.1403: because he was not aware of the way the testing was performed, he was not ensuring that the samples were tested as required.
- Whether or not the laboratory tested all samples on the same instrument, Petitioner Medicos impermissibly referred its PT samples.
- Lab staff may not have even casual conversations with staff working in other labs. Allowing the *same person* to test and report PT results of two different labs violates section 493.801.

Issues:

- Intentional PT Referral
- Laboratory Director Responsibilities

Statutory/Regulatory References:

- 42 U.S.C. §§ 263a(h)(2), 263a(i)(4)
- 42 C.F.R. § 493.61(b)(1)
- 42 C.F.R. § 493.801(b)(4)
- 42 C.F.R. § 493.803(a)
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1405
- 42 C.F.R. § 493.1407
- 42 C.F.R. § 493.1840(b)(1)(B)
- 42 C.F.R. § 493.1844(c)(4) and (7)

Dr. Kenneth U. Ihenetu, Ph.D., DABCC, FACB, Laboratory Director of EMS Toxicology, LLC vs. CMS

Docket No. C-17-1216
Decision No. CR5494
Date: December 20, 2019

CLIA #: 29D209777
State: Nevada
Type of Certificate:
DAB/ALJ: Leslie C. Rogall

Basis for Sanction(s):

- CMS explained that Petitioner, as the laboratory director, was an operator of the laboratory.
- Owners and operator(s) (including the laboratory director) are prohibited from owning or operating (or directing) a laboratory for at least two (2) years from the date of the revocation.
- CMS filed objections to all of Petitioner's exhibits and his two declarations. (Petitioner did not respond to any of CMS's objections, nor did he submit any filings or motions requesting any relief following CMS's filing of its objections.)
- Condition-level deficiency existed because EMS's "significant deficiencies" had "presented serious problems that had the potential to adversely affect patient test results."
- The Petitioner's "failure to prevent, identify, and correct these issues thus likewise constituted a serious problem with the potential to adversely affect patient test results."
- EMS's and Petitioner's joint failure to comply with 42 C.F.R. § 93.1445(e)(3)(ii), stated that "[b]y failing to follow its own procedures to verify accuracy and precision of its testing before reporting out results, EMS . . . could not ensure its patient test results were accurate and reliable, and therefore was at risk for reporting inaccurate and unreliable test results to patients."

Argument(s):

- Petitioner's primary argument opposing the revocation, is that CMS abused its discretion and acted arbitrarily and capriciously in revoking EMS's CLIA certificate. And argues that subjecting him to the two-year prohibition mandated by 42 U.S.C. § 263a(i)(3) is also arbitrary and capricious.
- Petitioner asserts that CMS did not initially explain its basis for revoking EMS's CLIA certificate and only belatedly provided a post-hoc rationalization for the first time in this proceeding.
- Petitioner also points to the non-exclusive list of factors that CMS, by regulation, has indicated it will consider when deciding which sanctions to impose against a deficient laboratory under CLIA.
- Petitioner argues that he is an innocent victim of EMS's "fraud" and does not deserve to be a "scapegoat" for EMS's failures. Petitioner argues that he did his best to

implement measures to maintain or return EMS to CLIA compliance, but was undercut by a fraud scheme perpetrated by EMS's owners that thwarted his efforts.

- Petitioner argues that the ALJ “must consider the totality of the facts, which are essentially equitable reasons, to determine whether the penalties to which [sic] CMS seeks to impose are justified by the facts.”
- Petitioner states that he expected that witnesses (to include the unnamed “Principals”) would testify about circumstances such as the laboratory’s bankruptcy, the laboratory’s “failures to implement processes and procedures from Petitioner,” and threats to sue him if he resigned.
- Petitioner stated he intended to request a subpoena to obtain the testimony of Isaac Park, who he identified as a “former employee” of the laboratory. Petitioner stated that Mr. Park will testify “as to the compliance with the SODs as well as the conduct of EMS during this period including the termination of employees and the bankruptcy.”
- Petitioner argues that he provided a “proper validation plan to EMS as required” and “implemented standards within the written protocol which are within the industry standard.”
- Petitioner also asserts that that the survey findings “were incorrect.”
- Petitioner asserted that the deficiencies “did not directly impact patients’ management because the two physicians working with EMS . . . were duly informed about EMS . . . problems with the Nevada/CMS survey, but no evidence was shown that EMS Toxicology results were inaccurate or negatively impacted patient management.”

Ruling Excerpt(s):

- Given the seriousness of those deficiencies, I conclude that, at the time of the April 2017 survey, EMS’s laboratory director did not provide overall management and direction and thus did not comply with the laboratory director CLIA condition for laboratories performing high complexity testing. I further conclude that, because EMS was noncompliant with a CLIA condition at the time of the April 2017 survey, CMS had a basis, even considering this condition-level deficiency alone, to revoke EMS’s CLIA certificate.
- Dr. Kenneth U. Ihenetu, Ph.D., DABCC, FACP was the laboratory director for EMS Toxicology, LLC when CMS proposed to revoke its certificate to operate as a clinical laboratory under the CLIA. I conclude there was a basis to revoke EMS’s CLIA certificate due to failings directly attributable to Petitioner
- Because Petitioner was EMS’s laboratory director during the period examined by the survey in this case, he is prohibited from owning, operating, or directing a laboratory for a period of two years, effective the date of this decision. see
- The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including the authority to inspect and sanction laboratories that fail to comply with the regulatory requirements.
- Under the regulations, a single condition-level deficiency is an adequate basis for principal and alternative sanctions.
- The regulations define “operator” which includes the laboratory director.
- CMS has the burden of presenting sufficient evidence to prove a prima facie case of noncompliance with one or more CLIA conditions; the petitioner then has the ultimate burden of showing by a preponderance of the evidence (i.e., more likely than not) that it was in compliance with CLIA conditions.

- Regarding the imposition of sanctions, the issue to be resolved by the ALJ is not whether CMS properly exercised discretion in imposing either principal or alternative sanctions, but rather, whether a basis existed for the imposition of sanctions under governing statutory and regulatory authorities based upon the evidence before the ALJ.
- Petitioner, through his counsel, failed to adhere to the requirements of both the Civil Remedies Division Procedures (CRDP) and my Pre-Hearing Order with respect to the filing of exhibits and declarations.
- Based on Petitioner's failure to identify some of the proposed witnesses with any specificity (i.e., "Principals of EMS") and his inability to provide an address or location for any of the proposed witnesses, it appears that Petitioner did not undertake meaningful efforts to timely request that any of these witnesses voluntarily provide written direct testimony.
- Petitioner has not provided any explanation for his failure to submit the written direct testimony of his proposed witnesses as directed in the ALJ's Pre-Hearing Order.
- Even if Petitioner had requested that ALJ issue a subpoena to compel the testimony of any of his proposed witnesses, such testimony would be irrelevant to the factual bases supporting the condition-level and standard-level deficiencies that are the focus of this decision.
- Petitioner, as the laboratory director, personally failed ensure that the laboratory was compliant with the conditional-level requirement to provide overall management and direction of the laboratory and several associated standard-level deficiencies. The testimony he has proposed is irrelevant to his individual performance as the laboratory's director.
- Petitioner has not shown that the proposed testimony regarding the laboratory's bankruptcy petition or its staffing is relevant to the cited deficiencies that directly relate to his role as the laboratory director.
- Petitioner does not assert the laboratory was in compliance with all of the CLIA requirements addressed herein; it is unclear why Petitioner would expect Mr. Park would testify to such compliance when Petitioner did not do so himself.
- There was a legal basis to revoke EMS's CLIA certificate; specifically, CMS may revoke a laboratory's CLIA certificate if the laboratory has any condition-level deficiencies "at the time of the survey."
- EMS did not comply with the standard at 42 C.F.R. § 493.1445 because Petitioner, as laboratory director, did not ensure compliance with four separate elements of the standard set forth at 42 C.F.R. § 493.1445(e)(3)(ii), (4)(iii)-(iv), and (5).
- It is plainly evident that Petitioner did not ensure that EMS's verification procedures were "adequate to determine the accuracy, precision, and other pertinent performance characteristics" of its testing methods. Surveyor correctly observed that this failure to identify acceptability criteria for its carryover studies rendered those studies "meaningless."
- Even though Petitioner submitted multiple plans of correction with accompanying documents, Petitioner never once submitted a different version of the Validation Plan that corrected (or omitted) the patently obvious deficiencies discussed above. Despite Petitioner's unsupported claim, the only version of the Validation Plan in the record is the facially deficient version that was neither "proper" nor "within the industry standard."
- No documentation pre-dating the survey indicates that EMS or Petitioner investigated unacceptable proficiency testing results or submitted any reports to Petitioner or a

technical consultant as required by the laboratory's policy. This lack of documentation evidences that neither EMS nor Petitioner, as its laboratory director, investigated EMS's unacceptable proficiency testing results, nor made any attempt to correct the problems giving rise to those unacceptable results, prior to the survey. Bolstering these inferences is the fact that someone marked up the proficiency testing reports after the survey, as is evident in the newly marked up documents EMS submitted to the state agency and CMS.

- EMS's unacceptable proficiency testing results undeniably constituted failures in quality that EMS and Petitioner were obligated to correct.
- By failing to take corrective action, Petitioner failed to assure the integrity of EMS's testing results and, by extension, the quality of its laboratory services. Petitioner did not ensure that EMS's quality control and quality assessment programs were maintained to assure the quality of EMS's laboratory services and to identify obvious failures in quality as they occurred.
- No regulation specifies the precise relationship between standard-level and condition-level deficiencies or specifies how to determine when standard-level deficiencies rise to the level of a condition-level deficiency. However, CMS elaborated guidance in the State Operations Manual (SOM).
- Petitioner himself, recognized his shortcomings as a laboratory director when he conceded that "there is only so much one can do when the lab ownership and its staff fail to comply."
- Even if Petitioner was a victim of fraud, that has no bearing on the appropriateness of the revocation sanction and its attendant collateral consequences for Petitioner. This is not the appropriate forum to remedy any harm Petitioner may have suffered from a purported fraud scheme.
- So long as CMS had a basis for the sanctions it imposed (which it did), it did not act arbitrarily and capriciously, and the ALJ is not empowered to overturn those sanctions for equitable reasons.
- Based on the revocation of EMS's CLIA certificate, Petitioner, as EMS's laboratory director, is subject to the two-year prohibition on owning, operating, or directing a CLIA laboratory, pursuant to 42 U.S.C. § 263a(i)(3), effective the date of this decision.
- The two-year prohibition is triggered automatically by statute against any owner or operator, including a laboratory director who is an operator, of a laboratory that has had its CLIA certificate revoked.
- It is hardly arbitrary or capricious to prohibit from owning or operating a CLIA laboratory any owner or operator (to include a laboratory director filling the role of an operator) of a laboratory that has demonstrated an inability to comply with CLIA requirements. The obvious fear is that an irresponsible or neglectful owner or operator will simply move on to another laboratory, to the detriment of Medicare beneficiaries and the general public.

Issues:

- Revocation of CLIA certificate
- Two-year laboratory director prohibition
- Condition-level noncompliance

Statutory/Regulatory References:

- 42 U.S.C. § 263a(d), (f)
- 42 U.S.C. § 263a(h)-(i)
- 42 U.S.C. § 263a(i)(1)
- 42 U.S.C. § 263a(i)(3)
- 42 C.F.R. § 493.1
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.17(a)
- 42 C.F.R. § 493.25(a)-(b)
- 42 C.F.R. § 493.1230
- 42 C.F.R. § 493.1250
- 42 C.F.R. §§ 493.1403, 493.1405, 493.1407, 493.1441, 493.1443, and 493.1445
- 42 C.F.R. § 493.1441
- 42 C.F.R. §§ 493.1806-.1844
- 42 C.F.R. § 493.1806(a)
- 42 C.F.R. § 493.1807(a)
- 42 C.F.R. §§ 493.1812-.1816
- 42 C.F.R. § 493.1814(a)(2)
- 42 C.F.R. § 493.1816(b)
- 42 C.F.R. § 493.1840(a)(8)
- 42 C.F.R. § 493.1840(e)
- 42 C.F.R. § 493.1842(a)(1-2)
- 42 C.F.R. § 493.1840(d)(1)
- 42 C.F.R. § 493.1840(e)(1)
- 42 C.F.R. §§ 493.1844(a)(b)(c)(d)(f)
- 42 C.F.R. § 498.58
- 42 C.F.R. § 498.60(b)(1)

Laboratory Corporation of America Holdings, Inc. vs. CMS
Docket No: C-17-1147
Decision No. CR5523
Date: 1/31/2020

CLIA #: 34D0655205
State: North Carolina
Type of Certificate: Certificate of Accreditation
DAB/ALJ: Leslie A. Weyn

Basis for Sanction(s):

- CMS asserts that Petitioner failed to comply with the CLIA condition of participation for proficiency testing (PT) because it engaged in prohibited inter-laboratory communications concerning the results of PT samples. CMS stated that the Petitioner communicated with Castle Medical LLC (Castle), a laboratory located in Smyrna, Georgia, the results Petitioner obtained by analyzing proficiency testing (PT) samples Castle had improperly referred to Petitioner.
- CMS contends also that Petitioner failed to comply with the CLIA condition of high complexity laboratory director responsibilities because its laboratory director failed to provide overall management and direction of Petitioner, as evidenced by its deficient practices in the area of proficiency testing. CMS further argues that Petitioner's multiple missteps in handling the improperly referred PT samples demonstrate that Petitioner's laboratory director did not discharge his responsibilities.
- CMS argues that Petitioner's lab director failed to ensure that Petitioner complied with PT testing requirements in two ways: 1) he failed to ensure that Petitioner did not engage in prohibited inter-laboratory communications regarding PT results; and 2) he failed to ensure that Petitioner immediately reported to CMS that Petitioner had received improperly referred PT samples, as required.
- CMS argues additionally that Petitioner's director failed in his supervisory duties based on Petitioner's delay in notifying CMS of Castle's improper referral of PT samples. CMS contends that, upon receipt of PT samples from Castle on November 10, 2016, Petitioner's personnel should have identified them as improperly referred PT samples and immediately reported receipt of them to CMS.

Argument(s):

- Petitioner argues that CMS failed to establish a prima facie showing of condition-level violations by either the laboratory or its director. Therefore, in Petitioner's view, the sanctions should be vacated.
- Petitioner argues that the prohibition against inter-laboratory communications is inapplicable to it because it was not the laboratory which made the improper referral of PT samples, but rather, was the laboratory which unknowingly received the PT samples as a result of an improper referral.
- Petitioner contends that the regulations do not support CMS's position that immediate notification of the improper referral was required; nevertheless Petitioner asserts that it did promptly notify CMS of the improper referral.

- Petitioner argues that nothing in the regulations prohibits a laboratory that receives a PT sample as a result of an improper referral from testing the PT samples.
- Petitioner counters that the regulations do not contain any requirement that an improper referral must be *immediately* reported to CMS. Petitioner claims that it “*did* promptly notify CMS of the improper referral,” with the notification being delayed two days “by virtue of the Thanksgiving holiday.” Petitioner contends that its inability to notify CMS sooner did not cause or threaten any harm.

Ruling Excerpt(s):

- CMS’s motion for summary judgment and deny Petitioner’s cross-motion for summary judgment. CMS had a legal basis for its determination to impose the alternative sanctions of a directed plan of correction and a CMP against Petitioner.
- A laboratory is entitled to notice and an opportunity for a hearing before an administrative law judge to contest imposition of CLIA intermediate (alternative) sanctions.
- Summary judgment is appropriate and no hearing is required where either: there are no genuine disputes of material fact and the only questions that must be decided involve application of law to the undisputed facts; or the moving party prevails as a matter of law even if all factual disputes are resolved in favor of the party against whom the motion is made.
- The condition for enrollment and testing of samples, codified at 42 C.F.R. § 493.801, requires that “[e]ach laboratory” must enroll in a PT program and “[t]he laboratory must test the samples in the same manner as patients’ specimens.” Based on the context, it is clear that the references to “[t]he laboratory” are synonymous with “[e]ach laboratory”. The phrase “[t]he laboratory” throughout the standard applies to *any* laboratory that receives a PT sample from a PT program in which it is enrolled.
- The plain meaning of the plural “laboratories” is that *all* laboratories enrolled in a PT program are prohibited from engaging in inter-laboratory communications regarding PT results.
- To read the regulation to prohibit only one party from engaging in improper communications would defy common sense. The regulation is plainly intended to deter laboratories from comparing PT results to improve the accuracy of the results. To compare results, more than one party must participate. It would make no sense to find noncompliance by the laboratory that asked whether its PT results were accurate, but to find blameless the laboratory that answered the query. Each party to such an exchange has engaged in an improper communication prohibited by 42 C.F.R. § 493.801(b)(3).
- The regulation prohibits “*any* inter-laboratory communications pertaining to the results of proficiency testing sample(s). A violation occurred because Petitioner communicated to Castle the results Petitioner obtained by testing PT samples which were improperly referred to Petitioner by Castle.
- Petitioner engaging in improper inter-laboratory communications regarding PT samples reflects unfavorably on the lab director’s overall management and direction of the laboratory.
- November 10 through November 28 spans 18 days, and Petitioner was in possession of the PT samples during the entire 18-day period. Contrary to what Petitioner argues, notifying CMS of the improperly referred PT samples on the 18th day cannot be considered “prompt”.

- Petitioner’s violation of 42 C.F.R. § 493.801(b)(4) is evidence that Petitioner’s lab director failed in his duty to oversee laboratory operations in violation of 42 C.F.R. § 493.1441 because it is apparent that Petitioner failed to implement procedures that would have enabled its staff to identify improperly referred PT samples upon receipt. Had staff done so, they would have been in a position to notify CMS of the improper referral well before roughly two weeks had elapsed.
- All that is required for CMS to impose one or more principal or alternative sanctions against a laboratory is a determination that the laboratory is noncompliant with a single CLIA condition of participation; no showing of harm is required.
- The undisputed evidence establishes that, under Petitioner’s laboratory director’s supervision, staff did not competently perform their duties nor did they maintain the integrity of the PT process. Petitioner’s staff failed to identify the improperly referred PT samples from Castle at the outset and failed to notify CMS promptly of the receipt of the samples. Further, not only did Petitioner’s staff test the improperly referred PT samples, but lab personnel also released some of those PT results to Castle, thereby engaging in prohibited inter-laboratory communications. These violations in the area of PT all point to a breakdown in Petitioner’s testing processes and general lab operations. Accordingly, I find that Petitioner’s lab director did not provide necessary management and direction of the lab, violating 42 C.F.R. § 493.1441.
- CMS is authorized to impose the alternative sanctions of a directed plan of correction and a CMP against Petitioner as remedies for Petitioner’s noncompliance with CLIA conditions.
- CMS’s determination to impose a CMP, and the amount of the CMP imposed, are not initial determinations and, therefore, are not subject to appeal.

Issues:

- Intentional PT Referral
- Laboratory Director Responsibilities

Statutory/Regulatory References:

- 42 U.S.C. § 263a *et seq*
- 42 U.S.C. § 263a(f)(1)
- 42 U.S.C. § 263a(h)(3)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.25(b)
- 42 C.F.R. § 493.801
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1443
- 42 C.F.R. § 493.1445
- 42 C.F.R. § 493.1777
- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1808(a)
- 42 C.F.R. § 493.1840(a)(7)
- 42 C.F.R. § 493.1842(a)
- 42 C.F.R. § 493.1844(a)(2) and (3), (b)(3)

Charles S. Pewitt, D.O., d/b/a Jackson Medical Center vs. CMS
Docket No: C-20-192
ALJ Ruling No. 2020-6
Date: 2/14/2020

CLIA #: 26D0969305
State: Missouri
Type of Certificate: Certificate of Compliance
DAB/ALJ: Leslie C. Rogall

Basis for Sanction(s):

- CMS specifically requested that Petitioner submit a *directed portion of a plan of correction*, and not “corrective action.”
- CMS unambiguously informed Petitioner that it had imposed sanctions on October 8, 2019, and that Petitioner had until November 25, 2019, to request a hearing.

Argument(s):

- Petitioner argues that due to the security procedures required by CMS and its efforts to submit scores of encrypted email messages, it “did not timely file a request for appeal because it was under the mistaken impression that CMS accepted its corrective action.”

Ruling Excerpt(s):

- A party affected by an adverse determination must file its request for hearing no later than 60 days from the date that it receives notice from CMS. Receipt of the notice is presumed to be five days after the date of notice unless shown otherwise. An affected party may request that an ALJ extend the date to file a hearing request; however, the affected party must show good cause in order for the ALJ to grant such a request. If a hearing request is untimely and there is no good cause to extend the filing date, then an ALJ may dismiss the hearing request.
- An adjudicator must consider the relevant circumstances of each case to determine whether there is “good cause” to extend the filing deadline.
- Petitioner’s belief that no further action was required because it had submitted evidence of correction *prior* to the imposition of sanctions was both misguided and mistaken.
- CMS clearly explained that a directed portion of a plan of correction was an alternative sanction, and CMS gave no indication that such a submission constituted “corrective action” that would obviate the need to request a hearing.
- CMS did not afford Petitioner another opportunity to submit a credible allegation of compliance and acceptable evidence of correction when it imposed sanctions, and the technical difficulties Petitioner had in complying with the alternative sanction of a directed portion of the plan of correction are wholly irrelevant to why it failed to timely submit a request for hearing.
- The Board has consistently ruled that where, as here, a party consciously chooses for reasons of its own not to request a hearing, it must accept the consequences of its inaction.

- The request for an extension of time to file a request for hearing filed by Petitioner, Charles S. Pewitt, D.O., d/b/a Jackson Medical Center, is denied because Petitioner did not establish good cause to extend the time for filing.

Issues:

- Timely request for hearing

Statutory/Regulatory References:

- 42 U.S.C. § 263a *et seq*
- 42 C.F.R. § 493.1832(b)(2)
- 42 C.F.R. §§ 493.1844(a), (b)
- 42 C.F.R. §§ 498.40(a)(2), (c)
- 42 C.F.R. § 498.22(b)(3)
- 42 C.F.R. § 498.40(c)
- 42 C.F.R. § 498.70(c)

Kensington Diagnostics LLC vs. CMS
Docket No: A-19-131
Decision No. DAB 2992
Date: 3/16/2020

CLIA #: 05D2087480
State: California
Type of Certificate: Certificate of Registration
DAB/ALJ: Christopher S. Randolph, Constance B. Tobias, Leslie A. Sussan

Basis for Sanction(s):

- The Petitioner was in violation of three condition required for CLIA certification.

Argument(s):

- Kensington contends that it had no obligation to comply with section 493.1236(c)(1) because it did not report carisoprodol test results to “patients or providers” and because “no clinical actions were being taken on the results.”
- Kensington asserts that it does not report the results of any test unless the test is “fully verified and compliant with CLIA standards”; that it followed that protocol for the carisoprodol test; and that there is “no possibility of clinical harm” to patients if results are not reported and no action is taken based on them.
- “Being a high complexity CLIA certified lab,” says Kensington, “we are well within our rights and abilities to add additional tests to our menu after we evaluate the performance of said reagent on our machine.”
- Kensington contends that the CMP is excessive given the size of its laboratory. Kensington requests that the Board grant it “equitable relief” by “adjust[ing] the penalty “to reflect the size of our operation both in volume, days open and actively testing.”
- Kensington contends in its opening appeal brief that the sanctions imposed by CMS should be rescinded or overturned because CMS’s surveyor’s actions constitute “affirmative misconduct” by CMS (e.g., alterations to some its test reports).

➤ Ruling Excerpt(s):

- Kensington has failed to identify any unsupported finding of material fact, prejudicial legal error, or abuse of discretion by the ALJ. Moreover, Kensington has not justified its request that the Board hold a hearing to receive in-person testimony from its owner and two employees.
- The “conditions” for CLIA certification are general requirements, while the “standards” are “specific components of the conditions.”
- If Petitioner wishes to waive an oral hearing that is Petitioner’s right but Petitioner must file a written waiver of the right to appear and present evidence at a hearing on the record in accordance with 42 C.F.R. § 498.66(a). If the waiver of oral hearing is not opposed by CMS and the waiver is accepted, a schedule for the filing of briefs and documentary evidence will be adopted. Petitioner is advised, however, that a waiver . .

. will not result in Petitioner’s case be[ing] moved ahead of other pending cases for purposes of decision.

- A single condition-level deficiency sufficed to warrant the imposition of sanctions.
- The Board may not review the CMP amount chosen by CMS.
- The ALJ committed no error in concluding that Kensington had violated the standard in 42 C.F.R. § 493.1236(c)(1).
- Kensington’s position is that these requirements are inapplicable to “research” or validation testing by a laboratory otherwise subject to CLIA so long as the results of the testing are not “reported.” However, the CLIA statute and regulations contain no such research or test-specific exemption.
- Because Kensington does not dispute that it violated the condition-level requirement in section 493.1230, we summarily affirm the ALJ’s conclusion to that effect as well as his ultimate holding that CMS lawfully revoked Kensington’s CLIA certificate and imposed a CMP.
- Kensington’s argument appears to confuse the remedial purpose of an accruing CMP to motivate the noncompliant provider with the idea that CMS must itself be taking remedial action or continuously communicating with the provider. The duty to remediate is with the laboratory.
- Kensington’s request to present in-person testimony as unjustified for several reasons:
 - Kensington does not contend that its proposed witnesses would offer relevant and material in-person testimony that clarifies or supplements the statements contained in their declarations of record;
 - Kensington has not alleged that the substance of the proposed in-person testimony, to the extent it would supplement its witness declarations, could not have been included in those declarations while the case was pending before the ALJ;
 - Kensington had an opportunity to present in-person testimony to the ALJ but expressly waived that opportunity in August 2017.
- Based on the foregoing analysis, we affirm the ALJ’s August 5, 2019 decision in this case.

Issues:

- Condition-Level Noncompliance
- Revocation of CLIA certificate
- Two year prohibition for owners/operators

Statutory/Regulatory References:

- 42 U.S.C. §§ 263a(a)-(c), (f)
- 42 U.S.C. § 263a(g)
- 42 C.F.R. § 493.1
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.3
- 42 C.F.R. § 493.45(g)
- 42 C.F.R. § 493.5(c)
- 42 C.F.R. § 493.1230
- 42 C.F.R. § 493.1235

- 42 C.F.R. § 493.1236
- 42 C.F.R. § 493.1239

Laboratorio Concordia Lugaro vs. CMS
Docket No: C-19-1093
Decision No. CR5589
Date: 4/16/2020

CLIA #: 40D0658188
State/Territory: Puerto Rico
Type of Certificate: Certificate of Compliance
DAB/ALJ: Steven T. Kessel

Basis for Sanction(s):

- CMS rests its case principally on its allegation that, based on Ms. Del Toro's admission, the Petitioner intentionally referred proficiency testing samples to another laboratory for testing.

Argument(s):

- Ms. Del Toro contended that Petitioner did so because the Puerto Rico Proficiency Testing Program told her that the tests should be run at Laboratorio Clinico Central "because it was like an internal procedure" due to the fact that both Petitioner and the other laboratory had common ownership and laboratory directors (Ms. Del Toro).
- Petitioner asserts that "Mrs. Del Toro never admitted to . . . [referring] those proficiencies exercises to Laboratorio Clinico Central."
- Petitioner contends that the surveyor's notes, which were made during the inspection of Petitioner's facility, do little to support the surveyor's testimony or CMS's contentions.
- Petitioner argues that: "Maybe the best evidence against CMS is the testimony of Mrs. Vanessa Segarra [sic] . . . which, in the relevant . . . [part] says that they were unable to corroborate that the proficiencies exercises involved here [were] done at . . . [Petitioner's laboratory]."
- Petitioner asserts in a plan of correction that it submitted in response to findings that it had violated CLIA, that it had submitted only one sample to Laboratorio Clinico Central for testing.

Ruling Excerpt(s):

- Summary judgment in favor of the CMS against Petitioner. Imposition revocation of Petitioner's CLIA certificate; cancellation of its approval to receive Medicare payments; and a civil money penalty of \$2,000 for each of the eight instances in which Petitioner improperly referred proficiency testing samples to another laboratory is sustained.
- The common and ordinary meaning of "intentional" is an act that is knowing and willful or deliberate as opposed to something that is accidental. An intentional referral of a proficiency test occurs whenever a laboratory knowingly refers a test to another laboratory for testing. Specific intent to violate CLIA or its regulations is not an element of an intentional referral.
- It does not matter that Ms. Del Toro may have incorrectly concluded that a laboratory that shared common ownership and direction with Petitioner could perform proficiency

testing on Petitioner's behalf. Petitioner's motive in referring proficiency tests to another laboratory for testing is not relevant. What matters here is that Petitioner knowingly referred the test samples to another laboratory. That satisfies that statutory definition of an intentional referral of proficiency testing samples.

- The referrals in this case were not harmless errors....When a laboratory refers its proficiency testing samples to another laboratory, it defeats the purpose of proficiency testing. A principal purpose of CLIA is to assure that a *specific* laboratory conducts clinical tests in a way that satisfies standards of care for laboratories. When another laboratory performs proficiency testing on a laboratory's behalf, the results say nothing about the performance of the referring laboratory. Referred test results can mask poor performance by the referring laboratory. Improperly performed tests by a laboratory can have a deleterious effect on the health and safety of the individual whose samples are being tested. An error by a laboratory can result in a life-threatening misdiagnosis.
- The Petitioner was afforded the opportunity to provide written declarations, under oath, from any potential witnesses. Petitioner did not offer a sworn statement from Ms. Del Toro. Consequently, Petitioner's assertion that Ms. Del Toro denies having made admissions is pure speculation and not admissible evidence.
- A power failure affecting Petitioner's facility is no justification for an intentional referral.

Issues:

- Intentional PT Referral

Statutory/Regulatory References:

- 42 U.S.C. § 263a *et seq*
- 42 U.S.C. § 263a(d)(1)(E)
- 42 U.S.C. § 263a(i)(4)
- 42 C.F.R. § 493.801(b)(4)
- 42 C.F.R. § 493.801(b)(5) and (6)
- 42 C.F.R. § 493.843(e)
- 42 C.F.R. § 493.1100
- 42 C.F.R. § 493.1105(a)(6)
- 42 C.F.R. § 493.1283(a)
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1407(e)(4)(i)
- 42 C.F.R. § 493.1407(e)(4)(iv)
- 42 C.F.R. § 493.1804(b)(2)
- 42 C.F.R. § 493.1806(c)(3)
- 42 C.F.R. § 493.1834
- 42 C.F.R. § 493.1834(d)(2)(i) and (ii)
- 42 C.F.R. § 493.1834(e)(1)(ii)(B)
- 42 C.F.R. § 493.1840(b)
- 42 C.F.R. § 493.1844(c)(4)

Albert Cohen, M.D. vs. CMS
Docket No: C-18-214
Decision No. CR5616
Date: 5/21/2020

CLIA #: N/A
State: Florida
Type of Certificate: N/A
DAB/ALJ: Steven T. Kessel

Basis for Sanction(s):

- Summary judgment in favor of CMS affirming CMS's determination to prohibit Petitioner, Albert Cohen, M.D., from owning, operating, or directing a CLIA laboratory for a period of two years.
- Petitioner was the laboratory director of Delray Medical Center (Delray).
- CMS determined to revoke Delray's CLIA certificate and impose a civil money penalty (CMP) and directed plan of correction based on proficiency testing (PT) referral.
- Based on the revocation, CMS prohibited Albert Cohen, M.D. from owning, operating, or directing any other CLIA laboratory for a period of two years.
- Emergency Center Lake Worth (Lake Worth) was also affiliated with Delray.
- Prior to assigning the case to an administrative law judge (ALJ), Delray and Lake Worth entered into a settlement agreement with CMS, and withdrew their request for a hearing.

Argument(s):

- Petitioner's main contention was that PT samples referred by Delray to Lake Worth were for tests that Delray did not perform and had never performed. Further, Petitioner argued as a result PT samples at issue were not Delray's samples. Therefore, according to the Petitioner, the regulations governing PT were never triggered and do not apply.
- Next, Petitioner maintained that sending PT samples from Delray to Lake Worth did not constitute "referrals" of these samples. Petitioner argued that "to refer" means bringing something to another person's attention in order to obtain information. Petitioner contended that Delray did not seek information from Lake Worth because it needed no information from that laboratory concerning RSV tests that it did not perform.
- Additionally, Petitioner contended that, if Delray referred PT samples to Lake Worth, he is not culpable because the referrals were not intentional. Petitioner claimed Delray could not have intentionally referred PT samples to Lake Worth for "analysis" inasmuch as it was not conducting clinical tests for RSV.
- Finally, Petitioner challenged CMS's findings that he failed to perform his duties as a laboratory director and that the action to bar him from owning, operating, or directing a laboratory was arbitrary, capricious, and an abuse of discretion.

Ruling Excerpt(s):

- Both Delray and Lake Worth were certified to perform specific tests for the presence of Human Respiratory Syncytial Virus (RSV). A clinical laboratory is not excused from the requirement to comply with PT requirements by the fact that a laboratory is not currently performing tests for which it is certified. The regulation clearly state that a laboratory is prohibited from referring a proficiency sample “for any analysis for which it is certified to perform in its own laboratory.”
- Undisputed facts related to PT referral plainly establish a violation of CLIA and its regulations which provides CMS with the authority to revoke Delray’s CLIA certificate thus triggering the two year prohibition. That is, twice, Delray sent PT samples to Lake Worth, received test results from Lake Worth, and reported those test results as if it had performed them.
- Whatever the Accreditation Organization (AO) may have found, its findings on the issue of intent are not relevant here. The AO’s opinion is not binding on CMS. Nor is there any evidence that the AO applied or even considered the regulatory definition of “intentional” in evaluating Delray’s actions.
- For regulatory purposes, “intentional” means a deliberate referral of a testing sample. It is no excuse that the referring laboratory believes it is lawful to refer a testing sample. A referral is intentional where a laboratory intends that another laboratory receive the sample and test it even if the referring laboratory operates under the misguided believe that it is doing so legitimately.
- Delray is not cleared of fault as they reported the referral as soon as its management discovered it. The reporting does not contradict the fact that Delray referred PT samples, twice, and reported PT results as its own.
- The regulations require, in part, that a clinical laboratory director provide overall management and direction in accordance with the requirements. Petitioner Cohen’s compliance or lack of compliance with this regulatory requirement is not the legal authority for CMS’s imposition of bar on owning, operating, or directing a laboratory. That authority is a direct consequence of Delray’s unlawful referral of PT samples to Lake Worth.
- The ALJ may decide whether CLIA and governing regulation give CMS authority to impose whatever remedies it determines to impose. The ALJ may not question CMS’s wisdom and judgment in doing so.

Issues:

- Intentional PT Referral
- Two-year prohibition of Laboratory Director
- Testing of PT samples for which a laboratory is certified to perform

Statutory/Regulatory References:

- 42 U.S.C. § 263a
- 42 U.S.C. § 263a(f)(3)(A)
- 42 U.S.C. § 263a(i)(3)
- 42 U.S.C. § 263a(i)(4)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.801
- 42 C.F.R. § 493.801(b)(4)
- 42 C.F.R. § 493.1441

➤ 42 C.F.R. § 493.1840(a)(8)

Charles S. Pewitt, D.O., d/b/a Jackson Medical Center vs. CMS
Docket No: A-20-66
Decision No. 3009
Date: 7/31/2020

CLIA #: 26D0969305
State: Missouri
Type of Certificate: Certificate of Compliance
DAB/ALJ: Leslie A. Sussan, Constance B. Tobias, Susan S. Yim

Basis for Sanction(s):

- On December 3, 2019, CMS informed Petitioner that the time for filing a request for hearing had expired, with no appeal having been filed. Accordingly, wrote CMS, the “sanction action” was “final.”
- CMS opposed the December 18, 2019 motion, urging the ALJ to dismiss the request for hearing filed late and without good cause.

Argument(s):

- Petitioner’s argued that “the restrictions imposed by CMS’s proscribed manner and method of communication and IT systems has prejudiced [Petitioner], created an undue burden, is procedurally deficient, and has violated [Petitioner’s] right to due process.”
- Petitioner does not dispute the ALJ’s findings that, on September 25, 2019, CMS notified Petitioner that a request for hearing to challenge the sanctions CMS imposed was due on November 25, 2019, but that it filed its request for hearing after the due date. However, Petitioner denies that it “consciously” chose not to appeal, asserting that it has good cause for an extended appeal due date because “it was told by CMS” that its corrective actions “would be acceptable and in reliance on that [it] submitted proof of its corrective action[s] and waited for CMS to confirm receipt”.
- Petitioner states that it “attempted to elicit confirmation from CMS that it had received all of the submission and did not believe that anything further was required.”

Ruling Excerpt(s):

- The Board affirms the February 14, 2020 Ruling (ALJ Ruling No. 2020-6). The ALJ concluded that, despite clear notice of the right to appeal and detailed instructions for filing a timely appeal, Petitioner did not timely appeal and that its “explanations” for late filing “do not fall within any reasonable definition of the term ‘good cause’.
- A failure to comply with even a single condition is a ground for CMS to impose one or more principal or alternative sanctions.
- A party affected by an adverse determination must file its request for hearing no later than 60 days from the date that it receives notice from CMS. Receipt of the notice is presumed to be five days after the date of notice unless shown otherwise. An affected party may request that an ALJ extend the date to file a hearing request; however, the affected party must show good cause in order for the ALJ to grant such a request. If a hearing request is untimely and there is no good cause to extend the filing date, then an ALJ may dismiss the hearing request.

- The ALJ noted that Petitioner did not dispute receiving CMS’s proposed sanctions letter and notified Petitioner that a request for hearing had to be filed within 60 days of receipt of the letter.
- The ALJ also noted that Petitioner did not dispute that CMS informed Petitioner that its response to the notice of proposed sanctions was unacceptable, that CMS would be imposing the proposed sanctions, and that a request for hearing had to be filed by a within 60 days.
- Whatever “technical difficulties” Petitioner allegedly had in complying with the alternative sanction of a directed portion of the plan of correction, the ALJ said, they were “wholly irrelevant to why” Petitioner failed to appeal timely.
- The ALJ also rejected Petitioner’s argument “blam[ing] CMS’s computer security requirements and its need to send encrypted emails” to CMS, offered as an explanation for not filing a timely appeal. The ALJ reasoned that the “difficulties” Petitioner purportedly had in submitting information about the physicians and patients who had used the laboratory’s services since June 28, 2017, owing to CMS’s computer security requirements were “wholly irrelevant and [did] not establish good cause for extending the filing deadline.”
- The ALJ rejected the argument that, due to CMS’s computer security procedures and the need to send encrypted emails, Petitioner operated under a mistaken impression that CMS had accepted its corrective actions.
- Petitioner cannot reasonably and credibly claim that it believed that simply submitting a spreadsheet containing the names and addresses of all patients identified as being affected by the alleged deficiencies (directed portion of a plan of correction) and mailing certified letters to each patient would “remedy” all the noncompliance found at its laboratory and undo the sanctions that it was previously told had been imposed.
- If Petitioner elected to spend its time and resources on completing the directed portion of a plan of correction, then, as the ALJ said, “it must accept the consequences of its inaction” in not appealing despite having been told clearly and unambiguously, and twice, that, in order to be timely, an appeal must be filed within 60 days. If Petitioner labored under a belief that satisfactory completion of the directed portion of a plan of corrective action was all that was required, such a mistaken belief is not attributable to CMS’s actions.

Issues:

- Timely request for hearing

Statutory/Regulatory References:

- 42 U.S.C. § 263a *et seq*
- Social Security Act § 1902(a)(9)(C)
- 42 C.F.R. §§ 440.2(b), 440.30(c)
- 42 C.F.R. § 493.1
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.5
- 42 C.F.R. § 493.17
- 42 C.F.R. § 493.20
- 42 C.F.R. § 493.25

- 42 C.F.R. § 493.1230
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1409
- 42 C.F.R. § 493.1773(a)
- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1807
- 42 C.F.R. § 493.1808
- 42 C.F.R. § 493.1812 through 493.1816
- 42 C.F.R. §§ 493.1832(a), (b)(2)
- 42 C.F.R. § 493.1834
- 42 C.F.R. § 493.1844(a), (b), (c), (f)
- 42 C.F.R. § 498.22(b)(3)
- 42 C.F.R. §§ 498.40(a)(2), (c)
- 42 C.F.R. § 498.70(c)
- 42 C.F.R. § 498.82(a)
- 42 C.F.R. §§ 498.86(a), (b)

UNEVX, Inc. d/b/a R.E.D. Laboratories vs. CMS
Docket No: C-19-73
Decision No. CR5723
Date: 9/29/2020

CLIA #: 29D2019771
State: Nevada
Type of Certificate: Certificate of Compliance
DAB/ALJ: Leslie C. Rogall

Basis for Sanction(s):

- The state agency determined that Petitioner was out of compliance with five conditions required for CLIA certification and Medicare coverage of its services.
- The state agency found Petitioner's allegation of compliance not credible and evidence of correction unacceptable and gave Petitioner another opportunity to submit a credible allegation of compliance with acceptable evidence of correction.
- Petitioner has not offered any argument, much less evidence, to refute the factual determination that it did not have a technical supervisor, as required.
- As there is no question that Petitioner failed to have a Technical Supervisor; that failure to have a Technical Supervisor is a condition-level violation; and that CMS may impose the full range of sanctions based on condition-level non-compliance, CMS respectfully submits that summary judgment is proper here.

Argument(s):

- Petitioner did not dispute any of the undisputed facts presented by CMS in its motion for summary judgment. In fact, Petitioner limited its arguments to CMS's imposition of the principal sanction of revocation.
- Although Petitioner recognized that it cannot challenge the amount of a CMP, the Petitioner argued that the per-day CMP is "excessive," in that it was based on multiple condition-level deficiencies, whereas CMS's motion for summary judgment is supported by only one condition-level deficiency.
- Petitioner explained that it "sincerely wishes to come into compliance with the requirements that apply to it and cooperate with the appropriate regulatory agencies in so doing." Petitioner offered that it "would welcome the opportunity to be assisted in returning to full compliance."

Ruling Excerpt(s):

- ALJ concluded there was a basis to revoke Petitioner's CLIA certificate due to its failure to have a technical supervisor, which placed Petitioner out of compliance with a condition required for CLIA certification and Medicare coverage.
- Petitioner's CLIA certificate is revoked effective the date of this decision granting CMS's motion for summary judgment.
- Although Petitioner generally disputes the sanctions imposed, it has not, at any point, challenged the determination that it was not compliant with the requirement that it have a technical supervisor.

- Summary judgment is appropriate because material facts are not in dispute.
- Petitioner has not submitted evidence to refute undisputed material facts presented by CMS that it was not in compliance with 42 C.F.R. § 493.1447 when it did not have a technical supervisor at the time of the March 2018 survey.
- “Even if [post-survey corrective action] met the regulatory standard, however, it is irrelevant since the salient question here is whether laboratory] had the requisite record system at the time of the survey.” Because Petitioner was not compliant with a condition-level requirement at the time of the March 2018 survey, CMS had a legitimate basis to revoke Petitioner’s CLIA certificate.
- The amount of the CMP imposed by CMS is not an initial determination that is subject to review by an ALJ, therefore Petitioner is not entitled to a hearing to challenge it.
- Because CMS has presented undisputed evidence of the condition-level deficiency that Petitioner failed to have a technical supervisor at the time of the survey, CMS had a legitimate basis to revoke its CLIA certificate.
- CMS has the burden of presenting sufficient evidence to prove a *prima facie* case of noncompliance with one or more CLIA conditions.
- ALJ is not authorized to reduce a CMP that is within the range of permissible CMPs because the imposition of a CMP is not an initial determination that is subject to ALJ review.

Issues:

- Condition-Level Noncompliance
- Technical Supervisor

Statutory/Regulatory References:

- 42 U.S.C. §§ 263a (a), (h)(2)(i)
- 42 C.F.R. § 102.3
- 42 C.F.R. § 493.1
- 42 C.F.R. § 493.17(a)
- 42 C.F.R. §§ 493.25(a), (b)
- 42 C.F.R. § 493.1230
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1290
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1447
- 42 C.F.R. § 493.1449
- 42 C.F.R. § 493.1451
- 42 C.F.R. §§ 493.1806(a), (b)
- 42 C.F.R. § 493.1814(a)(2)
- 42 C.F.R. § 493.1834(d)(2)(ii)
- 42 C.F.R. § 493.1840(e)(1)
- 42 C.F.R. § 493.1844

Calvin S. Rosenfeld, M.D., P.A. vs. CMS
Docket No: C-18-1283
Decision No. CR5736
Date: 10/16/2020

CLIA #: 10D0277889
State: Florida
Type of Certificate: Certificate of Compliance
DAB/ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

- Petitioner did not comply with two CLIA conditions of certification, 42 C.F.R. §§ 493.803(a) and 493.1403: 1) it did not successfully participate in proficiency testing in the specialty of hematology for the analyte RBC; and 2) its lab director did not assure that the lab complied with proficiency testing requirements.

Argument(s):

- The Petitioner blames its poor performance on old equipment and asserts that the new equipment “will obviate any future proficiency inadequacies.”

Ruling Excerpt(s):

- Until December 20, 2018, Petitioner Rosenfeld violated statutory and regulatory proficiency testing requirements.
- Because the laboratory director did not fulfill these responsibilities, the laboratory was out of compliance with the condition governing laboratory director because he/she did not ensure that the laboratory is enrolled in an approved proficiency testing program, that the samples are tested as required, and that the laboratory establishes and maintains acceptable levels of analytical performance for each test system.
- The undisputed evidence establishes that the lab returned to compliance on December 20, 2018, the date it achieved satisfactory performance in two consecutive testing events. It therefore corrected the deficiency cited under section 493.803(a) (successful participation in proficiency testing). Because the deficiency cited under section 493.1403 (lab director) derived from the lab’s proficiency testing failures, it also achieved compliance with that requirement as of December 20, 2018.

Issues:

- Unsuccessful Participation in Proficiency Testing
- Laboratory Director Responsibilities

Statutory/Regulatory References [to support sanctions]:

- 42 U.S.C. §§ 263a(d), 263a(f), 263a(h), 263a(i)(1)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.801

- 42 C.F.R. §§ 493.803(a), (b)
- 42 C.F.R. §§ 493.851(a), (b), (f), (g)
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1405
- 42 C.F.R. § 493.1407
- 42 C.F.R. § 493.1804(b)(1)(ii)
- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1807
- 42 C.F.R. § 493.1826(c)(1)
- 42 C.F.R. § 493.1844(c)(4)

Gamma Healthcare, Inc (GHC) vs. HHS
Case No. 6:20-CV-033337-MDH
United States District Court For the Western District of Missouri
Date: 10/28/2020

CLIA #: 26D1041510, 26D2102945
State: Missouri
Type of Certificate: Certificates of Compliance
United States District Judge: Douglas Harpool

Basis for Sanction(s):

- CMS argues that the potential harm to Plaintiff is outweighed by public safety concerns.
- CMS suspended Plaintiff's federal authority to operate as clinical labs, effective October 26, 2020, pursuant to the CMS' authority to suspend Plaintiff's lab certificates in advance of an administrative hearing.
- CMS contends that due process was satisfied here, as Plaintiff was given notice prior to the suspension taking place. The Defendants did exercise their discretion to suspend Plaintiff's license with only 5 days' notice due to their determination that Plaintiff's labs posed "immediate jeopardy" to human health and the public.
- Plaintiff at no point alleges that CMS did not follow their own procedural and statutory requirements in their decision to suspend Plaintiff's licenses. Additionally, Plaintiff does not identify a challenge to any particular regulation or statute.

Argument(s):

- Plaintiff requests the Court issue a Temporary Restraining Order (TRO) to prohibit CMS from suspending and revoking GHC's CLIA Certificate until such time as the Court is able to determine whether the preliminary injunction should remain in effect as a permanent injunction pending Plaintiff's opportunity to exhaust its administrative appeal remedies.
- Plaintiff's raises the following claims: Injunctive Relief based on allegations of due process violations; Violation of Equal Protection Guarantees of the Fourteenth Amendment; and Violation of Due Process Guarantees of the Fourteenth Amendment.
- Plaintiff argues that irreparable harm would result to it from the exhaustion of administrative remedies here, and the purposes of exhaustion would not be served here by requiring further administrative procedures. Specifically, the suspension would allegedly force Plaintiff's labs to close, as 65% of Plaintiff's revenue is dependent upon Medicare certification.
- Plaintiff suggests that its due process rights were violated due to the suspension.

Ruling Excerpt(s):

- Plaintiff's Motion and Preliminary and Permanent Injunctive Relief is denied.
- Generally, the Secretary cannot suspend a lab's CLIA certification before an administrative hearing, assuming the lab wishes to contest the suspension. However, if the Secretary determines that a lab's failure to comply with federal standards presents

an imminent and serious risk to human health, the Secretary may suspend the lab's certification prior to a hearing.

- In cases of extreme and repetitive noncompliance, the regulations permit the Secretary to suspend a lab's certification prior to a hearing, on a mere five days' notice.
- "The burden of establishing that federal jurisdiction exists 'rests upon the party asserting jurisdiction.'"
- There is case law that suggests that procedural due process challenges to the pre-hearing suspension of CLIA certificates are not valid. Both cases suggested that CLIA certificate holders lack a constitutionally protected property interest in a CLIA certificate, and, in any event, a presuspension, adversarial administrative hearing was not required in light of the regulatory notice and "some kind of hearing" procedures provided.
- Plaintiff's challenge is not "a substantial constitutional challenge capable of overcoming the bar on review."
- The "collateral" exception to the exhaustion of administrative remedies is not applicable to the claims in Plaintiff's complaint because they directly challenge CMSs' substantive determinations in imposing remedies against it.
- The law affords substantial deference to CMSs' exercise of discretion in how CMS go about achieving the statutory and regulatory objectives of certifying clinical labs.

Issues:

- II - Suspension of a certificate prior to hearing

Statutory/Regulatory References:

- 42 U.S.C. § 263a
- 42 U.S.C. §§ 405(h), 1395ii (making § 405(h) applicable)
- 42 C.F.R. § 493.1804
- 42 C.F.R. § 493.1806
- 42 C.F.R. §§ 493.1812(a), (b)
- 42 C.F.R. § 493.1840(d)(2)

Justin Camillo and ACN Medical Labs vs. CMS

Docket No: C-19-747

Decision No. CR5861

Date: April 29, 2021

CLIA #: 26D2147784

State: Missouri

Type of Certificate: Certificate of Accreditation

DAB/ALJ: Carolyn Cozad Hughes

Basis for Sanction(s):

- CMS concluded that the lab's deficiencies posed immediate jeopardy to patient health and safety.
- Petitioner did not comply with nine conditions of certification: §§493.801 (Enrollment and Testing of PT Samples, 493.5400 (Analytic Systems), 493.1403 (Moderate Complexity; Laboratory Director, 493.1409 (Moderate Complexity; Technical Consultant), 493.1421 (Moderate Complexity; Testing Personnel), 493.1441 (High Complexity; Laboratory Director), 493.1447 (High Complexity; Technical Supervisor, 493.1459 (High Complexity; General Supervisor, and 493.1487 (High Complexity; Testing Personnel)
- Petitioners submitted a Allegation of Compliance which CMS determined to not be credible.
- CMS detailed the plan's multiple problems and advised Petitioners that the lab's CLIA certificate would be revoked and that the CMP of \$19,787 per day would continue until the lab met all condition-level requirements or its CLIA certification was revoked.

Argument(s):

- Petitioners appealed CMS's determination "that the plan of correction and rebuttal of alleged violations was not a credible allegation of compliance." The appeal also listed Petitioners' multiple grievances against one of the surveyors, the survey process generally, and CMS's review process. It did not mention any of the cited deficiencies.
- Petitioners concede that the lab was not enrolled in a proficiency testing program, but assert that it should not have been required to enroll because the lab began testing in October 2018, when no testing events were scheduled for chemistry or immunology.
- Petitioners argued that they were not required to keep the manuals at the lab because no testing occurred on the day of the survey.
- Petitioners also rely on their plan of correction, claiming that the lab had cutoff values for these analytes and that staff gave one of the surveyor's package inserts with the approved cutoff values. Multiple pages of package inserts do not satisfy the requirement that the manual provide specific ranges and reference intervals for each analyte. As CMS noted when it rejected Petitioners' plan of correction, "the lab's submission consists of 29 pages of package inserts, which contain multiple cutoff values for specific analytes." Petitioners were required to "indicate specifically where the cutoff values, in use at ACN Labs, approved by the laboratory director, for each analyte are located."

Ruling Excerpt(s):

- ALJ grants CMS’s motion for summary judgment and deny Petitioners’. The undisputed evidence establishes that Petitioner ACN was not in compliance with all Medicare conditions of certification, and CMS was therefore authorized to impose sanctions. Summary judgment is appropriate if a case presents no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law.
- Petitioner’s Exhibit 3 (P. Ex.3.) Petitioners have had ample opportunity to respond to CMS’s objections by showing good cause for the late submission and by substituting a conforming declaration. They have not done so. Moreover, the ALJ agreed with CMS that the proposed testimony is irrelevant. In it, Mr. Howard alleges surveyor bias, based on experiences unrelated to this case. And even if his charges related to surveyor performance here, the Departmental Appeals Board has repeatedly rejected, as irrelevant, attacks based on surveyor bias or survey performance. For all of these reasons, the ALJ found P. Ex. 3 inadmissible.
- Petitioners’ hearing request addresses none of the December 17, 2018 deficiency findings. Instead, it appeals CMS’s determination that “the plan of correction and rebuttal of alleged violations was not a credible allegation of compliance.” The request also attacks the surveyors as biased and alleges a conspiracy between the state and CMS to violate the civil rights of Petitioners and others. These are not issues that the ALJ has the authority to review. The determination to reject a plan of correction is not listed as an initial determination and is therefore not reviewable.
- The ALJ does not have authority to review Petitioners’ Constitutional challenges (e.g., allegations how the survey was conducted).
- CMS was authorized to impose sanctions, and, as noted above, the regulations limit the ALJ’s authority to review those sanctions. In any event, Petitioners present no arguments or evidence showing that the sanctions imposed were improper.
- The undisputed evidence establishes that ACN lab did not meet multiple standards for monitoring and evaluating the overall quality of its analytic systems. These standard-level deficiencies were very serious. They were of such character as to affect adversely the health and safety of its patients, which puts the lab out of compliance with a condition of certification.
- Instead of actual evidence, Petitioners rely on the allegations of compliance asserted in the lab’s plan of correction. Even a credible allegation of compliance (and no evidence suggests that these were credible) does not demonstrate that the lab complied with the conditions of certification.
- The regulation is unambiguous: all CLIA-certified labs must enroll. There is no “new lab” exception to this requirement. That the lab was new is an ongoing theme in Petitioners’ defenses. They offer no support for their argument that a new lab should not be subject to all of the CLIA requirements. Those requirements are in place to protect the health and safety of those tested, and individuals whose samples are tested in a new lab need the protections afforded by CLIA just as much as those whose samples are tested in more established labs. The ALJ explained that there are no “new lab” exceptions to the regulatory requirements. At a minimum here, ACN was required to produce its “initial comparative studies performed during validations.” It has produced no such documentation.
- Petitioners submitted no documents or affidavits to counter CMS’s determination the accuracy of creatinine testing was compromised due to using expired reagents

- Petitioners claim that “they were looking into the reasoning for the red flagged results” and that the lab director’s own review and evaluation “showed perfect control.” Again, such unsupported assertions are insufficient to establish a dispute of material fact that would preclude my entering summary judgment.
- In reviewing the lab’s data and patient test reports, the surveyors found nothing that identified the personnel who performed certain tests (DxC700 AU and Unicel Dx1 600). The lab consultant confirmed that the lab could not identify who had performed those tests. The ALJ found no response to this in Petitioners’ submissions. The lab’s plan of correction suggests that it is not required to identify who performed the tests. This position is simply inconsistent with the regulation.

Issues:

- Laboratory Director, Other Personnel
- Proficiency Testing
- Analytic Systems

Statutory/Regulatory References:

- 42 U.S.C. §§ 263a(i)(1)(f)(h)(2)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 498.3
- 42 C.F.R. § 498.5
- 42 C.F.R. § 498.20(a)(1)
- 42 C.F.R. § 498.40 through § 498.78.
- 42 C.F.R. § 493.801
- 42 C.F.R. § 493.803(a)
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 495.1251(b),
- 42 C.F.R. § 493.1252(a)(b)
- 42 C.F.R. § 493.1253(b)(1)(2)
- 42 C.F.R. § 493.1256(d)(10), (g)
- 42 C.F.R. § 493.1283(a)
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1407(e)(3)(iii), (e)(5), (e)(8), and (e)(11)
- 42 C.F.R. § 493.1409
- 42 C.F.R. § 493.1411;
- 42 C.F.R. § 493.1421
- 42 C.F.R. § 493.1423(b)(1)-(4)(i)
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1443
- 42 C.F.R. § 493.1447
- 42 C.F.R. § 493.1449
- 42 C.F.R. § 493.1459
- 42 C.F.R. § 493.1487
- 42 C.F.R. § 493.1773(c)
- 42 C.F.R. § 493.1777
- 42 C.F.R. § 493.1804(b)(1)

- 42 C.F.R. § 493.1806
- 42 C.F.R. § 493.1807
- 42 C.F.R. § 493.1844(a)(1)-(2),(b),(c)(4)

Laboratorio Concordia Lugaro vs. CMS
Docket No: C-21-426
Decision No.: CR5976
Date: November 9, 2021

CLIA #: 40D0658188
State: Puerto Rico
Type of Certificate: Certificate of Compliance
DAB/ALJ: Steven T. Kessel

Basis for Sanction(s):

- A surveyor/medical technologist completed a survey of Petitioner's laboratory on March 21, 2019. The findings, if not rebutted by the preponderance of the evidence, are ample basis to conclude that Petitioner failed to comply with CLIA conditions of participation, including, but not limited to, the condition governing proficiency testing. (The ALJ found the surveyor's testimony credible.)
- Petitioner's motive in referring proficiency tests to another laboratory for testing is not relevant. What matters here is whether Petitioner knowingly referred the test samples to another laboratory. CMS determined to impose principal and alternative sanctions against Petitioner. CMS based this determination both on Petitioner's unlawful referrals of proficiency testing samples to another laboratory and on Petitioner's additional condition-level noncompliance with CLIA requirements.
- Petitioner's referral of even one proficiency test to another laboratory sustains the determination to revoke Petitioner's CLIA certificate. Other failures by Petitioner to comply with CLIA conditions are additional grounds for imposing sanctions.

Argument(s):

- Petitioner's exhibits include an affidavit. That affidavit constitutes Petitioner's principal affirmative defense to CMS's allegations of noncompliance.
- Petitioner argues that the sometimes cryptic statements in the surveyor notes prove that the Petitioner did not admit referring eight proficiency testing events to another laboratory.
- Petitioner relies on an affidavit and on what it claims are inconsistencies in the surveyor's testimony.
- The Petitioner admits that she referred its May 2018 proficiency testing samples to another laboratory, Laboratorio Clinico Central. She contends that she was authorized to do so by the Puerto Rico Department of Health due to the loss of electrical power resulting from Hurricane Maria. She denies referring other proficiency testing samples to other laboratories and denies having admitted to the surveyor that she did so. She asserts that she performed the June 2018 proficiency testing at Petitioner's facility because those tests could be performed manually. Thereafter, according to Petitioner, electrical power was restored, and she performed all proficiency testing on Petitioner's premises.

Ruling Excerpt(s):

- The ALJ sustained the determination of the Centers for Medicare & Medicaid Services (CMS) to impose the following remedies against Petitioner, Laboratorio Concordia Lugaro: revocation of Petitioner’s CLIA certificate; cancellation of its approval to receive Medicare payments; and a civil money penalty of \$2,000 for each of the instances in which Petitioner either improperly referred proficiency testing samples to another laboratory or falsely reported proficiency testing results.
- The record also supports CMS’s determination to impose civil money penalties against Petitioner as alternative sanctions. CMS offered proof that Petitioner made seven referrals of proficiency test samples to another laboratory and, in an eighth instance, reported the results of another laboratory’s proficiency testing as if it had performed the test. These improper referrals and improper reporting of test results justify the imposition of alternative sanctions including civil money penalties.
- Neither the statute nor implementing regulations define what is an intentional referral of a proficiency test. The common and ordinary meaning of “intentional” is an act that is knowing and willful or deliberate as opposed to something that is accidental. An intentional referral of a proficiency test occurs whenever a laboratory knowingly refers a test to another laboratory for testing. Specific intent to violate CLIA or its regulations is not an element of an intentional referral.
- Petitioner’s motive in referring proficiency tests to another laboratory for testing is not relevant. What matters here is whether Petitioner knowingly referred the test samples to another laboratory. Ms. del Toro admits to having made an intentional referral. That admission, in and of itself, justifies CMS’s determination to revoke Petitioner’s CLIA participation.
- When a laboratory refers proficiency testing samples to another laboratory it defeats the purpose of proficiency testing. A principal purpose of CLIA is to assure that a *specific* laboratory conducts clinical tests in a way that satisfies standards of care for laboratories. When another laboratory performs proficiency testing on a laboratory’s behalf the results say nothing about the performance of the referring laboratory. Referred test results can mask poor performance by the referring laboratory.
- The referrals in this case were not harmless errors. Even if Ms. del Toro honestly believed that she could refer testing samples to another laboratory, her decision to do so masked potentially poor performance by Petitioner and endangered the health and safety of individuals whose specimens Petitioner tested.
- The failure by Petitioner to maintain records of proficiency testing not only is by itself a regulatory violation, but it is strong evidence that Petitioner did not do proficiency testing on its premises. It thus corroborates Mr. Rivera’s account of what Ms. del Toro told him.

Issues:

- Intentional Proficiency Testing Referral

Statutory/Regulatory References:

- 42 U.S.C. § 263a *et seq*
- 2 U.S.C. § 263a(f);
- 42 U.S.C. § 263a(i)(1)(C)
- 42 U.S.C. § 263a(i)(3)
- 42 U.S.C. § 263a(i)(4)
- 42 U.S.C. § 263a(d)(1)(E)
- 42 C.F.R. § 493
- 42 C.F.R. § 493.801(b)(4)
- 42 C.F.R. § 493.801(b)(5)
- 42 C.F.R. § 493.843(e)
- 42 C.F.R. § 493.1100
- 42 C.F.R. § 493.1105(a)(6)
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1407(e)(4)(i)
- 42 C.F.R. § 493.1407(e)(4)(iv)
- 42 C.F.R. § 493.1804(b)(2)
- 42 C.F.R. § 493.1806(b)
- 42 C.F.R. § 493.1807(a)
- 42 C.F.R. § 493.1808(a),
- 42 C.F.R. § 493.1806(c)
- 42 C.F.R. § 493.1840(b)(1)(i)
- 42 C.F.R. § 493.1834(d)(2)(ii)
- 42 C.F.R. § 493.1842(a)
- 42 C.F.R. § 493.1844(c)(4), (7)
- 45 C.F.R. Part 102.

Ellington Behavioral Health vs CMS

Docket No: C-19-257
Decision No. CR6031
Date: February 23, 2022

CLIA #: 07D2006352
State: Connecticut
Type of Certificate: Certificate of Accreditation
DAB/ALJ: Scott Anderson

Basis for Sanction(s):

- State agency surveyors conducted a license renewal inspection of Petitioner's facility and found multiple state licensing and CLIA deficiencies.
- Petitioner was out of compliance with two conditions required for CLIA certification and Medicare coverage of its services.
- CMS advised Petitioner of its noncompliance with the two CLIA conditions and requested that Petitioner submit a credible allegation of compliance and evidence of correction for cited deficiencies.
- CMS found Petitioner's allegations of compliance not credible and evidence of correction unacceptable.
- CMS gave Petitioner another opportunity to submit a credible allegation of compliance with evidence of correction.
- CMS gave Petitioner an opportunity to submit evidence or information as to why the proposed sanctions should not be imposed.
- Petitioner wanted to avoid sanctions, stated that Petitioner "has no future plans to resume laboratory testing," and indicated that Petitioner would request a hearing if that would prevent monetary sanctions.
- Petitioner, through its owner, timely requested a hearing before an ALJ.

Argument(s):

- Petitioner asserts that it hired a Technical Supervisor due to COLA, who then worked in laboratory operations under two laboratory directors.
- Petitioner also asserts that "[a]ll regular laboratory procedures were continued..." indicating that Petitioner had complied with CLIA requirements after the COLA survey.
- Petitioner maintains in briefing that it had no physicians or clients "using the lab prior or since June 4, 2018," as it was a physician-owned laboratory processing patient samples from its own facility.
- Petitioner then states that it "suspended all patient testing on June 4, 2018 due to other unforeseen office developments."
- Petitioner concludes by stating that the laboratory director, technical supervisor, and laboratory personnel were discharged several months after the CLIA survey due to insufficient revenue and that the laboratory ceased operations.

Ruling Excerpt(s):

- Petitioner was not in compliance with six of the standards under the Analytic Systems Condition level requirement to maintain a CLIA certificate.
- Petitioner presented no evidence to show that it was in compliance with the identified standards under 42 C.F.R. § 493.1250 (Analytic Systems, Tag D5400) at the time of the survey. Petitioner's hearing request and subsequent submissions challenge CMS's initial determinations to revoke Petitioner's CLIA license, impose a CMP, and direct a portion of the plan of correction.
- Petitioner, at length, discusses its multiple post-survey plans of correction and efforts, I have no authority to consider whether Petitioner corrected any deficiencies.
- The determination to reject a plan of correction is not listed as an initial determination and is thus not reviewable.
- CMS was also authorized to impose the other principal and alternative sanctions specified, based on Petitioner's noncompliance.
- I direct CMS to determine whether Petitioner ceased to function as a laboratory, as alleged by Petitioner's filings, and to consider limiting the length of the per-day CMP to a date when Petitioner no longer continued to operate a laboratory.

Issues:

- Analytic Systems
- Laboratory Director

Statutory/Regulatory References:

- 42 U.S.C. § 263a(f)
- 42 U.S.C. § 263a(h)(3).
- 42 U.S.C. § 263a(d),
- 42 U.S.C. § 263a(e).
- 42 U.S.C. § 263a(i).
- 42 C.F.R. pt. 493.
- 42 C.F.R. § 493.1
- 42 C.F.R. §§ 493.1250 through 493.1283
- 42 C.F.R. § 493.1289
- 42 C.F.R. § 493.1804
- 42 C.F.R. § 495.1441
- 42 C.F.R. pt. 498, subpt. D
- 42 C.F.R. § 498.3(b)
- 42 C.F.R. § 498.20(a)(1)
- 42 C.F.R. § 498.40(a)
- 42 C.F.R. § 498.40(b)
- 42 C.F.R. § 498.70(b)

David L. Smalley, Ph.D. Vs Xavier Becerra, Secretary of HHS
Case No. 4:22CV399 HEA
United States District Court Eastern District of Missouri Eastern Division
Date: July 6, 2022

CLIA #: 26D1041510
State: Missouri
Type of Certificate: Certificate of Compliance
United States District Judge: Henry Edward Autrey

Basis for Sanction(s):

- CMS argues that because the laboratory's CLIA certificate was revoked (as part of a settlement agreement), the two-year prohibition for the laboratory director applies.

Argument(s):

- Plaintiff argues that he was denied his constitutional right to due process because he was not given the opportunity to participate in the appeal of CMS's decision to sanction the lab and himself.
- Plaintiff challenges the imposition of a minimum two-year disqualification by CMS from acting as the laboratory director of any clinical laboratory in the United States.
- Plaintiff alleges that his education and experience qualify him to serve as the laboratory director of a high-complexity laboratory in accordance with CLIA and its implementing regulations.
- Plaintiff was not made aware of Gamma's filing of an appeal, nor did Gamma or CMS contact him at that time.
- Defendant moves to dismiss this action for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

Ruling Excerpt(s):

- A clinical laboratory must obtain and maintain a CLIA certificate to operate anywhere in the United States (except in CLIA-exempt States).
- A threshold requirement for any clinical laboratory to operate is the engagement of a laboratory director who meets the qualification requirements set forth in CLIA regulations. The laboratory director is responsible for the overall management and direction of the entire laboratory and personnel. The name of the laboratory director is listed on the CLIA-certification and any change to the laboratory director requires notification to CMS.
- When condition level deficiencies that pose immediate jeopardy are identified during an on-site survey, CMS may impose "principal sanctions" (i.e., suspension, limitation, or revocation of a laboratory's CLIA certificate) prior to the laboratory and its owners and operators having a chance to respond to or correct the deficiencies.
- The CLIA statute and regulations permit the laboratory to appeal the imposition of any principal or alternative sanction by requesting a hearing before an Administrative Law Judge ("ALJ").

- Individuals who own or operate a laboratory that has had its CLIA certificate revoked are prohibited from owning or operating any other CLIA-certified (or -waived) laboratory in the United States for two (2) years (or for as long as the laboratory's certificate remains revoked), whichever is longer. The regulations include the laboratory director in the definition of an "operator" of the laboratory if specified criteria are met.
- Under Federal Rule of Civil Procedure 12(b)(1), a party may move to dismiss an action based on lack of subject matter jurisdiction. The Eighth Circuit has held that "[i]n deciding a motion under Rule 12(b)(1), the district court must distinguish between a facial attack—where it looks only to the face of the pleadings—and a factual attack—where it may consider matters outside the pleadings."
- Under a facial challenge, the reviewing court examines the complaint to determine if the plaintiff has satisfactorily alleged grounds for subject matter jurisdiction. The nonmoving party is afforded the same protections he would receive were he defending against a Rule 12(b)(6) motion.
- A factual challenge, on the other hand, tests the factual basis the nonmoving party has asserted for subject matter jurisdiction. Matters outside of the pleadings may be considered by the reviewing court and the nonmoving party is afforded no Rule 12(b)(6)-type protections.
- To survive a motion to dismiss for lack of subject matter jurisdiction, the party asserting jurisdiction has the burden of establishing that subject matter jurisdiction exists.
- Gamma's attorneys informed Plaintiff via email (6/11/2021) that Gamma had agreed to a settlement with CMS concerning the sanctions against the laboratory, which included revocation of its CLIA certificate, effective May 25, 2021, and waiver of any appeal rights. CMS never contacted Plaintiff and, instead, requested that Gamma's attorney obtain his signature on an attestation acknowledging the settlement terms. Plaintiff refused to sign the attestation.
- Plaintiff argues that he was denied his constitutional right to due process because he was not given the opportunity to participate in the appeal of CMS's decision to sanction the lab and himself. The record before the Court, however, belies Plaintiff's position.
 - Plaintiff acknowledges that he was the director of the laboratory. Under the applicable law and regulations, "operator" includes a director.
 - Plaintiff's responses to the notices received establish his position as an operator/director. Upon receiving the notices, Plaintiff responded on behalf of the laboratory in an effort to resolve the issues presented after the inspections.
 - Plaintiff's timely responses to CMS's proposed and actual sanction notices demonstrate that he received CMS's notices and reveal his efforts to cure the defects CMS found.
 - Plaintiff's extensive history of operating laboratories gives rise to the inference that Plaintiff is familiar with the procedures through which an operator would challenge the two-year suspension.
 - The notices informing Plaintiff of the potential suspension is clearly indicative of the need to pursue the appeal remedies available to Plaintiff.
- ALJs interpret the regulations' term "laboratory" "to include any individual who CMS is treating as an owner or operator."
- Plaintiff cannot establish a waiver of sovereign immunity because there has been no final agency action *vis a vis* Plaintiff. Despite Plaintiff's participation in the process

preceding the appeal, Plaintiff did nothing to protect his interest at the appeal level, even though he was continuously notified of the revocation of the CLIA certification and two-year suspension of him acting as a director of any CLIA laboratories. Accordingly, there has been no final agency action from which Plaintiff can claim a waiver of sovereign immunity.

- Plaintiff has failed to establish a waiver of sovereign immunity which would entitle him to pursue this action against Defendant Secretary in his official capacity. Since the Court lacks subject matter jurisdiction over this action, the Court cannot consider Plaintiff's Motion for Preliminary Injunction.

Issues:

- Two-year laboratory director prohibition
- Appeal process

Statutory/Regulatory References:

- 42 U.S.C. §§ 263a–263a-7
- 42 U.S.C. § 263a(i)(1)
- 42 U.S.C. § 263a(i)(2)
- 42 U.S.C. § 263a(i)(3)
- 42 U.S.C. § 263a(k)
- 42 C.F.R. § 488.1
- 42 C.F.R. § 493.1 et seq
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.51, 63
- 42 C.F.R. § 493.1403
- 42 C.F.R. § 493.1405-06
- 42 C.F.R. § 493.1441
- 42 C.F.R. § 493.1443
- 42 C.F.R. § 493.1812
- 42 C.F.R. § 493.1844
- 42 C.F.R. § 493.1844(a)(1)-(2)
- 42 C.F.R. § 493.2001
- 42 C.F.R. § 498.40 through 498.78
- 42 C.F.R. § 1001.3001(a)

Vitas Laboratory, LLC vs. CMS

Docket No: C-18-32
Decision No. CR6135
Date: August 22, 2022

CLIA #: 16D2126753
State: Iowa
Type of Certificate: Certificate of Compliance
DAB/ALJ: Keith W. Sickendick

Basis for Sanction(s):

- Missouri state surveyors attempted to perform an unannounced survey of Vitas, but the surveyors found that no laboratory existed at the address listed for Vitas in the CMS-116.
- CMS alleged that Vitas submitted false information that resulted in a CLIA certificate of compliance being inappropriately issued.
- Petitioner misrepresented the status of Vitas' operations when he applied for a CLIA certificate for Vitas and is this is a basis for revocation of Vitas' CLIA certificate.
- The pictures also reflect files, unidentifiable supplies, various items of office furniture, and equipment including computer monitors, a light box like one that may be used to view an x-ray, eye chart, telephone, printer/copier, facsimile machine, and a calculator, among other things. The pictures do not show any identifiable laboratory testing equipment and Vitas does not assert that they do. Vitas also does not assert that the pictures include any employees performing laboratory testing.
- Vitas' CLIA certificate is revoked effective the date of this decision.
- CMS advised Petitioner that CMS proposed to revoke Vitas' CLIA certificate based on the misrepresentation in the application for a CLIA certificate that Vitas existed as a laboratory. CMS granted Petitioner and Petitioner 10 days to respond.

Argument(s):

- Vitas states in its request for hearing that all information included in Vitas' application for a CLIA certificate was accurate.
- Vitas states that prior to filing the application it had a laboratory at 1429 Hazel Street, Carthage, Missouri.
- Vitas filed a photograph of the front door signage for the laboratory with its request for hearing.
- Vitas filed an email to Vitas from COLA that shows COLA was attempting to schedule an accreditation survey of Vitas.
- I accept Vitas' assertions as true for purposes of summary judgment.
- Vitas does not assert in its request for hearing that it ever conducted any testing of human specimens at 1429 Hazel Street in Carthage, Missouri.
- Vitas argues all information included in the CMS-116 was accurate.
- Petitioner states that he signed no CMS-116 form for Vitas; he did not receive, review, or sign any documents or work from Vitas; he was not requested to participate in any

onsite review of Vitas; he did not approve or sign any documents to establish Vitas as a laboratory or for Vitas to begin operations; he authorized no one to sign his name or otherwise act in his stead to establish laboratory operations of Vitas; and he did not sign any document to enroll Vitas in the COLA accreditation program.

- CMS and Vitas do not challenge Petitioner's affidavits or allege that his statements are not true.

Ruling Excerpt(s):

- Petitioner was listed as Vitas' laboratory director in the application for a CLIA certificate discussed in this decision.
- Petitioner was not an operator of Vitas within the meaning of the regulations.
- Petitioner had no right to request a hearing, and he is not subject to the application of 42 U.S.C. § 263a(i)(3).
- The allegation is not that Vitas provided false information in its CMS-116 application, but rather, that Vitas misrepresented that a laboratory existed as suggested by the Application for Certificate of Accreditation.
- The ALJ concluded CMS has made a prima facie showing of a basis to revoke Vitas' CLIA certificate of registration.
- There is also no dispute that Petitioner was listed as Vitas' laboratory director on the Application for Certificate of Accreditation.

Issues:

- Revocation of Vitas' CLIA certificate
- Two-year prohibition for the Laboratory Director

Statutory/Regulatory References:

- 42 U.S.C. § 263a(a)-(d), (h)-(i)
- 42 U.S.C. § 263a(f)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.45
- 42 C.F.R. § 493.57
- 42 C.F.R. §§ 493.1806-.1842
- 42 C.F.R. § 493.1844(d)(2)
- 42 C.F.R. § 493.1844(d)(4)
- 42 C.F.R. § 493.1844(a), (f)
- 42 C.F.R. § 493.1844(b)
- 42 C.F.R. § 493.1844(c)(4)
- 42 C.F.R. § 493.1844(f)(1)
- 42 C.F.R. pt. 498, subpt. D
- 42 C.F.R. § 498.66

Vitas Laboratory, LLC and Chenbo Dong, Ph.D. vs. CMS
Docket No: C-18-521 (Vitas) and C-18-770 (Dong)
Decision No. CR6142
Date: August 22, 2022

CLIA #: 26D2132750
State: Missouri
Type of Certificate: Certificate of Registration
DAB/ALJ: Keith W. Sickendick

Basis for Sanction(s):

- CMS alleged that Vitas submitted false information that resulted in a CLIA certificate of compliance being inappropriately issued.

Argument(s):

- Vitas states in its request for hearing that all information included in Vitas' application for a CLIA certificate was accurate.
- Dong states that he signed no CMS-116 form for Vitas; he did not receive, review, or sign any documents or work from Vitas; he was not requested to participate in any onsite review of Vitas; he did not approve or sign any documents to establish Vitas as a laboratory or for Vitas to begin operations; he authorized no one to sign his name or otherwise act in his stead to establish laboratory operations of Vitas; and he did not sign any document to enroll Vitas in the COLA accreditation program.
- Vitas argues that CMS filed a combined prehearing brief and motion for summary judgment in violation of the Prehearing Order.
- Vitas also argues that there are due process concerns because CMS argues different grounds for revocation in its motion than those cited by the notices sent to Taylor.

Ruling Excerpt(s):

- Vitas' CLIA certificate is revoked, effective the date of this decision. Billy Taylor is subject to the two-year prohibition.
- CMS advised Taylor and Dong that CMS proposed to revoke Vitas' CLIA certificate based on the misrepresentation in the application for a CLIA certificate that Vitas existed as a laboratory.
- Because there was no laboratory and no testing of human specimens, it was impossible for Dong to have any responsibility for overseeing all facets of laboratory operations and the safety and reliability of the testing of specimens. Accordingly, Dong could not be an operator within the meaning of the regulations, he had no right under the statute or regulations to request an ALJ hearing to challenge the CMS initial determination to revoke, and he is not subject to the application of 42 U.S.C. § 263a(i)(3) as a matter of law.
- A laboratory owner and operator have the right to request a hearing rather than the laboratory.
- The Secretary has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more

- requirements for certification.
- The Secretary has through the regulations delegated broad authority to CMS to ensure that laboratories perform as Congress intended, including the authority to inspect and sanction laboratories that fail to comply with the regulatory requirements.
 - CMS has the burden of coming forward with sufficient evidence to prove a prima facie case of noncompliance with one or more CLIA conditions.
 - The petitioner then has the ultimate burden of showing by a preponderance of the evidence that it was not out of compliance with the conditions placed at issue by CMS in its prima facie case.
 - If summary judgment is appropriate, no hearing is required. Summary judgment is appropriate, and no hearing is required, where either: there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made.
 - Vitas does not assert in its request for hearing that it ever conducted any testing of human specimens at 1429 Hazel Street in Carthage, Missouri.
 - The pictures do not show any identifiable laboratory testing equipment and Vitas does not assert that they do. Vitas also does not assert that the pictures include any employees performing laboratory testing.
 - CMS need not show that a misrepresentation was intentional to revoke pursuant to 42 U.S.C. § 263a(i)(1). The Board found that Congress imposed no requirement of intent related to revocation based on misrepresentation under 42 U.S.C. § 263a(i)(1)(A) and 42 C.F.R. § 493.1840(a)(1) and that a careless or negligent misrepresentation is a sufficient basis for revocation of a CLIA certificate.
 - The amount of testing done and when it was done at Vitas at 1429 Hazel Street in Carthage, Missouri misrepresent that Vitas was operating as a laboratory. Even if one accepts the position discussed hereafter that a laboratory need not be testing specimens when an initial application for a CLIA certificate is filed, the laboratory's failure to begin testing when it received a certificate of registration that allows testing is a misrepresentation regarding the laboratory's readiness to begin testing.
 - I conclude CMS has made a prima facie showing of a basis to revoke Vitas' CLIA certificate of registration pursuant to 42 C.F.R. § 493.1840(a)(1) because the June 2017 Application for Certificate of Accreditation misrepresented that Vitas was operating as a laboratory or was prepared to operate as a laboratory when a CLIA certificate was issued.
 - The regulations provide clear notice that a laboratory with a CLIA certificate of registration that is filing an application for a CLIA certificate of compliance or for a certificate of accreditation must be open and operating and prepared for inspection by CMS or the state agency.
 - CMS generally has no discretion in applying the two-year prohibition of 42 U.S.C. § 263a(i)(3), other than identifying who are owners and operators subject to the prohibition. The statute does not grant the Secretary or CMS discretion not to apply this provision of the statute to owners and operators, except in a limited circumstance not presented in this case.
 - Further, no statutory or regulatory provisions grant an owner or operator of a laboratory that had its CLIA certificate revoked a right to ALJ review of the CMS determination that they are owners and operators for purposes of application of the two-year prohibition.

- While the regulatory language suggests that the right to request a hearing is with the laboratory, the statute is clear that it is the owners and operators of the laboratory who have the right to request a hearing.
- The Congressional committee clearly intended to prevent owners and operators who failed to properly administer a CLIA laboratory, leading to revocation of that laboratory's CLIA certificate, from simply opening another laboratory. The language of the above-quoted text further indicates that the committee intended to apply the two-year ban to owners and operators when their conduct "precipitated a revocation" of the CLIA certificate or they bore "ultimate responsibility for the conduct" that led to the revocation.

Issues:

- Misrepresentation
- Revocation
- Two-year prohibition

Statutory/Regulatory References:

- 42 U.S.C. § 263a(a)-(d), (f)
- 42 U.S.C. § 263a(i)
- 42 U.S.C. § 263a(h)-(i)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.45
- 42 C.F.R. § 493.57
- 42 C.F.R. §§ 493.563-.569
- 42 C.F.R. §§ 493.1771-.1773, 493.1777-.1780
- 42 C.F.R. §§ 493.1806-.1842
- 42 C.F.R. § 493.1806(a)
- 42 C.F.R. § 493.1807(a)
- 42 C.F.R. § 493.1816(b)
- 42 C.F.R. § 493.1842(a)(1)
- 42 C.F.R. § 493.1842(a)(2)(i)
- 42 C.F.R. § 493.1840
- 42 C.F.R. § 493.1840(a)
- 42 C.F.R. § 493.1840(d)(1)
- 42 C.F.R. § 493.1840(e)
- 42 C.F.R. § 493.1844
- 42 C.F.R. § 493.1844(a)-(b)
- 42 C.F.R. § 493.1844(c)(4)
- 42 C.F.R. § 493.1844(d)(2)(4)
- 42 C.F.R. § 493.1844(f)(1)
- 42 C.F.R. § 498.66

David L. Smalley, Ph.D. vs CMS

Docket No: C-22-724
ALJ Ruling No. 2023-3
Date: November 14, 2022

CLIA #: 26D1041510
State: Missouri
Type of Certificate:
DAB/ALJ: Leslie A. Weyn

Basis for Sanction(s):

- Petitioner was the laboratory director and operator of the laboratory.
- (CMS) provided notice that it was imposing sanctions based on the noncompliance found during the surveys.
- CMS notice warned that, once revoked, both the owner(s) and operator(s) (including a director) would be prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the revocation.
- Almost two years after the deadline to request a hearing and over a year after the case had been dismissed, Petitioner filed correspondence, that he is entitled to a hearing before an administrative law judge to contest CMS's sanctions.
- Petitioner's filing appeared to be untimely for the September 2020 notice imposing sanctions, I directed Petitioner to show cause why his case should not be dismissed.

Argument(s):

- Petitioner confirms he is not seeking to vacate the dismissal in Docket No. C-21-11 because, he asserts, he was not a party to that case or its final disposition.
- Petitioner contends instead that there is good cause for his untimely hearing request given the "[c]onfusion" or "lack of legal clarity" over whether he, as a lab operator, has a right to a hearing independent from that of the lab owners.
- Petitioner asserts that, due to circumstances beyond his control, he was unaware that Gamma's owners had filed a hearing request in October 2020, and that, as soon as he was advised of the settlement of Gamma's appeal, he engaged in good faith efforts to clarify whether he had an independent right to appeal.
- Petitioner has not established good cause for filing his hearing request untimely.

Ruling Excerpt(s):

- Petitioner was not prevented from himself requesting a hearing by the November 25, 2020 deadline specified in the CMS notice.
- Petitioner acknowledges that, as of June 11, 2021, he knew that Gamma's owners and CMS had settled the pending appeal.
- Gamma's owners asked Petitioner to sign the settlement agreement and acknowledge the sanction that would be imposed against him.
- Petitioner is seeking equitable relief more generally because, in his view, he was unfairly deprived of his right to a hearing. I cannot grant such relief.

- Petitioner has not established good cause to file a hearing request out of time. I therefore dismiss this case.

Issues:

- Suspension and revocation of CLIA certificate
- Petitioner requested dismissal

Statutory/Regulatory References:

- 42 U.S.C. § 263a(i)(3)
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.1840(a)(8))
- 42 C.F.R. § 493.1844(f)
- 42 C.F.R. § 493.1844(a)(2)
- 42 C.F.R. § 498.40(c)(2)
- 42 C.F.R. § 498.70(c)
- 42 C.F.R. § 498.72
- 42 C.F.R. § 498.72
- 42 C.F.R. § 498.82(a)(2)
- 42 C.F.R. pt. 498, subpt. D

Quantum Laboratory, LLC vs. CMS
Docket No: C-22-703
Date: March 31, 2023
CLIA #: 26D2184797

State: MO
Type of Certificate: Certificate of Compliance
DAB/ALJ: Leslie C. Rogall

Basis for Sanction(s):

- Petitioner did not provide the requested information by the deadline.
- Petitioner was directed to register for DAB E-File and request access to the case, or alternatively, request a waiver of the DAB E-File requirement.
- Petitioner was directed to provide notice if they intended to seek substitute counsel.
- Petitioner was directed to provide notice of whether they intended to file a pre-hearing exchange, and if so, whether it required an extension of its deadline.
- Petitioner's failure to comply suggested that they had abandoned their hearing request.

Argument(s):

- Petitioner's then-counsel requested that she be allowed to withdraw from representation of Petitioner.
- Counsel submitted evidence directing Petitioner to inform the court whether it intended to file a pre-hearing exchange or an extension of the pre-hearing exchange deadline.
- Petitioner has abandoned their hearing request, and therefore, I dismiss Petitioner's request for hearing.

Ruling Excerpt(s):

- Petitioner's failure to comply suggested that they had abandoned their hearing request.
- Petitioner failed to comply with the order directing them to show cause, therefore I would dismiss the case for abandonment.
- The court would dismiss a case for abandonment if the requesting party "fails to appear" by filing required documents or exhibits.

Issues:

- Order of Dismissal

Statutory/Regulatory References:

- 42 C.F.R. § 498.69

Quantox Lab, LLC vs. CMS
Docket No: C-20-219
Decision No.: CR6293
Date: June 2, 2023

CLIA #: 26D2135849
State: MO
Type of Certificate: Certificate of Compliance
DAB/ALJ: Scott Anderson

Basis for Sanction(s):

- CMS advised Petitioner that, based on the survey, Petitioner was noncompliant with four CLIA conditions of participation, as well as with several standards, and that its deficient practices posed immediate jeopardy to patient health and safety.
- CMS found that Petitioner continued to be noncompliant with Condition-level requirements and that immediate jeopardy remained uncorrected.
- Petitioner requested a hearing to challenge CMS's determination of noncompliance with CLIA requirements and the imposition of sanctions.
- CMS continued to communicate with Petitioner concerning a return to compliance.
- CMS found that Petitioner continued to be out of compliance with CLIA requirements and that immediate jeopardy continued to exist.
- CMS advised Petitioner that the previously imposed sanctions remained imposed and that its CLIA certificate was suspended.

Argument(s):

- CMS's Motion for Summary Judgment should be denied because there are multiple disputed issues of material fact arising from CMS' failure to find and articulate evidence to support its finding of immediate jeopardy.
- CMS's conclusions are based on conjecture and, as a matter of law, cannot support such a finding.
- Petitioner stated the Board should also reject CMS's substantive finding of immediate jeopardy because CMS ignored the applicable law and regulatory requirements in determining that any deficiencies constituted immediate jeopardy.
- Petitioner stated the Board should also reject CMS' astonishing attempt to impose nearly \$4 million in civil monetary penalties – in a case where CMS did not identify a single affected patient – on the basis that such a penalty violates the Excessive Fines Clause of the Eighth Amendment to the United States Constitution.
- Petitioner stated CMS failed to establish evidence that the deficiencies created a likelihood of "serious injury, serious harm, serious impairment or death" and failed to identify any patients or likely to be affected by the alleged noncompliance.
- Petitioner has not disputed the finding that no quality control records were available for review, nor has it denied its own employee's statement that it failed to establish and maintain a quality control program.

Ruling Excerpt(s):

- Although Petitioner did not raise issues in its prehearing brief over which I have jurisdiction, the following findings and conclusions show that CMS met its burden to provide prima facie evidence that Petitioner had condition-level deficiencies.
- I conclude that Petitioner was out of compliance with these standards, resulting in Petitioner's failure to meet the overall Laboratory Director condition.
- Petitioner's noncompliance with the four standard-level requirements discussed above under the Laboratory Director condition shows that Petitioner's lab director failed to fulfill his duties to provide the "overall management and direction" of the laboratory.
- In its response to CMS's motion for summary judgment, Petitioner failed to present any evidence to rebut CMS's prima facie case, much less show compliance by a preponderance of the evidence.

Issues:

- Laboratory Director
- Analytic Systems

Statutory/Regulatory References:

- 42 U.S.C. § 263a
- 42 U.S.C. § 263a(d), (f)
- 42 U.S.C. § 263a(e)
- 42 U.S.C. § 263a(i)
- 42 U.S.C. §§ 263a(h)
- 42 C.F.R. § 493.1
- 42 C.F.R. § 493.2
- 42 C.F.R. § 493.5(a)
- 42 C.F.R. § 493.5(c)(5)
- 42 C.F.R. § 493.1100
- 42 C.F.R. § 493.1230
- 42 C.F.R. § 493.1250
- 42 C.F.R. § 493.1441
- 42 C.F.R. §§ 493.1445(e)
- 42 C.F.R. § 493.1487
- 42 C.F.R. § 493.1804(a)
- 42 C.F.R. §§ 493.1806-493.1844
- 42 C.F.R. Part 498