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

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

Basis for Sanction(s):

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

Arguments:

Petitioner alleges that:

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

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

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

Ruling excerpts:

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

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

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

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

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

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

Basis for Sanction(s):

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

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

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

Arguments:

Petitioner asserts that:

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

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

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

Ruling excerpts:

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

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

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

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

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

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

Basis for Sanction(s):

Appeal of ALJ decision in CR358.

Arguments:

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

Ruling excerpts:

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

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

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

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

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

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

Basis for Sanction(s):

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

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

Arguments:

Petitioner argues that its practice does not violate the regulation.

Ruling excerpts:

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

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

HCFA properly imposed principal sanctions against Petitioner.

Other cases referenced:

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

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

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

Basis for Sanction(s):

Petitioner intentionally referred its proficiency testing samples.

Arguments:

Petitioner argues that:

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

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

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

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

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

Ruling excerpts:

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

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

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

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

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

Other cases referenced:

Long Medical Laboratory v. HCFA [CR334]

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues that:

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

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

- the referral was made for internal quality control measures;

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

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

Ruling excerpts:

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

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

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

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

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

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

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

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

Basis for Sanction(s):

Petitioner manifested deficiencies that represented an immediate jeopardy.

The plan of correction did not correct the deficiencies.

Arguments:

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

Ruling excerpts:

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

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

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

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

Further disposition:

Decision affirmed on appeal. See DAB1624.

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

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

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

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

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

Basis for Sanction(s):

Laboratory appeal of ALJ decision in CR451.

Arguments:

Petitioner asserted that:

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

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

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

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

Ruling excerpts:

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

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

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

Arguments:

Petitioner contends that it was in compliance with deficiencies.

Ruling excerpts:

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

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

A petitioner must prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with relevant statutory and regulatory provisions. The petitioner, not HCFA, bears the ultimate burden of persuasion. This case is governed by the burden of proof set forth in Hillman.

Other cases referenced:

Hillman Rehabilitation Center [DAB1663]

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

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

Basis for Sanction(s)

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

Arguments

Petitioner argues that:

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

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

Ruling excerpts

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner's asserts that:

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

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

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

Ruling excerpts:

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

The evidence establishes that Petitioner was the CLIA laboratory director.

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

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

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

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

Other cases referenced:

Hillman Rehabilitation Center [CR500] [DAB1663]

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues that:

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

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

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

Ruling excerpts:

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

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

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

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

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

Basis for Sanction(s)

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

Arguments

Petitioner argues that:

- the proficiency tests were performed as required;

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

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

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

Ruling excerpts

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

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

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

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner:

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

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

Ruling excerpts:

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

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

Other cases referenced:

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

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues:

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

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

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

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

Ruling excerpts:

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

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

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

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

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

Other cases referenced:

Hillman Rehabilitation Center [CR500] [DAB1663]

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

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

Basis for Action(s):

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

Arguments:

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

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

Ruling excerpts:

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

Other cases referenced:

Hillman Rehabilitation Center [CR500] [DAB1663]

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

Carlos A. Cervera, M.D., Director, San Fernando Diagnostic Laboratory, Inc. v. HCFA
Docket No. C-99-797

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

Basis for Action(s):

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

Arguments:

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

Ruling excerpts:

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

Appeal of ALJ decision in CR599.

Arguments:

Petitioner argues:

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

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

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

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

Ruling excerpts:

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

The ALJ correctly assigned the burden of proof.

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

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

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

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

Other cases referenced:

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

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

Other cases referenced:

Hillman Rehabilitation Center [DAB1663] [CR500].

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues:

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

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

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

Ruling excerpts:

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

Appeal of ALJ decision in CR632.

Arguments:

Petitioner:

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

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

Ruling excerpts:

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

The right to inspect is unconditional.

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues:

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

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

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

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

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

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

Ruling excerpts:

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

The Fifth Amendment right against self-incrimination is inapplicable.

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

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

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

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

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

Other cases referenced:

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

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues:

- laboratory technician performing PT was not an employee;

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

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

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

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

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

Ruling excerpts:

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

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

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

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

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

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

Other cases referenced:

Long Laboratory v. HCFA [CR344]

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

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner asserts:

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

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

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

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

Ruling excerpts:

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

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

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

[The ALJ] disagrees with the *Blanding* decision to the extent that it supports the proposition that an unlawful "referral" of a testing sample to another laboratory may occur without an actual physical transport of the sample from one laboratory to another. (Ruling reversed by DAB1756.)

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

Other cases referenced:

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

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues:

- there was no intentional referral of proficiency testing samples;

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

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

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

Ruling excerpts:

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

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

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

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

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

Other cases referenced:

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

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

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

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

Basis for Sanction(s):

Appeal of ALJ decision in CR642.

Arguments:

Petitioner:

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

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

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

Ruling excerpts:

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s)

Appeal of ALJ decision in CR688.

Arguments

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

Ruling excerpts

DAB concluded that the challenged FFCLs are 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 Elsenety, M.D., Et. Al. v. HCFA [CR779] Docket No. C-01-218 through C-01-233

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

Basis for Sanction(s):

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

Arguments:

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

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

Petitioners opposed HCFA's motion for summary disposition.

Ruling excerpts:

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

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

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

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

Other cases referenced:

Oakland Medical Group, P.C. [CR688]

United States of America v. Edison Medical Laboratory Service Corporation
[Civil Action No. 01-2872 (KSH)]

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

Basis for Action(s):

Order to show cause and temporary restraining order.

Arguments:

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

Ruling excerpts:

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

Further Disposition:

Consent Decree filed July 6, 2001.

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

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

Basis for Action(s):

Plaintiffs' motion for preliminary injunctive relief.

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

Arguments:

Plaintiff:

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

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

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

Ruling excerpts:

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

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

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

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues that:

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

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

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

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

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

Ruling excerpts:

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

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

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

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

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

Other cases referenced:

Stanley Boykansky, M.D. [CR690] [DAB1756]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1663]
Blanding Urgent Care Center Laboratory [CR438]
Oakland Medical Group [DAB1755]

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

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

Basis for Action(s):

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

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

Arguments:

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

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

Ruling excerpts:

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

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioners argue:

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

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

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

Ruling excerpts:

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

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

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

Appeal of ALJ decision in CR779

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

Arguments:

Petitioners argue that:

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

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

Ruling Excerpts:

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner alleges:

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

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

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

CMS argues that:

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

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

Ruling excerpts:

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

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

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

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

CMS is without authority to impose sanctions against Petitioner.

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner alleges that:

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

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

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

Ruling excerpts:

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

Appeal of ALJ decision in CR805.

Arguments:

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

Ruling Excerpts:

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

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

Other cases referenced:

Ward General Practice Clinic [DAB1624]
Edison Medical Laboratories [DAB1713]
Hillman Rehabilitation Center [DAB1611]
Oakland Medical Group, P.C. [DAB1755]
Stanley Boykansky, M.D. [DAB1756]
Garden City Medical Center [DAB1763]
Evette Elsenety, M.D., et al. [DAB1796]

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner asserts that:

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

- Statement of Deficiencies was procedurally and substantively defective;

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

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

- he is entitled to a hearing;

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

Ruling excerpts:

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

Summary judgment is appropriate in this case.

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

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

Referenced Cases:

Hillman Rehabilitation Center [CR500] [DAB1611]

RNA Laboratories, Inc. and Ter-Zakarian Medical Clinic v. CMS [DAB1820]
Docket No. A-2002-20

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

Basis for Sanction(s):

Appeal of ALJ decision in CR829.

Arguments:

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

Ruling excerpts:

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

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

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

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

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

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

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

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

Other cases referenced:

Garden City Medical Center [DAB1763]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1611]
Everett Rehabilitation and Medical Center [DAB1628]
Melvin C. Murphy, M.D., P.C. [CR590]
Thyroid Specialty Laboratory [CR501]
Oakland Medical Group, P.C. [DAB1755]
Blanding Urgent Care Center Laboratory [CR438]
Boykansky [DAB1756]

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

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

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

The statute does not require evidence of actual physical transport.

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues that:

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

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

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

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

Ruling excerpts:

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

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

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

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

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

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

Other cases referenced:

RNA Laboratories, Inc. and Ter-Zakarian Medical Clinic [CR829]
Eugene R. Pocock, M.D. [CR527]
Sentinel Medical Laboratories, Inc. [DAB1762]
Edward Ming-Che Lai, M.D. [CR848]
Wayne E. Imber, M.D. [CR661] [DAB1740]
Richard A. Fishman, D.O. [CR100]
Serban I. Cociaba, M.D. [CR654]
Morton Markoff, D.O. [CR538]

Alaa Ahmed, M. Sc., Ph.D., (Global Esoteric Reference Labs, Inc.) v. CMS [CR946]
Docket No. C-01-455

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues that:

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

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

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

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

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

Ruling excerpts:

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

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

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

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

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

Other cases referenced:

Long Medical Laboratory [CR334]

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner argues that:

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

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

Ruling excerpts:

CMS' motion for summary judgment is granted.

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

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

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

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

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

Other cases referenced:

Garden City Medical Clinic [DAB1763]
Everett Rehabilitation and Medical Center [DAB1628]
Primary Care Medical Group [CR439]
Long Medical Laboratory [CR 334]
Oakland Medical Group [DAB1755]
Southfield Medical Clinic [CR667]

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

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

Ruling excerpts:

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

Repeated unsuccessful PT performances

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

Failure to submit an acceptable plan of correction

Arguments:

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

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

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

Ruling excerpts:

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

Petitioner alleges:

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

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

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

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

Ruling excerpts:

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

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

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

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

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

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

Other cases referenced:

RNA Laboratory, Inc. [DAB1820]
Ward General Practice Clinic [DAB1624]
Preferred Family Clinic [CR975]
Emil S. Sitto, M.D. [CR935]
Edison Medical Laboratories, Inc. [DAB1713]
Hillman Rehabilitation Center [DAB1611]
Southfield Medical Clinic [CR667]
Stanley Boykansky, M.D. [DAB1756]
Oakland Medical Group [DAB1755]

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

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

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

Basis for Sanction(s):

Appeal of ALJ Decision in CR957.

Arguments:

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

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

Ruling excerpts:

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

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

Ruling excerpts:

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

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

Petitioner had Condition-level deficiencies that posed immediate jeopardy.

Other cases referenced:

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

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

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

Basis for Sanction(s):

Appeal of ALJ Decision in CR946.

Arguments:

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

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

Ruling excerpts:

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

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

Other cases referenced:

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

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

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

Basis for Sanction(s):

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

Arguments:

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

Ruling excerpts:

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

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

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

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

Other cases referenced:

Hospicio San Martin [DAB1554]

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

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

Basis for Sanction(s):

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

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

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

Arguments:

CMS --

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

Petitioner --

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

Ruling excerpts:

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

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

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

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

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

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

Basis for Sanction(s):

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

Arguments:

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

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

Ruling excerpts:

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction:

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

Arguments:

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

Background Information:

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

Ruling Excerpts:

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

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

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

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

Other cases referenced:

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

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

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

Basis for Sanction:

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

Background Information:

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

Arguments:

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

Ruling Excerpts:

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

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

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

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

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

Other cases referenced:

Hillman Rehabilitation Center [DAB1611]
Ward General Practice Clinic [DAB1624]
Beechwood Sanitorium [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 [CR1108] 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)]
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