**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Huntington Beach Clinical Laboratory, Inc.,
Howard Pfupajena, M.D., Director,
(CLIA Number: 05D1080532),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-192

Decision No. CR2490

Date: January 17, 2012

# DECISION

Huntington Beach Clinical Laboratory, Inc. (Huntington or lab) was a California clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a *et seq*. Finding that the lab: 1) misrepresented its annual testing volume; and 2) performed and represented that it was authorized to perform tests that its CLIA certificate did not authorize, the Centers for Medicare and Medicaid Services (CMS) has imposed sanctions against the lab, its owner, and its director – it revoked the lab's CLIA certificate and cancelled its approval to bill the Medicare program.

Neither the lab nor its owner appealed. In a submission, which CMS accepted as an "appeal," lab director Howard Pfupajena, M.D. (Petitioner), does not challenge CMS's findings regarding Huntington's deficiencies but suggests that he should not be sanctioned because he resigned from his position as director before the lab lost its certification.

For the reasons set forth below, I find that, during his tenure as Huntington's director, the lab failed to comply with CLIA requirements, and I therefore sustain the sanctions imposed against Director Pfupajena.

**Background**

To ensure the accuracy and reliability of laboratory tests, and thus the health and safety of those tested, CLIA creates a federal certification process for laboratories that perform clinical diagnostic tests on human specimens. Public Law No. 100-58, *amending* section 353 of the Public Health Service Act, 42 U.S.C. § 263a *et seq.*; *see* H.R. REP. NO. 100-899, at 8, *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829. To be certified, a laboratory must meet requirements set out in the statute and regulations. 42 U.S.C. § 263(a)(f)(1)(E); 42 C.F.R. Part 493. The statute gives the Secretary of Health and Human Services broad enforcement authority, which the Secretary has delegated to CMS. If a laboratory does not comply with the Secretary's rules, CMS may suspend, limit, or revoke its CLIA certificate and/or impose alternative sanctions (directed plan of correction, state monitoring, civil money penalty). 42 C.F.R. § 493.1806.

Here, CMS initially determined that: 1) in applying for CLIA certification, Huntington misrepresented its annual testing volume; 2) Huntington performed and represented that it was authorized to perform tests that its CLIA certificate did not authorize; and 3) Huntington employed a director (Dr. Pfupajena) who was prohibited from owning, operating or directing any laboratory. In a letter dated September 28, 2010, CMS advised the lab, its owner, and Director Pfupajena that it was therefore revoking the lab's CLIA certificate (pursuant to 42 C.F.R. § 493.1840(a)(1), (a)(2), and (a)(3)), and cancelling the lab's approval to receive Medicare payments (pursuant to 42 C.F.R. §§ 493.1808(a) and 493.1842(a)(1). The letter also explained that the CLIA statute prohibits the owner or operator (which includes the director), from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. CMS Ex. 2. The letter then advised the lab of its appeal rights. CMS Ex. 2 at 2.

Neither Huntington nor its owner appealed. On October 1, 2010, however, CMS received a letter from Director Pfupajena, dated August 24, 2010, but postmarked September 28, 2010, in which he requested "reconsideration" of CMS's determination to sanction him.[1] He claimed that he should not have been prohibited from directing

[1] The August 24, 2010 date was obviously a mistake, because the letter refers to CMS's September 3, 2010 warning letter (CMS Ex. 1). In the September 3 letter, CMS warned that it would sanction the lab and explained the reasons. It also offered the recipients ten days from the date of the notice, or until September 13, 2010, in which "to provide evidence as to why these sanctions should not be imposed." CMS Ex. 1. None of the recipients responded within the ten-day period.

Huntington, based on his earlier affiliation with Bixby Clinical Laboratory, because he resigned from his position as Bixby's director prior to that lab's loss of certification. He also maintained that he should not be sanctioned for Huntington's deficiencies because he resigned from his position as Huntington's director in August 2010. CMS Ex. 4.

CMS accepted that Director Pfupajena had resigned as Bixby's director by a written statement dated July 20, 2009, and that the appropriate state agency received notice of his resignation on August 12, 2009. Bixby's actionable conduct apparently occurred after the date of Director Pfupajena's resignation, so CMS removed "prohibition of the director" as a basis for sanctioning Huntington. CMS Ex. 3; CMS Ex. 18 at 6-7 (Jew Decl. ¶ 16).

With respect to Huntington, however, the state agency had no record of Director Pfupajena's resignation. CMS Ex. 3; CMS Ex. 18 at 6 (Jew Decl. ¶ 16). In any event, because the wrongful misrepresentations occurred prior to the date of his purported resignation, CMS advised Director Pfupajena that it would continue to consider him "the responsible director in connection with the [Huntington] sanction action." CMS Ex. 3; CMS Ex. 18 at 6-7 (Jew Decl. ¶ 16).

CMS also advised Director Pfupajena that it would treat his letter as a hearing request and forwarded his letter to the Civil Remedies Division. CMS Ex. 3 at 2-3.

On January 4, 2011, I issued an initial pre-hearing order, directing the parties to file their pre-hearing exchanges, which were to include proposed exhibits, witness lists, witness declarations, and a written brief containing "any argument [the] party intends to make." Initial Pre-hearing Order ¶¶ 1, 7 (January 4, 2011). I directed CMS to file its exchange no later than May 11, 2011, and Petitioner to file its exchange no later than June 10, 2011. The order warned that I could impose sanctions pursuant to section 1128A(c)(4) of the Social Security Act (Act) if a party failed to comply. Initial Pre-Hearing Order ¶ 11.

I subsequently extended the deadlines by two weeks, ordering the filings no later than May 25, 2011 and June 24, 2011.

CMS timely filed its exchange. Petitioner, however, did not file anything and did not ask for an extension of time in which to file.[2] In an order dated July 21, 2011, I directed Petitioner to show cause why his case should not be dismissed for abandonment pursuant to 42 C.F.R. § 498.69(b)(2). In the event that he had not abandoned his exchange, I ordered him to include his pre-hearing exchange with his showing of good cause. Order

[2] By failing to comply with my order, Director Pfupajena interfered with the "speedy" and "orderly" conduct of these proceedings, and could have been sanctioned. Act § 1128A(c)(4)(E); Initial Pre-Hearing Order ¶ 11 (Jan. 4, 2011).

to Show Cause (July 21, 2011). Petitioner responded in a letter dated August 1, 2011, received on August 5. He did not submit a prehearing exchange. He said that he had not abandoned his appeal but needed an additional, indefinite amount of time in which to seek counsel and prepare his defense. CMS objected to any additional extensions of time.

In a ruling dated September 21, 2011, I denied Petitioner's request for extension. My January 4, 2011 order afforded him ample time in which to obtain counsel and prepare his case. That he failed to do so does not constitute good cause. Nevertheless, I declined to dismiss under 42 C.F.R. § 498.69(b)(2), which authorizes dismissal where the party fails to respond to a "show cause" notice with a showing of good cause. Instead, I closed the record and issue this decision on the merits.[3]

CMS has submitted a written brief and twenty exhibits (CMS Exs. 1-20). In the absence of any objection, I admit into evidence CMS Exs. 1-20.

**Discussion**

> *Petitioner is subject to the mandatory two-year prohibition on owning, operating or directing a laboratory, because, during his tenure as Huntington's director, the lab failed to comply with CLIA requirements and its certification was revoked.*[4]

The owner or operator (which includes the director) of any laboratory that has had its CLIA certificate revoked may not own or operate another CLIA-certified lab for two years. 42 U.S.C. § 263a(i)(3); 42 C.F.R. § 493.1840(a)(8).

Here, no one disputes that Huntington violated CLIA rules and is subject to sanction. The lab's January 11, 2010 application for certification, which was signed by Director Pfupajena, said that its annual test volume would be 8,500. CMS Ex. 6 at 3, 4. Based on this representation, CMS imposed a CLIA fee of $1,174 for a compliance survey and $150 for a certificate fee. CMS Ex. 1. Because fees are based on the lab's annual testing volume, the amounts would have been higher had the lab more accurately reported its testing volume. CMS Ex. 1; see 42 C.F.R. § 493.649(a). In fact, Medicare billing data showed that, from February through at least June 2010, the lab billed Medicare for *120,782* tests, more than 14 times the reported volume. CMS Ex. 15; CMS Ex. 18 at 4

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[3] The ALJ need not hold an oral hearing if the affected party concedes all material facts. *Sol Teitelbaum, M.D.*, DAB No. 1849 at 10 (2002) (*citing Glenburn Home*, DAB No. 1806 at 17 (2002)).

[4] My findings of fact/conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

(Jew Decl. ¶ 11); *but see* CMS Ex. 1 (suggesting that the billing continued through August 9, 2010). Huntington did not report the increase. Remarkably, just two individuals – Director Pfupajena and one other employee – supposedly performed all of these tests. CMS Ex. 11; CMS Ex. 12 at 1.

The lab was certified to perform three tests only: urinalysis, endocrinology and toxicology. CMS Ex. 18 at 2 (Jew Decl. ¶ 6). Nevertheless, it billed Medicare for many tests outside these subspecialities. In fact, the lab was not authorized to perform 92% of the tests for which it billed Medicare. CMS Ex. 16; CMS Ex. 18 at 4-5 (Jew Decl. ¶ 12). And it did not report that it had performed tests outside its certificate, which is required by 42 C.F.R. § 493.51(b). CMS Ex. 18 at 3-4 (Jew Decl. ¶ 10).

Petitioner has not challenged any of this. He admits that he became Medical Director in January 2010, which was when the lab applied for CLIA certification, but pleads ignorance regarding the lab's billing activities. He complains that he was unable to contact the lab's owner, even though he "visited the facility and left messages with the receptionist." Finally, he claims that he sent a letter of resignation to the owner's address and to the appropriate state agency in August 2010. CMS Ex. 4.

Thus, by his own admission, as well as CMS's uncontroverted documentation, Director Pfupajena served as Huntington's director from the time it applied for CLIA certification until a few weeks before CMS sent its warning letter (September 3, 2010). CMS Exs. 4, 6, 7, 9, 10, 11, 12.

The lab director provides the lab's "overall management and direction." 42 C.F.R. § 493.1403. He is responsible for the operation and administration of the lab, which includes assuring compliance with applicable regulations. 42 C.F.R. § 493.1407. Director Pfupajena well understood his responsibilities.[5] On January 11, 2010, he signed an attestation in which he agreed to assume "all directorship responsibilities" and confirmed that he understood that, with the lab owner, he would be held responsible for any violations. If, during his tenure as director, violations were found that led to revocation of the lab's CLIA certificate, he acknowledged that, pursuant to the CLIA statute and regulations, he would be prohibited from owning, operating or directing another clinical lab for two years from the date of the revocation. Finally, Petitioner acknowledged that he would "continue to be held responsible as a laboratory director of this laboratory until the day that the California Department of Public Health **receives** a signed statement from me notifying the Department of my resignation or termination." CMS Ex. 9 (emphasis in original).

[5] I note also that, since 1996, Petitioner has served as director of eight other labs. CMS Ex. 18 at 5 (Jew Decl. ¶ 13).

Petitioner concedes that he was Huntington's director until at least August 2010. He claims that he sent his letter of resignation to the state agency at that time. CMS Ex. 4. He has provided no evidence of his resignation, and the state agency denies receiving such a letter. CMS Ex. 18 at 6-7 (Jew Decl. ¶ 16). In any event, he acknowledges that he was director from January through August 2010. Huntington provided the testing volume misrepresentations to CMS in January. CMS Ex. 10. The billing documents for the unauthorized testing show that it occurred between February and at least June 2010, when Petitioner admits he was the director. That he managed to tender a resignation letter a few weeks before CMS sent its first notice, on September 3, does not make him any less accountable for the rule violations that occurred on his watch.

**Conclusion**

During Petitioner's tenure as Huntington's director, the lab failed to comply with CLIA requirements, so CMS has revoked its CLIA certificate and cancelled its approval to bill the Medicare program. Pursuant to 42 U.S.C. section 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), CMS may prohibit Director Pfupajena from owning, operating or directing a laboratory for two years from the date of Huntington's revocation. I sustain its determination to do so.

/s/
Carolyn Cozad Hughes
Administrative Law Judge