Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Center Clinical Laboratory,	DATE: February 15, 1995
Petitioner,	
- v. -	Docket No. C-93-096 Decision No. CR358
Health Care Financing Administration.	

DECISION

This action was brought by Center Clinical Laboratory (Petitioner) to contest the findings made and actions taken by the Health Care Financing Administration (HCFA) to enforce the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The administrative actions at issue ensued from a survey conducted by HCFA's agent under CLIA, the New Jersey Department of Health (State agency), during February and March of 1993. HCFA Exhibits (Ex.) 1, 1a, 1b, 127, 128. HCFA agreed with the State agency that Petitioner failed to meet various conditions of coverage necessary for CLIA certification. HCFA Ex. 127. Between May 27 and June 1, 1993, HCFA imposed various sanctions on what HCFA called a "fast-track" pursuant to its determination that Petitioner posed "immediate jeopardy" to patient health and safety.[1] HCFA Posthearing Brief (Br.) at 8. After

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[1] "Immediate jeopardy" is defined by 42 C.F.R. § 493.2, as follows:

> a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the

(continued...)

deciding to suspend Petitioner's CLIA certificate while imposing an "alternative sanction"[2] and directing Petitioner to submit its list of clients for notice of the sanctions, HCFA then revoked Petitioner's CLIA certificate either on June 1 or June 25 of 1993.[3] HCFA Br. at 2; HCFA Ex. 127, 128. Petitioner timely filed a request for hearing.

During a prehearing conference with the parties, I established one of the issues in this case as "[w]hether the sanctions imposed by HCFA against the laboratory are sanctions authorized by the Act." Order and Notice of Hearing dated October 20, 1993. With respect to the burden of proof in this case, I stated that HCFA "shall have the burden of coming forward with evidence that the sanctions it imposed are authorized." Id. Neither party objected. During hearing,[4] HCFA specifically noted the foregoing issue in questioning a HCFA official. E.g., Tr. 24.

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[1](...continued)
laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Condition level deficiency means "noncompliance with one or more condition level requirements." 42 C.F.R. § 493.2.

[2] As I will explain below, all laboratories are subject to three alternative sanctions authorized by the regulations: 1) a "directed plan of correction;" 2) "state onsite monitoring," or 3) a "civil money penalty." 42 C.F.R. § 493.1806(c). Laboratories that participate in Medicare are subject to an additional alternative sanction, suspension of their Medicare payments. 42 C.F.R. § 493.1807(b).

[3] HCFA states in its posthearing brief that the effective date of the revocation was June 1, 1993. HCFA Br. at 1. HCFA's letter of June 1, 1993 indicated an effective date of June 25, 1993. HCFA Ex. 128.

[4] The transcript of hearing (Tr.) incorrectly designates Leslie A. Weyn as an attorney who appeared on behalf of the Department of Health and Human Services. Tr. 2. Ms. Weyn is a staff attorney with the Departmental Appeals Board of HHS. She was present at the hearing as an assistant to me and did not have any representational role in this case.

For the reasons that follow, I have decided in favor of Petitioner on the issue of whether the sanctions HCFA imposed were authorized by law. I have not decided the other issues raised by the parties, i.e., whether deficiencies existed as alleged by HCFA and whether such deficiencies warrant sanctions for reasons I discuss below, which include Petitioner's closure since May of 1993. The authority issue is dispositive for deciding which party is entitled to the relief sought. My finding that HCFA imposed sanctions that were unauthorized entitles Petitioner to the relief it seeks: restoration of its CLIA certificate. See Petitioner's Posthearing Brief (P. Br.) at 19.

ISSUES AND CONCLUSIONS

All issues resolved in this decision relate to HCFA's authority to impose the following sanctions against Petitioner under the facts of this case:

A. suspending Petitioner's CLIA certificate effective June 1, 1993 (HCFA Ex. 127);

B. imposing the "alternative sanction" of directing Petitioner to provide an "acceptable plan of correction .... prior to June 1st," or have its CLIA certificate revoked (HCFA Ex. 127);

C. requiring Petitioner to submit a list of its clients within 10 days of May 27, 1993, to enable HCFA to send out notices of the sanctions imposed against Petitioner (HCFA Ex. 127);

D. "suspending [Petitioner's] approval to receive Medicare payment for services ....." effective June 1, 1993 (HCFA Ex. 127);

E. revoking Petitioner's CLIA certificate effective either on June 1 or June 25, 1993 (HCFA Br. at 1; HCFA Ex. 128);

F. continuing in effect the "suspension" of Petitioner's approval to receive Medicare payment for services (HCFA Ex. 128).

With respect to HCFA's authority to impose the foregoing sanctions in this case, I have concluded that:

1. HCFA's decision of May 27, 1993 to suspend Petitioner's CLIA certificate effective June 1, 1993, was premature and not in accordance with HCFA's obligations under 42 C.F.R. § 493.1812.

2. HCFA's decision to impose an alternative sanction of directing Petitioner to submit an "acceptable plan of correction . . . prior to June 1st" was improper, and the "alternative sanction" imposed by HCFA was not authorized under the regulations.

3. HCFA's "suspending [Petitioner's] approval to receive Medicare payment for services ...." was an invalidly imposed principal sanction, and HCFA has not imposed a directed portion of a plan of correction within the meaning of the regulations.

4. HCFA's actions of June 1, 1993, purporting to revoke Petitioner's CLIA certificate and cancel Petitioner's approval to receive Medicare payment also exceeded its authority under the regulations.

5. HCFA's actions and omissions in this case do not represent harmless error.

6. It is not necessary or feasible for me to decide at this time whether Petitioner had condition level deficiencies in February through March of 1993.

ANALYSIS OF LAW AND FACTS

I. HCFA's actions on May 27, 1993 exceeded those authorized by the Secretary's regulations.

I will begin my analysis of HCFA's authority to impose the particular sanctions at issue by focusing on the following portions of HCFA's letter dated May 27, 1993:

> You are out of compliance with these conditions as evidenced by the State survey February 18 - March 10, 1993, and subsequent State analysis of your records. The State has recommended to our office that these deficiencies, which result from the pervasive occurrence of management sanctioned fictitious patient test results and fabricated control data, has created a situation of immediate jeopardy to patient health and safety.

> Accordingly, we have determined that it is necessary to apply the principal sanction of suspension of your CLIA registration certificate effective June 1, 1993. In addition, we are also suspending your laboratory's approval to receive Medicare payment for services concurrently with the CLIA suspension. You should . . . provide a list of the names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory during the past year, within ten days of this notice.
>
> You should be aware that 42 C.F.R. 493.1832 provides that your clients should be notified of this action. In addition, as an alternative sanction under this regulation, you are directed to provide an acceptable plan of correction to the cited deficiencies prior to June 1st. Should you fail to provide an acceptable plan of correction your CLIA certification will be finally revoked. [A]ny implementation will be subject to State onsite monitoring.

HCFA Ex. 127.

HCFA's letter purports to notify Petitioner that HCFA has determined that Petitioner's deficiencies pose immediate jeopardy to patients. As a result of this determination, HCFA states that it is imposing four sanctions: (1) suspending Petitioner's CLIA certificate; (2) suspending Petitioner's approval to receive Medicare payments; (3) directing Petitioner to provide a list of its clients within ten days; and (4) directing Petitioner to provide an acceptable plan of correction prior to June 1st. For the reasons discussed below, I conclude that each of these sanctions, at least as applied by HCFA in this case, was unauthorized. As a preliminary matter, I will explain the rights and obligations that the regulations impose on HCFA when it makes a determination of immediate jeopardy.

A. The regulations specify the remedies HCFA may impose on laboratories it determines pose immediate jeopardy.

I do not have jurisdiction to review the merits of HCFA's determination that a laboratory's deficiencies pose immediate jeopardy. 42 C.F.R. § 493.1844(c)(6).

However, I have the authority to review HCFA's imposition of sanctions after it determines immediate jeopardy. See 42 C.F.R. § 493.1844(b)(1), (3).

Subpart R of 42 C.F.R. Part 493 sets forth the policies and procedures that HCFA is to follow to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act. 42 C.F.R. § 493.1800(b)(1). The Secretary has explained by regulation that the enforcement mechanisms set forth in subpart R are intended to protect those served by laboratories, to safeguard the general public against health and safety hazards, as well as "[t]o motivate laboratories to comply with CLIA requirements ...." 42 C.F.R. § 493.1804(a). Therefore, I will analyze the regulatory requirements and HCFA's actions in light of the remedial purpose of protecting public health and safety.

As HCFA was aware, the provisions of 42 C.F.R. § 493.1812 are applicable to cases where HCFA determines that a laboratory's condition level deficiencies pose immediate jeopardy. See, e.g., HCFA Ex. 128; HCFA Br. at 2. This regulation provides HCFA with two principal avenues by which to take action against a laboratory whose condition level deficiencies pose immediate jeopardy: one in an administrative forum and the other in federal court. 42 C.F.R. §§ 493.1812, 1844.

When HCFA chooses the administrative forum to protect the public's health and safety, HCFA assumes the following rights and obligations, pursuant to its immediate jeopardy determination:

> (a) HCFA requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.
>
> (b) If the findings of a revisit survey indicate that a laboratory has not eliminated the jeopardy, HCFA suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. HCFA may later revoke the certificate.

42 C.F.R. § 493.1812(a), (b). As defined by the Secretary's regulation and noted in HCFA's May 27, 1993 letter, the suspension or limitation of a CLIA

certificate constitutes a "principal sanction." 42 C.F.R. § 493.1806(b).[5]

In addition, HCFA may bring suit in federal court to enjoin or restrain the continuation of activities which, in HCFA's view, pose substantial hazards to the public health. 42 C.F.R. §§ 493.1806(d), .1812(c).[6]

In this case, HCFA did not bring any action in federal court against Petitioner, its managers, or its employees after finding immediate jeopardy. Therefore, based on HCFA's contention that it proceeded under 42 C.F.R. § 493.1812, I have compared HCFA's administrative actions to those required by subparts (a) and (b) of the regulation.

The plain language of subsections (a) and (b) of 42 C.F.R. § 493.1812 establishes a sequence of steps which HCFA must pursue in the administrative enforcement process. Specifically, the regulation requires HCFA to give a laboratory reasonable assistance and an opportunity to eliminate the problems which led to HCFA's finding of immediate jeopardy before HCFA formulates a decision on whether to suspend the laboratory's CLIA certificate. This sequence of steps advances the Secretary's interest in public health and safety. HCFA may not immediately suspend a CLIA certificate upon finding immediate jeopardy. If the immediate jeopardy is sufficiently significant to warrant discontinuing the laboratory's activities forthwith, the proper course for HCFA to take is to file suit and seek an injunction or restraining order in court. 42 C.F.R. § 493.1812(c).

Even after HCFA has taken the requisite steps that would permit it to suspend the laboratory's CLIA certificate, this principal sanction may be put into effect "no

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[5] For all laboratories, the revocation of a CLIA certificate is the other principal sanction the Secretary's regulations authorize HCFA to take. 42 C.F.R. § 493.1806(b). For laboratories that participate in Medicare, canceling their approval to receive Medicare payment is an additional principal sanction authorized by the Secretary's regulations. 42 C.F.R. § 493.1807(a).

[6] Criminal sanctions are available as well, whether or not there is immediate jeopardy. An individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined. 42 C.F.R. §§ 493.1800(a)(3)(i), 1806(e).

earlier than 5 days after the date of notice of suspension or limitation." 42 C.F.R. § 493.1812(b). However, there is no prohibition against putting these sanctions into effect after a longer period.

B. HCFA's decision of May 27, 1993 to suspend Petitioner's CLIA certificate effective June 1, 1993 was premature and not in accord with HCFA's obligations.

1. HCFA provided Petitioner with no meaningful opportunity to remedy the immediate jeopardy alleged by HCFA.

In this case, I find as a threshold matter that HCFA lacked the authority to suspend Petitioner's CLIA certificate on May 27, 1993. I have noted that one of the purposes of the regulations is to motivate laboratories to comply with CLIA requirements, so that the public may receive safe and reliable laboratory services. However, Petitioner's suspension, as implemented by HCFA, failed to serve this remedial purpose. This is so because HCFA failed to give Petitioner any meaningful opportunity to remove the alleged jeopardy.

When HCFA determines that a laboratory's deficiencies pose immediate jeopardy, HCFA may not suspend the laboratory's CLIA license until after HCFA has required the laboratory to take immediate action to remove the jeopardy and then found, pursuant to a revisit survey, that the laboratory has not eliminated the jeopardy. 42 C.F.R. § 493.1812(a), (b). I do not read HCFA's letter dated May 27, 1993 as meeting HCFA's obligation to direct Petitioner to take those specific actions that would immediately remove the jeopardy. 42 C.F.R. § 493.1812(a). HCFA's letter proceeded from summarizing the State agency's recommended findings of immediate jeopardy to HCFA's announcing: "Accordingly, we have determined that it is necessary to apply the principal sanction of suspension . . . ." HCFA Ex. 127.[7] HCFA's letter then informed Petitioner that suspension had been imposed and would take effect on June 1, 1993. HCFA Ex.

[7] HCFA itself described its May 27, 1993 letter as having "specified the non-compliant regulations and the conclusion that fictitious patient test results and fabricated control data created a situation of immediate jeopardy to the patient health and safety." HCFA Ex. 128.

127. The contents of the letter are insufficient to meet the remedial purposes of 42 C.F.R. § 493.1812.

HCFA has introduced an undated letter from the State agency to Petitioner, which may or may not have been sent in May of 1993. HCFA Ex. 1b; see Tr. 18. HCFA has not argued that this letter satisfies the requirements of 42 C.F.R. § 493.1812(a). However, had such an argument been made, I would reject it.

This undated letter indicates that a "Statement of Deficiencies (HCFA 2567)" (HCFA Ex. 1 at 1 - 6) prepared by the State agency surveyors also was sent to Petitioner as an enclosure and that the State had made a determination of imminent jeopardy due to fictitious, unsubstantiated, or unreliable patient test results. HCFA Ex. 1b. However, even assuming that the undated letter was sent prior to May 27, 1993 and that HCFA's agent may require Petitioner to take those immediate actions necessary for the removal of imminent jeopardy,[8] the State agency's letter did not tell Petitioner the actions that must be taken by Petitioner to remove the jeopardy. The undated letter merely told Petitioner that, if Petitioner disputed the correctness of the cited deficiencies, Petitioner could forward a "credible allegation of compliance" to HCFA. HCFA Ex. 1b.

The information sent by the State agency and HCFA to Petitioner concerning the immediate jeopardy determination does not obviate the need for HCFA to require Petitioner to remove the jeopardy alleged by HCFA. See 42 C.F.R. § 493.1812(a). HCFA sent Petitioner its letter dated May 27, 1993, and the State agency indicated that it was sending Petitioner the "Statement of Deficiencies (HCFA 2567)" and the "Survey Report" under separate covers.[9] However, the information

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[8] It is HCFA that must require the laboratory to take immediate action to remove the jeopardy and may impose alternative sanctions to help bring about compliance. 42 C.F.R. § 493.1812(a). Unlike other parts of the regulations, section 493.1812 does not state that either HCFA or HCFA's agents may take action. Compare 42 C.F.R. § 493.1812(a) with 42 C.F.R. § 493.1810(a). HCFA's agents are separately defined in the regulations. See 42 C.F.R. § 493.2.

[9] The State's undated letter does not mention that it was enclosing a copy of the more detailed "Survey Report" also prepared by the State surveyors (HCFA Ex. 1

(continued...)

contained in both the "Survey Report" and "Statement of Deficiencies" is at variance with the conclusions summarized by HCFA in its May 27, 1993 explaining its finding of immediate jeopardy.

The findings of the February/March 1993 survey are contained in the "Statement of Deficiencies (HCFA 2567)" and "Survey Report" forwarded to Petitioner by the State agency. In these documents, the State agency noted its conclusion that fictitious urine microscopic results were being reported routinely. HCFA Ex. 1 at 3, 7. However, with respect to whether such activities were known to Petitioner's management, the State surveyors had stated merely: "the director must either have been aware of how those results were obtained . . . or he must have been unaware of how the laboratory was being operated." HCFA Ex. 1 at 3 (emphasis added). With respect to the alleged fabrication of control data, the State agency's survey report informed HCFA: "[E]ither the laboratory's recorded control results were not genuine analytical values or, if they were real values, then the test system was consistently out-of-control." HCFA Ex. 1 at 26 (emphasis added). In its undated letter to Petitioner concerning its recommendations to HCFA, the State agency did not allege any "management sanctioned" improprieties; nor did the State agency allege any fabricated control data as a basis for its immediate jeopardy determination. HCFA Ex. 1b.

In the State's May 25, 1993 letter to notify Petitioner of the State's findings and the imposition of sanctions under State law, the State asserted management involvement in "deceptive practices." HCFA Ex. 114.[10]

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[9](...continued)
at 7 to 34). See HCFA Ex. 1b. However, the State sent a copy of the "Survey Report" with another letter to Petitioner dated May 25, 1993. HCFA Ex. 114.

The State's undated letter concerns the State's involvement with HCFA and the CLIA sanctions. The State's May 25, 1993 letter concerns only the State's findings and its imposition of sanctions under State law.

[10] In this case, the New Jersey Department of Health had a dual role. It acted as HCFA's agent under CLIA, and it took actions on behalf of the State of New Jersey to enforce and implement State laws. I have been referring to the New Jersey Department of Health as the "State agency" when it acted as HCFA's agent. I refer to
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The letter summarized the State of New Jersey's dealings with Petitioner. HCFA Ex. 114. The State noted that the alteration of control data had been observed during the surveys of 1990 and 1991, and that the State had assessed civil monetary penalties against Petitioner for these infractions in 1991. HCFA Ex. 114.

However, HCFA stated to Petitioner in its May 27, 1993 letter that it (HCFA) was using evidence from "the State survey February 18 - March 10, 1993," and that:

> The State has recommended to our office that these deficiencies, which result from the pervasive occurrence of management sanctioned fictitious patient test results and fabricated control data, has created a situation of immediate jeopardy . . . . Accordingly, . . . it is necessary to apply the principal sanction of suspension . . . .

HCFA Ex. 127. HCFA did not purport to have used the results of any earlier survey conducted by the State or for HCFA. Nor did HCFA purport to have taken into consideration the State's prior imposition of sanctions under State law during 1991.

Without doubt, HCFA may draw its own conclusions or adopt opinions that the State agency made known to HCFA but did not share with Petitioner. See HCFA Ex. 1a at 2.[11] However, the information made available to Petitioner on or about May 27, 1993 does not adequately inform Petitioner of the remedial actions that must be taken by Petitioner to remove the jeopardy perceived by HCFA. I trace the cause of HCFA's conduct in this action to the State agency's recommendation that "HCFA take appropriate action to remove that jeopardy," (HCFA Ex. 1a at 2)(emphasis added), by immediately precluding Petitioner's operation and by revoking Petitioner's CLIA certificate (HCFA Ex. 1b). HCFA appears to have accepted and followed the literal terms of those recommendations.

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[10](...continued)
it as "the State" or "the State of New Jersey" when I discuss actions it took on behalf of the State government to enforce the State's rights.

[11] The evidence does not show that the State agency shared with Petitioner the State agency's transmittal memo to HCFA (HCFA Ex. 1a). Moreover, HCFA's conclusions of May 27, 1993 are also not fully consistent with the transmittal report.

Such recommendations were inconsistent with the requirements of the Secretary's regulations, which obligate HCFA to give Petitioner appropriate notice of the necessary remedial actions and entitle Petitioner to a reasonable opportunity to remove the jeopardy before HCFA proceeds to close down Petitioner's operation as a means for removing the jeopardy. See, e.g., 42 C.F.R. §§ 493.1804(a)(3), 1812(a).

I am aware that the State agency believed Petitioner's managers were flouting federal law, as well as the laws of at least two States. For example, the State agency told HCFA in its transmittal report that Petitioner's managers had "irrevocably betrayed the public trust and . . . demonstrated that they are contemptuous of all laboratory laws and regulations," and "much of [Petitioner's] testing was performed in violation of New York State's laboratory laws." HCFA Ex. 1a at 2. Without doubt, the State agency was entitled to convey those opinions to HCFA in May of 1993, and HCFA could reasonably choose to believe the opinions of its agent when, as HCFA acknowledged at hearing, HCFA had had no direct dealings with Petitioner. E.g., Tr. 34 - 35, 38 - 39.[12] However, given the surveyors' comments in the "Survey Report" and "Statement of Deficiencies" that were transmitted to both HCFA and Petitioner (e.g., Tr. 14, 17 - 18, 32, 38 - 39), HCFA should have been aware of the possibility that Petitioner's management may not have known how the deficiencies found in 1993 had occurred or their full extent. Therefore, Petitioner's management may have needed HCFA's assistance to eliminate quickly any resultant jeopardy perceived by HCFA. If HCFA had followed the requirements of 42 C.F.R. § 493.1812 on May

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[12] At hearing, I had the opportunity to evaluate the demeanor of Petitioner's witnesses and to consider whether there was a basis for the State agency's opinion of Petitioner's management. I was not persuaded that Petitioner or its managers were contemptuous of laws and regulations, or that they had irrevocably betrayed the public trust. Nor was I persuaded that the New Jersey Department of Health, had the expertise or authority to determine whether Petitioner was performing tests in violation of New York State's laboratory laws. See HCFA Ex. 1a at 2. In fact, there was no evidence that Petitioner was operating in New York or obliged to follow New York's laboratory laws, even assuming that HCFA or the State of New York had authorized the New Jersey Department of Health to evaluate whether New Jersey laboratories are in compliance with New York laws.

27, 1993, its actions would have accommodated those possibilities and fulfilled the remedial purposes of the law.

I have considered the possibility of construing HCFA's imposition of an "alternative sanction" as HCFA's requirement that Petitioner take very immediate actions ("prior to June 1st") to remove the jeopardy. However, the nature of the "alternative sanction" in this case (i.e., for Petitioner to submit a plan of correction acceptable to HCFA) is so vague and subjective that it defeats the mandate of the regulation that HCFA require immediate action by Petitioner to remove the jeopardy. In addition to having placed Petitioner under an unreasonably short timetable (as discussed below), HCFA's letter did not specify those elements that must be contained in a plan that HCFA would find acceptable. HCFA Ex. 127. As also discussed below, the meaning HCFA has since given to its requirement for an "acceptable plan" is not persuasive, not consistent with other facts in this case, and could not have been anticipated by Petitioner.

In addition, even reading HCFA's May 27, 1993 letter as requiring immediate action by Petitioner to remove imminent jeopardy, the letter goes on to announce HCFA's decision, as of that date, to suspend Petitioner's CLIA certificate effective June 1, 1993, an action which was improper under the regulations. See, e.g., Tr. 39. Contrary to the requirements of 42 C.F.R. § 493.1812, HCFA made its decision to suspend the CLIA certificate before the expiration of the "alternative sanction" and without having made provisions for conducting any revisit survey that may have been warranted, if HCFA had given Petitioner a reasonable opportunity to remedy the alleged jeopardy.[13]

The unique facts in this case especially necessitated HCFA's issuing clear directives to Petitioner on how HCFA expected Petitioner to eliminate the jeopardy that allegedly existed at or about the time of its May 27, 1993 sanction notice. In addition to those discrepancies

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[13] HCFA contends that it would have conducted a revisit survey immediately if it had received an acceptable plan of correction. HCFA Br. at 45. As discussed below, the evidence does not support the existence of any intent on HCFA's part (as of May 27, 1993, when it issued its sanction notice) to obtain an "acceptable plan" from Petitioner or to conduct a resurvey.

already discussed above, I note also that the State of New Jersey had imposed various State sanctions against Petitioner pursuant to State law on May 25, 1993. The State summarily suspended Petitioner's license to operate as of May 25, 1993, it ordered Petitioner to cease and desist from all laboratory operations "effective immediately," and it assessed a fine of $100,000 against Petitioner. HCFA Ex. 114. There is no evidence that Petitioner had a license from another state. Petitioner has been closed since the end of May 1993. E.g., Tr. 935.

The regulations do not permit me to review the merits of HCFA's May 27, 1993 determination of immediate jeopardy. 42 C.F.R. § 493.1844(c)(6). However, the actions taken by the State of New Jersey on May 25, 1993, together with Petitioner's closure a few days thereafter, are intervening events that should have changed the conditions that had previously constituted immediate jeopardy. For example, the effect of the State's cease and desist order or Petitioner's closure should have eliminated the occurrence of those fabricated test results which, prior to May 25, 1993, had allegedly posed immediate jeopardy.

If HCFA concluded otherwise, I cannot disturb that conclusion. However, it behooves HCFA to explain the nature of the immediate jeopardy it perceived after the State of New Jersey had suspended Petitioner's license and placed it under a cease and desist order, and Petitioner had closed its operations. It behooves HCFA also to explain by what means it expected Petitioner to eliminate any immediate jeopardy perceived by HCFA when Petitioner was unable to operate as a laboratory in New Jersey, was not operating as a laboratory in New Jersey, and did not appear to have a license to operate as a laboratory elsewhere. Since the regulation contemplates the possibility of a revisit survey for HCFA to verify the elimination of the jeopardy (assuming that HCFA had truly discerned some immediate jeopardy that remained to be eliminated after May 25, 1993 and gave Petitioner the opportunity to remedy it), HCFA also should have explained how it could have resurveyed a laboratory to ascertain compliance when that laboratory could not operate and had closed. See 42 C.F.R. § 493.1812(b). No such explanation was made in HCFA's notice letters to Petitioner or in the proceedings before me. Under the Secretary's regulations, a determination of immediate jeopardy does not serve as an excuse for revoking a laboratory's CLIA certificate, as indicated by HCFA's actions in this case.

2. HCFA failed to adhere to the time requirements specified in the Secretary's regulation, and Petitioner's history does not excuse HCFA's omissions.

HCFA has failed also to comply with the regulatory requirement that HCFA "suspends ... the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension . . . ." 42 C.F.R. § 493.1812(b) (emphasis added). The regulation does not state that HCFA may place the sanction into effect on the fifth day after the date of notice. I read the words as meaning that the sanction may go into effect only when five full days have elapsed after the date of notice. Here, there are only four full days between the date of HCFA's notice letter (May 27, 1993) and the effective date of suspension (June 1, 1993).

HCFA argues that the five day limitation of 42 C.F.R. § 493.1810(c)(2)(i) authorized HCFA to take swift action. HCFA Br. at 43. However, I note that 42 C.F.R. § 493.1810 is titled "[i]mposition and lifting of alternative sanctions." This regulation does not pertain to the imposition of principal sanctions such as the suspension of Petitioner's CLIA certificate. The swiftness of HCFA's actions cannot be contrary to the Secretary's regulation that is applicable to the course of action HCFA has chosen (e.g., imposing the principal administrative sanction of suspension, as opposed to seeking a temporary restraining order in court).

HCFA contends that Petitioner had "a history back in 1990 and 1991 of deficiencies" relating to fictitious reporting of data. Tr. 8. According to HCFA, Petitioner had several years of notice and warnings to stop reporting fictitious test results and fabricating control data. HCFA Br. at 49. HCFA claims also to have given Petitioner "three opportunities" (i.e., three surveys) before HCFA decided that Petitioner was no longer trustworthy. Tr. 8. However, I find that Petitioner's history does not justify HCFA's imposing sanctions prematurely.

The regulation HCFA applied against Petitioner was 42 C.F.R. § 493.1812 (e.g., HCFA Br. at 2), which did not take effect until February 28, 1992. 57 Fed. Reg. 7237 (1992). Even if the regulation could be applied retrospectively to sanction Petitioner for the results of the 1990 and 1991 surveys, the evidence does not establish that any notice of immediate jeopardy was issued to Petitioner pursuant to the 1990 or 1991

surveys. Nor does the evidence establish that HCFA had required the laboratory to take immediate action to remove any immediate jeopardy that may have resulted from the 1990 or 1991 deficiencies.[14]

In addition, HCFA's letter dated May 27, 1993 referred only to the February/March 1993 survey and the conclusions based on that survey. HCFA Ex. 127. HCFA did not claim to have reviewed any Statement of Deficiencies or Survey Report for the 1990 or 1991 surveys when it decided to impose sanctions on May 27, 1993. HCFA's official testified that, in order to make the decisions reflected in its letter of May 27, 1993, HCFA had reviewed four documents it received from the State agency: the transmittal form and attachment (HCFA Ex. 1a), the Statement of Deficiencies (HCFA Ex. 1 at 1 to 6), the surveyors' narrative report (HCFA Ex. 1 at 7 to 34), and an undated letter advising Petitioner of the State agency's recommendations to HCFA (HCFA Ex. 1b). Tr. 14 - 18. HCFA did not conduct an independent survey of Petitioner at any time, but a professional component of HCFA did evaluate the contents of the above-mentioned four documents. Tr. 34 - 35, 38 - 39.

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[14] On September 24, 1990, the State surveyed Petitioner to ascertain whether State and federal requirements were being met. HCFA Ex. 107. The State notified Petitioner that recurrence of the deficiencies found during the September 1990 survey (i.e., unsubstantiated or altered test results) would lead to adverse State licensure action, the imposition of financial penalties, and a determination that the laboratory was not in compliance with the Condition of Participation for providers of Medicare laboratory services. HCFA Ex. 107.

In January 1991, the State resurveyed Petitioner and concluded that Petitioner was altering control and patient test values. HCFA Ex. 110. Based on this survey, by notice dated February 21, 1991, the State sought to impose only State sanctions against Petitioner. HCFA Ex. 110. At an informal hearing before the State, the State and Petitioner reached an agreement; Petitioner waived its right to a formal hearing and agreed to pay, in installments, the $8,000 penalty assessed under State law. HCFA Ex. 110 - 13. Pursuant to the January 1991 survey, the State did not recommend that HCFA impose sanctions, and HCFA took no action against Petitioner.

HCFA sent no notice to Petitioner referencing the results of these two surveys.

Therefore, even though the survey conducted in 1993 was the third survey of Petitioner and might even be termed a "resurvey" due to requirements of the CLIA laws and the State agency's allocation of its resources,[15] the 1993 survey was not done in the context of 42 C.F.R. § 493.1812(b). In May of 1993, HCFA was not attempting to sanction Petitioner for the outcome of the 1990 and 1991 surveys. The Petitioner's history does not make valid HCFA's decision to summarily suspend Petitioner's CLIA certificate on May 27, 1993. For this reason, and for the reasons discussed above, HCFA's imposition of the principal sanction of suspension of Petitioner's CLIA certificate was unauthorized and premature.

C. HCFA's decision to impose the alternative sanction of directing Petitioner to submit an "acceptable plan of correction . . . prior to June 1st" was improper, and the "alternative sanction" imposed by HCFA was unauthorized.

1. HCFA lacked authority to impose any alternative sanction in the manner it did on May 27, 1993.

An alternative sanction may be imposed in lieu of, or in addition to, a principal sanction. 42 C.F.R. § 493.1806(c). In this case, HCFA imposed what it styled

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[15] According to testimony at the hearing, the CLIA laws require that laboratories be inspected at least once every two years. Tr. 53. Several months prior to February of 1993, HCFA sent out a letter to state agencies asking that priority be given to surveying various types of laboratories, including those that had been found out of compliance with conditions of participation in CLIA. Tr. 14. Gerda Duffy, the surveyor in charge of the team that surveyed Petitioner during February and March of 1993, testified to the shortage of staff (three people in addition to herself) to conduct CLIA inspections of the approximately 100 laboratories in New Jersey. Tr. 49, 53. As a result of the shortage of staff, she and her department use the priority instructions issued by HCFA. Tr. 54 - 55. Ms. Duffy claimed to have known of Petitioner's compliance history when the New Jersey Department of Health decided to survey Petitioner in the winter of 1993. Tr. 55.

an "alternative sanction" in addition to those principal sanctions it imposed. HCFA Ex. 127.[16]

However, just as HCFA's imposition of the principal sanction of suspension was unauthorized, HCFA's attempt to impose alternative sanctions was similarly flawed. Even though HCFA may use an alternative sanction to bring about compliance in the case of immediate jeopardy, HCFA may not impose any alternative sanction immediately upon finding imminent jeopardy. See 42 C.F.R. §§ 493.1810, 1812. Before deciding to impose any alternative sanction, HCFA has an obligation to notify the laboratory of HCFA's proposal to impose it, permit the laboratory an opportunity to respond, and acknowledge the receipt of any response provided by the laboratory. 42 C.F.R. § 493.1810(a) - (c); see also, 42 C.F.R. § 493.1832(b)(1)(i).

As applicable to this case, 42 C.F.R. § 493.1810 ([i]mposition and lifting of alternative sanctions) required HCFA to issue two distinct types of notices to Petitioner. Subsection (a) required HCFA to issue a "notice of noncompliance and of proposed [alternative] sanction"; subsection (c) required HCFA to issue a "notice of imposition of [alternative] sanction." [17] There are non-duplicative requirements specified in each of these subsections for the timing and contents of these two different types of notices; both must be sent out even if immediate jeopardy is involved.

To the extent that the notice requirements for imposing an alternative sanction may seem cumbersome in the context of an immediate jeopardy situation, I note that HCFA is not required to impose an alternative sanction to redress immediate jeopardy. 42 C.F.R. § 493.1812. HCFA must require the laboratory to take immediate action to remove the jeopardy; however, HCFA may impose an alternative sanction to help bring the laboratory into compliance. 42 C.F.R. § 493.1812(a). Therefore, if HCFA wishes to use an alternative sanction in an immediate jeopardy case, it also must adhere to the process and

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[16] I discuss, in subpart D, below, my reasons for having concluded that HCFA did not mean to say an "alternative to a sanction" when it used the term "alternative sanction" in its letter of May 27, 1993.

[17] Since the regulation is titled "[i]mposition and lifting of alternative sanction," I construe its subparts as dealing only with alternative sanctions.

purposes specified in the regulations applicable to alternative sanctions.

In a notice of noncompliance and of proposed alternative sanction, HCFA or its agent must state the rationale for the proposed alternative sanction and inform the laboratory that it has at least 10 days to respond to the notice. 42 C.F.R. § 493.1810(a), (b). Even when HCFA finds immediate jeopardy and wishes to impose an alternative sanction, there exists no regulatory authority for HCFA to dispense with notifying a laboratory of HCFA's finding of noncompliance and of the proposed sanction, as such notice is required by 42 C.F.R. § 493.1810(a). Nor is there any regulation authorizing HCFA to shorten or eliminate this minimum 10-day notice and response period for any reason when HCFA sends out its notice of noncompliance and of proposed sanction.

Assuming that HCFA has complied with the regulatory requirements for issuing a notice of noncompliance and of proposed alternative sanction, HCFA (not its agent) may then send out a notice of imposition of alternative sanction, which must contain, inter alia, written acknowledgement of any evidence or information the laboratory may have sent, along with the authority and rationale for the imposed sanction. 42 C.F.R. § 493.1810(c). It is the notice of the imposition of an alternative sanction (not the notice of noncompliance and of proposed alternative sanction) that HCFA must provide "at least 5 days before the effective date of the sanction" if HCFA finds immediate jeopardy. 42 C.F.R. § 493.1810(c)(2)(i). In the absence of immediate jeopardy, HCFA would be obligated to provide its notice of imposition of sanction at least 15 days before the effective date of the alternative sanction. 42 C.F.R. § 493.1810(c)(2)(ii).

In this case, HCFA failed to send out a notice of noncompliance and of proposed alternative sanction. HCFA also did not provide Petitioner with a minimum of 10 days to respond to such a notice. Instead, HCFA notified Petitioner of the noncompliance in the same May 27, 1993 letter that imposed an "alternative sanction." Even in imposing an "alternative sanction" in its May 27, 1993 letter, HCFA failed to give Petitioner notice "<u>at least 5</u> days <u>before</u> the effective date of sanction," June 1, 1993. 42 C.F.R. § 493.1810(c)(2)(i) (emphasis added); HCFA Ex. 127. The words used in the regulation cannot be read as authorizing HCFA to impose an "alternative sanction" that takes effect on the day of the notice

letter and lasts less than five days thereafter. HCFA Ex. 127 (see reference to "prior to June 1st").

Also, the State agency's undated letter to Petitioner does not satisfy the notice requirements of 42 C.F.R. § 493.1810. See HCFA Ex. 1b. First, HCFA's agent may give notice of the noncompliance and any alternative sanction it proposes against a laboratory; but HCFA itself must give written notice of HCFA's decision to impose an alternative sanction. 42 C.F.R. § 493.1810(a), (c). Therefore, the State's undated letter cannot be construed as a written notice of HCFA's decision to impose the "alternative sanction" at issue.

Next, with respect to the issue of whether the State's undated letter may constitute a valid notice of noncompliance and of proposed alternative sanction, there are several problems which preclude the letter from meeting the requirements of 42 C.F.R. § 493.1810(a). As already noted, notice of noncompliance and of proposed alternative sanction must precede the notice of imposition of alternative sanction. There is no proof in this case that the undated letter was sent out or received in advance of HCFA's May 27, 1993 decision to impose an alternative sanction that same day. See, e.g., Tr. 18.

Also, the State's undated letter does not inform Petitioner that the State agency, as HCFA's agent, is proposing to impose any alternative sanctions against Petitioner. Instead, the undated letter summarily asserts that the State agency has recommended that HCFA take "[i]mmediate action to preclude continued operation of the laboratory" and revoke Petitioner's CLIA certificate. HCFA Ex. 1b. Neither revocation nor the preclusion of continued operation is an alternative sanction, and neither is a sanction that can help bring Petitioner into compliance with the CLIA requirements. See 42 C.F.R. §§ 493.1806(c), 1807(b), and 1812(a). The undated letter also contains no projected effective date or duration of any proposed sanction, as required by 42 C.F.R. § 493.1810(a)(4). The undated letter from the State to Petitioner was not a notice of noncompliance and of proposed alternative sanction within the meaning of 42 C.F.R. § 493.1810(a).

This undated letter does not notify Petitioner that Petitioner has a minimum of 10 days to respond under 42 C.F.R. § 493.1810(a)(6). More importantly, even if the undated letter had been sent to Petitioner at the earliest possible date and contained something that could be considered a proposal to impose an alternative

sanction, this undated letter would not have provided Petitioner with the required 10 days to respond. Because the State agency did not send its survey findings and recommendations to HCFA prior to May 21, 1993 (HCFA Ex. 1a; Tr. 14, 18), the State's undated letter to Petitioner referencing those findings and recommendations to HCFA also could not have been sent before May 21, 1993. By May 27, 1993, HCFA had already made its decision to impose the "alternative sanction." HCFA Ex. 127. Therefore, even if the facts were construed in the best light possible for HCFA, Petitioner was still deprived of the 10 days to respond to any finding of noncompliance or proposed alternative sanction that may have been contained in the State's undated letter. 42 C.F.R. § 493.1810(a)(6), (b).

For all of the foregoing reasons, I conclude that on May 27, 1993, HCFA was without authority to put into effect what it styled an "alternative sanction."

2. The time limit imposed by HCFA in its "alternative sanction" was not intended to help bring Petitioner into compliance.

Deferring my discussion of the legitimacy of HCFA's "alternative sanction" in this case, I will discuss at this juncture the function served by HCFA's requiring Petitioner to submit an "acceptable plan of correction" prior to June 1, 1993.

The regulations permit HCFA to impose an alternative sanction "to help bring the laboratory into compliance." 42 C.F.R. § 493.1812(a). An alternative sanction continues until the earlier of either the laboratory's correcting all condition level deficiencies, or the effective date of HCFA's suspension, limitation, or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1810(d). The duration of an alternative sanction is subject to adjustment by HCFA, because it is dependent on the effective date of any suspension or other principal sanction HCFA imposes.

The chronology of events in this case does not permit the inference that HCFA was using its "alternative sanction" to achieve the goal specified by 42 C.F.R. § 493.1812(a). I note by way of example that the "alternative sanction" imposed by HCFA on May 27, 1993 referenced a deadline of "prior to June 1st" while the suspension HCFA had already decided to impose was scheduled to take effect immediately after the deadline, on June 1st. In addition to the previously discussed problems with the State's

undated letter and enclosure to Petitioner, there was also no evidence showing how or when the letter dated May 27, 1993 from HCFA's regional office in New York City was delivered to Petitioner's address in New Jersey, or whether it was delivered in sufficient time for Petitioner to have provided HCFA with anything prior to June 1, 1993. This is especially problematic when three of the four days permitted by the terms of HCFA's letter had been taken up by an intervening Saturday (May 29), Sunday (May 30), and legal holiday (Memorial Day, May 31). See HCFA Br. at 46.

Even if HCFA's May 27, 1993 letter had been hand-delivered to Petitioner's address on the same day, the "alternative sanction" imposed by HCFA was only in effect for less than five days. See 42 C.F.R. § 493.1810(d)(2). By providing Petitioner with less than five days to receive and act on HCFA's requirements under the "alternative sanction," HCFA was not using the "alternative sanction" to help Petitioner achieve compliance as required by 42 C.F.R. § 493.1812(a). The totality of facts discussed herein leaves little doubt that HCFA knew Petitioner would have no realistic chance to provide HCFA with an "acceptable plan of correction" prior to June 1, 1993. HCFA was using the "alternative sanction" to "preclude [Petitioner's] continued operation," as recommended by the State. HCFA Ex. 1b.

I find disingenuous HCFA's arguments that "[t]he enforcement regulations allow five days to correct immediate jeopardy situations without regard to holidays or weekends," (HCFA Br. at 46), and "[t]he regulations prescribe that, when immediate jeopardy exists, HCFA may require the laboratory to take immediate action to remove the jeopardy within five days from HCFA's notice." HCFA Br. at 43 (emphasis original). First, HCFA's letter did not even provide Petitioner with the five days HCFA now asserts the regulations prescribe. (May 27 to "prior to June 1" does not equal five days.) Also, it makes no sense for HCFA to think that Petitioner could have remedied any immediate jeopardy during those days when HCFA's notice letter was in transit and before Petitioner learned of HCFA's determinations or requirements. The State agency surveyors did not conduct what is commonly called an "exit conference" with Petitioner at the close of the February/March, 1993 survey; nor had they otherwise informally explained their conclusions to

Petitioner. HCFA Br. at 48.[18] In addition, no regulation specifies that immediate jeopardy must be eliminated by a laboratory within five days of the day a notice letter is dated. Nor do the regulations specify any deadline that must be imposed by HCFA when it requires immediate remedial action.

The regulation identified by HCFA to justify its actions requires a minimum of five full days between the date of the notice of imposed sanction and the effective date of the sanction. See HCFA Br. at 43 (citing 42 C.F.R. § 493.1810(c)(2)). This regulation does not authorize HCFA to require the submission of an "acceptable plan" in less than five days in this case. None of the Secretary's regulations means that, whenever HCFA sends out a notice identifying the sanctions that HCFA has decided to impose due to its determination of immediate jeopardy, HCFA then acquires the authority to set a deadline of less than five days for a laboratory to remove the immediate jeopardy. HCFA has the authority to set a deadline for a laboratory to eliminate immediate jeopardy and to bring itself into compliance. E.g., 42 C.F.R. § 493.1812(a). However, the deadline set by HCFA must be consistent with the remedial purposes of the law and appropriate to the circumstances of each case.

I have already noted that, on May 25, 1993, the State of New Jersey had summarily suspended Petitioner's license and ordered Petitioner to cease and desist from all

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[18] HCFA argues that the regulations do not require an "exit conference," that the lead surveyor had made herself available to answer questions from Petitioner's Director before the State sent its Statement of Deficiencies to Petitioner, and that Petitioner had received several years of notice and warning (i.e., since the 1990 survey) to stop creating fictitious results and data. HCFA Br. at 48 - 49. HCFA's arguments still raise the question of the reasonableness of HCFA's actions. For example, it does not seem reasonable to set a deadline of less than five days for an "acceptable plan" if HCFA were aware that the State agency had chosen not to conduct an "exit conference" for the 1993 conference and Petitioner's Director had chosen not to discuss the deficiencies prior to Petitioner's receiving written notice of them. Nor does it seem reasonable for HCFA to expect Petitioner to know (for purposes of submitting an "acceptable plan" prior to June 1st) how immediate jeopardy was created in 1993 by the same alleged deficiencies that apparently had not created immediate jeopardy in 1990 or 1991.

laboratory operations immediately, and Petitioner closed at the end of May 1993. HCFA has not identified any federal interest that was being served or protected by HCFA's imposing the "alternative sanction" at issue on May 27, 1993 and setting a deadline of "prior to June 1," after the State had already imposed its own sanctions against Petitioner. Therefore, even though HCFA has the discretion to set deadlines to bring about compliance and eliminate immediate jeopardy, HCFA has failed to exercise its discretion properly in this case.

3. HCFA has not provided a satisfactory explanation of what plan, if submitted prior to June 1, 1993, would have constituted an "acceptable plan of correction."

HCFA's May 27, 1993 letter stated that, under the "alternative sanction" imposed by HCFA, Petitioner should submit an "acceptable plan of correction" prior to June 1st for the State's review, and any implementation of that plan would be subject to onsite monitoring by the State agency. HCFA Ex. 127. Given the State of New Jersey's summary suspension of Petitioner's license on May 25, 1993 and Petitioner's obligation to comply immediately with the State's cease and desist order of the same date (HCFA Ex. 114), I am unable to imagine the nature of any plan of correction that Petitioner could have formulated and implemented, with onsite monitoring by the State agency, on or after May 27, 1993. HCFA has never satisfactorily defined an "acceptable plan of correction," as that term was used in its May 27, 1993 letter.

The regulations do not use the term "acceptable plan of correction" in the context of actions required when condition level deficiencies exist at a laboratory, as HCFA alleged was the case here. Instead, according to the Secretary's regulation:

> If a laboratory has deficiencies, that are not at the condition level, the following rules apply:
>
> > (a) Initial action. The laboratory must submit a plan of correction that is acceptable to HCFA in content and time frames.

42 C.F.R. § 493.1816 (emphasis added). Thus, HCFA's reference to an "acceptable plan of correction" in its May 27, 1993 letter is at least inconsistent with its

assertions that Petitioner's deficiencies were at the condition level and caused immediate jeopardy.

HCFA attempted to establish at hearing that an "acceptable plan of correction" is the equivalent of, or must include, "a credible allegation of compliance." HCFA's May 27, 1993 letter stated that Petitioner should submit an "acceptable plan of correction" for review by the State. HCFA Ex. 127. However, the official testifying for HCFA at hearing, Dudley Lamming, stated that "acceptable" meant acceptable to Annemarie Schmidt, his supervisor at HCFA and the person who signed the notice letters on HCFA's behalf. Tr. 39 - 40. Even though Mr. Lamming did not claim to have made any of the decisions at issue on HCFA's behalf (See Tr. 39 - 40), I must consider his explanations of what might have been construed as an "acceptable plan" by HCFA because HCFA did not call Ms. Schmidt to testify.

Mr. Lamming merged the concept of "a credible allegation of compliance" with the "acceptable plan of correction" required by HCFA's May 27, 1993 letter. He said, for example, that HCFA gave Petitioner time to "come in with a credible plan of compliance" (Tr. 39) and that Petitioner's alternative to a hearing was to provide HCFA with "an acceptable credible allegation of compliance" (Tr. 44). A "credible allegation of compliance," as explained by Mr. Lamming and as defined by regulation, must be made by a representative of a laboratory that has a history of maintaining a commitment to compliance and of taking corrective action when required. Tr. 19; 42 C.F.R. § 493.2. Also, according to Mr. Lamming, none of Petitioner's responses were credible and acceptable to HCFA because none contained any admission of the deficiencies found by HCFA. See Tr. 22 - 23, 32, 46 - 47. He especially noted that even Petitioner's last letter to HCFA's Regional Office (i.e., Petitioner's request for hearing dated June 15, 1993) could not be considered an acceptable or credible plan of correction because it lacked an admission of the deficiencies.[19] Tr. 22 - 23, 47.

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[19] I conclude that HCFA introduced Mr. Lamming's testimony analyzing Petitioner's subsequently filed request for hearing as a possible "plan of correction" because HCFA is aware of the problems associated with writing Petitioner a letter on May 27, 1993 to require a response "prior to June 1st." Mr. Lamming's testimony concerning the hearing request was elicited by HCFA without even an allegation that the responsible decision-maker, Annemarie Schmidt, had undertaken the analysis described by Mr. Lamming.

HCFA's efforts to equate "acceptable plan of correction" with an admission of deficiencies and a "credible allegation of compliance" further underscore that HCFA knew or should have known that it was imposing conditions with which Petitioner could not meaningfully comply. First of all, Petitioner had received instructions from the State agency which conflicted with HCFA's position that a credible allegation of compliance must contain an admission of the alleged deficiencies. The State agency's undated letter to Petitioner indicates that "a credible allegation of compliance" should be used to challenge the alleged deficiencies:

> If you believe that the cited deficiencies are not substantially correct, it is your responsibility to contact the federal regional office (RO) with a credible allegation of compliance. The RO will advise you of the sanctions to be imposed and/or the enforcement actions to be taken. At that time you will also be notified of your appeal rights.

HCFA Ex. 1b (emphasis added).

Moreover, the State agency believed that Petitioner had a poor and deteriorated compliance record, and Mr. Lamming stated the same conclusions in his testimony for HCFA. E.g., Tr. 23, 47; HCFA Ex. 110 and 114. If an "acceptable plan of correction" were "a credible allegation of compliance" or must contain "a credible allegation of compliance," then the opinions of HCFA and the State agency that Petitioner's compliance record was poor and deteriorated would have automatically precluded their accepting any plan submitted by Petitioner between May 27 and 31, 1993. See 42 C.F.R. § 493.2. In addition, the regulations provide that "a credible allegation of compliance" must be "realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation." 42 C.F.R. § 493.2. As noted above, there was no exit interview conducted after the February/ March 1993 survey, and at all times since May 25, 1993, Petitioner has been unable to operate due to the sanctions imposed under New Jersey law. Under the facts of this case, no plan formulated by Petitioner after receipt of HCFA's May 27, 1993 letter could have satisfied the "realistic" and "possible" elements of a "credible allegation of compliance." There was no legitimate reason for HCFA to require Petitioner to submit a plan of correction that HCFA would have to reject if HCFA were incorporating the requirements of "a credible allegation of compliance," as it alleged.

Even more importantly, under the regulations, a "credible allegation of compliance" serves to lift an alternative sanction already imposed. 42 C.F.R. § 493.1810(e)(2). Thus, by definition, a "credible allegation of compliance" or its equivalent cannot itself be an "alternative sanction." Therefore, I reject HCFA's ex post facto definition of its "alternative sanction" for this reason as well.

I also find unpersuasive HCFA's use of Petitioner's hearing request as evidence that Petitioner has remained unwilling to provide an "acceptable plan of correction." Petitioner filed the hearing request after the expiration of HCFA's unreasonably short deadline for submitting a plan of correction and after all sanctions had been imposed by HCFA. HCFA's own letters instructed Petitioner that its request for hearing should specify challenges to HCFA's findings. See HCFA Ex. 127, 128. Therefore, the absence of any plenary admissions of wrongdoing in Petitioner's July 15, 1993 request for hearing does not indicate that Petitioner was unwilling to prepare a plan acceptable to HCFA, if HCFA had provided reasonable advance notice and clearer directives concerning the contents of the plan it wanted from Petitioner. In addition, Mr. Lamming was questioned during hearing about Petitioner's more recent offer to do whatever the State agency wanted it to do and to have as many inspections made as the State agency wished; yet, Mr. Lamming's response was that HCFA's knowledge of such offers would not have necessarily made any difference in deciding that Petitioner never submitted an "acceptable" plan. Tr. 31 - 32; see also P. Ex. 24.

D. HCFA has not imposed an "alternative sanction" authorized by law.

Even though HCFA did not admit to having made any errors in this case, I have considered the HCFA may have meant to offer Petitioner the opportunity to submit an "acceptable plan of correction . . . prior to June 1st" as an alternative to a sanction, but it mistyped the foregoing phrase as an "alternative sanction" in its May 27, 1993 letter. However, HCFA cited 42 C.F.R. § 493.1832 in the sentence immediately preceding its statement,

> In addition, as an alternative sanction under this regulation, you are directed to provide an acceptable plan of correction to the cited deficiencies prior to June 1st.

HCFA Ex. 127. The regulation cited by HCFA in its May 27, 1993 letter deals with imposing a directed plan of correction and a directed portion of a plan of correction, which are alternative sanctions. Because HCFA has indicated its awareness of alternative sanctions in citing 42 C.F.R. § 493.1832, I do not find that HCFA had mistyped "an alternative to sanction" as "an alternative sanction." I conclude that HCFA meant to require the submission of an "acceptable plan of correction . . . prior to June 1st" as an "alternative sanction."

Even though I am without power to modify HCFA's choice of alternative sanctions, I have authority to decide whether a sanction imposed by HCFA was in fact an "alternative sanction" that HCFA had the discretion to impose. 42 C.F.R. § 493.1844(b)(3), (c)(4). Moreover, as discussed elsewhere in this decision, whether providing an "acceptable plan of correction . . . . prior to June 1st" is an authorized alternative sanction has ramifications for the legitimacy of other sanctions also imposed by HCFA. The facts before me establish that HCFA's "alternative sanction" was not authorized by law.

"Alternative sanction" is synonymous with the term "intermediate sanction" as used in section 1846 of the Social Security Act. 42 C.F.R. § 493.2. Section 1864 defines an intermediate sanction as a sanction that does not exceed one year and may be used by the Secretary in lieu of canceling immediately the clinical laboratory's approval to receive Medicare payments. Section 1846(a). The Act directed the Secretary to develop and implement a range of intermediate sanctions. Section 1846(b)(1). Accordingly, the regulations promulgated by the Secretary define "alternative sanctions" to include:

> (1) a directed plan of correction as set forth at 42 C.F.R. § 493.1832, and
>
> (2) state on-site monitoring as set forth at 42 C.F.R. § 493.1863.

42 C.F.R. §§ 493.1806(c).[20] HCFA's actions in this case do not fall within the definition of either of these alternative sanctions.

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[20] HCFA's requirement for the submission of an "acceptable plan of correction" prior to June 1, 1993, bears no resemblance to the other alternative sanctions authorized by law (i.e. civil monetary penalties and the suspension of Medicare payments).

Even though HCFA's "alternative sanction" in this case directs Petitioner to take an action within a specific time frame, I conclude that HCFA's requirement is not a directed plan of correction. See 42 C.F.R. § 493.1832. To impose a directed plan of correction, HCFA must:

> (i) [give] the laboratory prior notice of the sanction and opportunity to respond in accordance with 42 C.F.R. § 493.1810;
>
> (ii) [direct] the laboratory to take specific corrective action within specific time frames in order to achieve compliance.

42 C.F.R. § 493.1832(b)(1). These requirements were not satisfied by HCFA in this case. HCFA gave no notice of the sanction and no opportunity for Petitioner to respond in accordance with 42 C.F.R. § 493.1810. Placing the onus on Petitioner to submit a plan of correction prior to June 1, 1993 that would be acceptable to HCFA does not satisfy the requirement, under 42 C.F.R. § 493.1832(b)(1)(ii), that HCFA direct the laboratory to take specific corrective action.

If HCFA had intended to impose a directed plan of correction under 42 C.F.R. § 493.1832, HCFA failed also to apply the following relevant provisions of the regulation pertaining to a directed plan of correction:

> (c) Duration of directed plan of correction
> If HCFA imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:
>
> > (1) HCFA cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of HCFA's intent to suspend, limit, or revoke the laboratory's CLIA certificate.
> >
> > (2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate [becomes effective].

42 C.F.R. § 493.1832(c). With respect to the duration or termination of any directed plan of correction, 42 C.F.R. § 493.1934(c) is consistent with 42 C.F.R. § 493.1812 in

also not permitting HCFA to decide on suspending Petitioner's CLIA certificate on the same day that HCFA imposes a directed plan of correction.

HCFA's official, Mr. Lamming, testified that it was unacceptable to require the State agency or HCFA to tell Petitioner what to do as a plan of correction. See Tr. 31 - 32. This testimony reinforces my conclusion that HCFA's "alternative sanction" in this case was not intended to place Petitioner under a directed plan of correction. However, even if such had been HCFA's intent, HCFA's failure to follow the requisite regulatory steps shows that the "alternative sanction" HCFA imposed against Petitioner was unauthorized as a directed plan of correction.

Similarly, HCFA's reference, in its letter of May 27, 1993, to subjecting implementation of any "acceptable plan" to onsite monitoring by the State agency does not satisfy the regulatory definition of the alternative sanction of State onsite monitoring. See HCFA Ex. 127. As an alternative sanction, onsite monitoring must be required by HCFA on an intermittent or continuous basis, and the costs are to be paid by the laboratory, based upon a formula contained in the regulations. 42 C.F.R. § 493.1836(a). HCFA's imposition of its "alternative sanction" does not refer to any of the foregoing, even assuming there was some laboratory activity to be monitored in this case after the State of New Jersey suspended Petitioner's license and ordered it to cease all laboratory operations on May 25, 1993. See HCFA Ex. 114.

In addition, if it intended to impose onsite monitoring as an authorized alternative sanction, HCFA was required to notify Petitioner of the proposal to impose the onsite monitoring sanction, permit Petitioner at least 10 days to respond, and then notify Petitioner of the decision to impose this alternative sanction at least five days before the effective date of the sanction where immediate jeopardy is found. 42 C.F.R. § 493.1836(b) (incorporating the requirements of 42 C.F.R. § 493.1810). HCFA did not follow any of these procedures. Therefore, I conclude that HCFA's reference to the onsite monitoring of an "acceptable plan" also does not constitute an authorized alternative sanction.

E. HCFA's "suspending [Petitioner's] approval to receive Medicare payment for services . . . ." was an invalidly imposed principal sanction, and HCFA has not imposed a directed portion of a plan of correction within the meaning of the regulations.

The contents of HCFA's May 27, 1993 letter raise the question of whether, in directing Petitioner to provide a list of its clients within 10 days, HCFA intended to impose a directed portion of a plan of correction in conjunction with an alternative sanction of suspending all or part of Medicare payments to Petitioner. If HCFA intended to do so, I conclude that any such sanctions were invalidly imposed.

The regulation states that, when HCFA does not impose a directed plan of correction (and no directed plan of correction was imposed here), HCFA must at least impose a directed portion of a plan of correction when it imposes one of the remaining alternative sanctions of State onsite monitoring, civil monetary penalty, or suspension of Medicare payments. 42 C.F.R. § 493.1832(a). When it imposes a directed portion of a plan of correction, HCFA directs a laboratory to do the following:

> to submit to HCFA, the State survey agency, or other HCFA agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory . . . within any . . . timeframe specified by HCFA.

42 C.F.R. § 493.1832(b)(2)(i).[21] The purpose for imposing the directed portion of a plan of correction is to enable HCFA to notify the laboratory's clients of the laboratory's noncompliance, together with the nature, effective date, and status of the alternative sanctions imposed against the laboratory. 42 C.F.R. § 493.1832(b)(2)(ii).

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[21] By definition, a directed portion of a plan of correction involves only the submission and use of a list of the sanctioned laboratory's clients. 42 C.F.R. § 493.1832(b)(2). Therefore, the "acceptable plan of correction" required by HCFA cannot be considered a directed portion of a plan of correction.

Since the purpose of the directed portion of a plan of correction is to enable HCFA to give notice of the alternative sanction that was imposed against the laboratory, it would make no sense to construe the directed portion of a plan of correction as an alternative sanction in and of itself. See 42 C.F.R. § 493.1832(b)(2). A directed portion of a plan of correction has no purpose or use unless HCFA has imposed one of the three enumerated alternative sanctions. See 42 C.F.R. § 493.1832. In addition, the directed portion of a plan of correction is also not within the definition of a principal sanction. See 42 C.F.R. §§ 493.1806(b), .1807(a).

Neither may HCFA impose a directed portion of a plan of correction for a principal sanction. That is, HCFA is not entitled to require the submission of a client list when suspending, limiting, or revoking a CLIA certificate, or, in the case of a laboratory participating in Medicare, canceling the laboratory's approval to receive Medicare payment for services. See 42 C.F.R. §§ 493.1806(b), 1807(a), 1832(b)(3). However, if HCFA is imposing a principal sanction following an alternative sanction, and HCFA has already obtained a list of laboratory clients in conjunction with the use of an alternative sanction described above, then HCFA may use that list to give notice of the imposition of a principal sanction as well. 42 C.F.R. § 493.1832(b)(3).[22]

In this case, no alternative sanction of civil monetary penalty has been imposed by HCFA, and I have already found that HCFA has not imposed an alternative sanction of State onsite monitoring. However, HCFA's May 27, 1993 letter mentions three matters in succession: 1) suspending Petitioner's approval to receive Medicare payment for services concurrently with the CLIA suspension; 2) directing Petitioner to provide a list of clients within 10 days of the May 27, 1993 notice letter; and 3) the provision in 42 C.F.R. § 493.1832 referencing

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[22] The regulation at 42 C.F.R. § 493.1844(g) is in accord. It states in relevant part:

> If HCFA suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for its services, HCFA . . . may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at § 493.1832.

notice to Petitioner's clients. HCFA Ex. 127. HCFA's reference to these three matters raises the question of whether HCFA was properly imposing a directed portion of a plan of correction in conjunction with having imposed the alternative sanction of suspending Petitioner's Medicare payments, as authorized by 42 C.F.R. § 493.1832(a).

HCFA's May 27, 1993 reference to "suspending" Petitioner's "approval to receive Medicare payment for services concurrently with the CLIA suspension" is ambiguous, because HCFA has mixed words from the regulation describing a principal sanction with those describing an alternative sanction. For example, "suspension" of Medicare payment comes from the provision explaining an alternative sanction; while "approval to receive Medicare payment" and "concurrently with the CLIA suspension" are, respectively, words and concepts taken from the provision explaining a principal sanction. 42 C.F.R. §§ 493.1807(a), 1807(b), 1808(a).

HCFA's subsequent letter, dated June 1, 1993, resolves the ambiguity by representing that HCFA had suspended Petitioner's approval to receive Medicare payment under the authority of 42 C.F.R. § 483.1808. HCFA Ex. 128. The regulation cited by HCFA specifies in relevant part that, when HCFA suspends or revokes any CLIA certificate, HCFA concurrently cancels the laboratory's approval to receive Medicare payment for its services. 42 C.F.R. § 483.1808(a). Cancellation of Petitioner's approval to receive Medicare payment is a principal sanction. 42 C.F.R. § 493.1807(a). HCFA is not authorized to require a client list from Petitioner because HCFA has imposed a principal sanction. 42 C.F.R. § 493.1832(b)(3).

Since HCFA has authority to impose a directed portion of a plan of correction only in conjunction with an alternative sanction of civil monetary penalty, State onsite monitoring, or suspension of Medicare payments (42 C.F.R. § 493.1832(a)), HCFA's requirement for a client list from Petitioner was not an authorized directed portion of a plan of correction. I therefore conclude that HCFA's requirement that Petitioner provide a client list has no legal force under the facts of this case.

On the remaining question of whether HCFA's cancellation of Petitioner's approval to receive Medicare payment was authorized, I begin by noting that the legitimacy of this principal sanction is dependent upon the validity of HCFA's suspension of Petitioner's CLIA certificate. 42 C.F.R. § 493.1808. I have already discussed, in part I.B. of this decision, the reasons why HCFA's suspension

of Petitioner's CLIA certificate was improper and invalid. Therefore, HCFA's resultant cancellation of Petitioner's approval to receive Medicare payment concurrent with the suspension of the CLIA certificate is also invalid and not authorized by 42 C.F.R. § 493.1808.

II. HCFA's actions of June 1, 1993, purporting to revoke Petitioner's CLIA certificate and cancel Petitioner's approval to receive Medicare payment also exceeded its authority under the regulations.

I will next focus on HCFA's letter dated June 1, 1993, in which it announced the following actions:

> As of close of business June 1st, the State agency has advised us that it has not received an acceptable plan of correction from your laboratory. Therefore under the provisions of 42 C.F.R. § 493.1812, we are proceeding with the revocation of your CLIA certification. The effective date of the revocation will be June 25, 1993. Medicare payment suspension remains in effect in accordance with the provision of 42 C.F.R. § 493.1808.

HCFA Ex. 128. I conclude that HCFA was without authority to revoke Petitioner's CLIA certificate or "suspend" Medicare payments to Petitioner, as it purported to do on June 1.

In its letter, HCFA cited 42 C.F.R. § 493.1812 as authority for its decision to revoke Petitioner's CLIA certificate. However, HCFA implemented its revocation decision in a manner not permitted by that regulation. Even assuming that HCFA had imposed a valid alternative sanction in this case pursuant to 42 C.F.R. § 493.1812(a), the expiration date of the alternative sanction cannot immediately result in a decision by HCFA to revoke Petitioner's CLIA certificate as indicated in HCFA's June 1, 1993 letter.[23] The regulation cited by

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[23] The regulation at 42 C.F.R. § 493.1840(a)(7) authorizes the suspension, limitation, or revocation of a CLIA certification when the laboratory's owner, operator, or employee(s) fails to comply with an alternative sanction imposed under Subpart R. However, HCFA did not claim to have relied on this subsection. In addition, as I have already discussed, what HCFA called an "alternative sanction" is not cognizable under Subpart R.

(continued...)

HCFA plainly states that, if the jeopardy still persists after HCFA has satisfied its obligations (i.e., directed immediate action to remove the jeopardy, imposed an alternative sanction to help bring about compliance, conducted a revisit, and found that the jeopardy has not been eliminated), HCFA must first consider suspending or limiting the CLIA certificate before it may "later" revoke the certificate. 42 C.F.R. § 493.1812(a), (b). As discussed above, HCFA altered the process and prematurely decided on May 27, 1993 to suspend Petitioner's CLIA certificate effective June 1, 1993. On June 1, 1993, HCFA further abrogated the regulatory process and procedures by using the expiration of its "alternative sanction" as reason for imposing the revocation sanction against Petitioner.

In addition, contrary to regulation, HCFA made the revocation effective prior to an administrative law judge decision in this case. The regulation provides that, if HCFA has not determined immediate jeopardy and the laboratory appeals, no principal sanction (i.e., no suspension, limitation, or revocation of a laboratory's CLIA certificate) may go into effect prior to the administrative law judge's issuance of a hearing decision upholding the suspension or limitation. 42 C.F.R. §§ 493.1840(d), .1844(d)(2). Where HCFA has found immediate jeopardy and the laboratory appeals, only the suspension and limitation of a CLIA certificate may go into effect during the pendency of an appeal.[24] 42 C.F.R. § 493.1844(d)(2)(ii). There exists no exception to the rule that, if a hearing request has been filed, HCFA may not revoke a CLIA certificate until after an administrative law judge upholds the revocation in a decision issued pursuant to hearing. 42 C.F.R. §§

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[23](...continued)
The basic requirements of 42 C.F.R. § 493.1812 are not obviated when HCFA ties the failure to comply with an alternative sanction to immediate jeopardy. See 42 C.F.R. § 1840(d). In a later portion of this decision, I will discuss also the absence of any regulation permitting HCFA to revoke a CLIA certificate prior to an administrative law judge's decision upholding the revocation.

[24] If an administrative law judge's decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation. 42 C.F.R. § 493.1844(d)(4)(ii).

493.1840(e), .1844(d)(2).[25] If the continuation of any activity by the laboratory during the administrative appeal process constitutes a significant risk to public health, HCFA may file suit in federal court to restrain or enjoin such activity. 42 C.F.R. § 493.1812(c).

In this case, HCFA informed Petitioner, by letter dated June 1, 1993, that revocation of its CLIA certificate would become effective on June 25, 1993. HCFA Ex. 128.[26] HCFA did not acknowledge any exception to having the revocation go into effect on the date designated by HCFA. See, e.g., Tr. 43 - 44. HCFA continues to argue in these proceedings that the revocation of Petitioner's CLIA certificate was placed on a "fast-track" that involved the use of procedures applicable to immediate jeopardy cases and that the revocation imposed may be stopped only

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[25] The regulation titled "[e]ffective date of adverse action" is also in accord. It states, in relevant part:

> When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of [HCFA's] notice.

42 C.F.R. § 493.1844(h)(1)(emphasis added). Any revocation that takes place pursuant to an administrative law judge's decision would satisfy the requirement that the revocation take place at least five days after the day HCFA issued its notice letter.

[26] When sending out its sanction notice pursuant to a finding of immediate jeopardy, HCFA may specify an effective date for revoking a laboratory's CLIA certificate that is at least five days after HCFA's notice. 42 C.F.R. § 493.1844(h)(1). If HCFA determines that there exists no immediate jeopardy, HCFA may specify in its sanction notice an effective date for the revocation that is at least 15 days after HCFA's notice. 42 C.F.R. § 493.1844(h)(2).

Here, HCFA's June 1, 1993 letter indicates that it chose a revocation date of June 25, 1993, which suggests the possibility that HCFA no longer perceived any immediate jeopardy as of June 1, 1993. See 42 C.F.R. § 493.1844(h)(2) and my previous discussions of the sanctions imposed by the State of New Jersey on May 25, 1993. HCFA later stated in its post-hearing brief that it revoked Petitioner's CLIA certificate on June 1, 1993, which is not in compliance with any regulation.

through verification of Petitioner's compliance. E.g., HCFA Br. at 2, 8, 43. In fact, the revocation should not have gone into effect in this case.

For the foregoing reasons, I find that the decision made by HCFA on June 1, 1993 to revoke Petitioner's CLIA certificate was not authorized by 42 C.F.R. § 493.1812(b). I further find that HCFA was not authorized to make the revocation of Petitioner's CLIA certificate effective before I have issued my decision on Petitioner's appeal. Because the revocation action was unauthorized, HCFA also was without authority on June 1, 1993 to maintain in effect the prior cancellation of Petitioner's approval to receive Medicare payment.[27]

III. HCFA's actions and omissions in this case were not harmless errors.

I have considered the possibility that HCFA's actions and omissions in this case may have amounted to harmless error. I considered this possibility because HCFA sought to demonstrate through the use of the State agency surveyors' testimony that Petitioner's owner, the owner's father and brother, Petitioner's manager, and Petitioner's director were dishonest people who operated a facility that was long overdue for a shutdown. I have concluded that HCFA's errors in this case are too numerous, egregious, and prejudicial to be construed as harmless.

As the Secretary's agent under CLIA, HCFA's responsibility is to implement the Secretary's regulations. As earlier discussed, the regulations applicable to this case confer rights on laboratories operating under CLIA, and they limit the discretion HCFA may exercise in situations like this one, where HCFA received very strong urging from the State agency to terminate the operation of a laboratory without further ado. The deadlines and procedures set forth in the Secretary's regulations serve to protect the rights of the public at large as well as those of the laboratories operating under CLIA. The effects of those regulations would be rendered meaningless if HCFA were at liberty to

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[27] HCFA used the term "medicare payment suspension." HCFA Ex. 128. However, because it cited 42 C.F.R. § 493.1808 as authority, I find that HCFA was canceling Petitioner's approval to receive Medicare payment concurrent with HCFA's revocation of Petitioner's CLIA certificate.

deviate from the timetables and processes specified in those regulations whenever it thought its deviation harmless in the context of bringing about a result allegedly deserved by a laboratory.

There is no presumption in the Secretary's regulations that a laboratory should be shut down if it has condition level deficiencies, is alleged to have a poor compliance history, or poses immediate jeopardy. The Secretary's regulations make very clear that every laboratory, regardless of its offenses under CLIA, must be given an opportunity by HCFA to remedy its own deficiencies, including those deficiencies which resulted in HCFA's finding of immediate jeopardy. Such an opportunity cannot be provided by HCFA in a context devoid of fairness and reasonableness, as occurred here. For HCFA to close a laboratory, whether through the use of suspension or revocation of the laboratory's CLIA certificate, is to be a remedy of last resort -- not first resort -- under the Secretary's regulations. Yet, every action HCFA took from May 27, 1993 onward was directed at ensuring that Petitioner would close without affording it any meaningful opportunity to remedy the problems and retain its CLIA certificate.

I am not persuaded by HCFA's suggestion that Petitioner would have failed to remedy the jeopardy or failed to come into compliance with CLIA even if HCFA had fulfilled its obligations to Petitioner. The evidence before me indicates, for example, that, if HCFA had imposed a directed plan of correction as provided by the Secretary's regulations and for the purpose of helping to bring Petitioner into compliance, Petitioner's managers would likely have followed it. Moreover, at all times relevant to this case, HCFA had the opportunity to sanction Petitioner at the appropriate time, if circumstances warranted, and with use of the appropriate process.

I noted earlier, as a corollary matter, that the State of New Jersey summarily suspended Petitioner's license on May 25, 1993 and ordered Petitioner to cease and desist from all laboratory operations immediately. Such evidence fails also to indicate a need for HCFA to shortcut the rights and remedies specified by the Secretary's regulations after it asserted the existence of immediate jeopardy on May 27, 1993. In short, there was no legal or logical justification for HCFA to have preempted the timetables or procedures specified by the regulations applicable to this case.

Finally, the instant administrative hearing is at the end stage of the enforcement process, and I am unable to take the procedural steps that HCFA should have taken before the case reached me. The Secretary has vested in HCFA the discretion to initiate enforcement proceedings within the parameters created by her regulations. As discussed earlier, the Secretary's regulations require HCFA to determine, for example, whether deficiencies pose immediate jeopardy, what remedial actions are needed, when the resurvey is to be conducted, which sanctions (if any) should be proposed, and what effect is to be given to any responses Petitioner may provide to the proposed sanctions. E.g., 42 C.F.R. §§ 493.1810, .1812. HCFA is the only entity that has the authority to implement the remedies that were previously available, including directing the State agency to resurvey Petitioner to ascertain the elimination of immediate jeopardy, formulating a directed plan of correction, or requiring continuous or intermittent monitoring of a plan of correction by the State survey agency. E.g., 42 C.F.R. §§ 493.1832, .1836.

For the foregoing reasons, the enforcement process cannot be begun anew by an administrative law judge at the hearing stage of the case. Consistent with my duties as an adjudicator, I have determined that HCFA acted improperly in its dealings with Petitioner. HCFA's failure to exercise its discretion within the bounds of the regulations at the beginning stage of the enforcement process harmed Petitioner's rights and the rights of the public to proper implementation of the Secretary's regulations.

IV. It is not necessary or feasible for me to decide at this time whether Petitioner had condition level deficiencies in February through March of 1993.

I will not adjudicate the issue of whether HCFA, in analyzing information provided to it by the State agency, correctly found condition level deficiencies based on the survey conducted during February and March of 1993. There is no need to do so given what has taken place since May of 1993. Whether or not condition level deficiencies existed in February and March of 1993, Petitioner has been closed since May of 1993. E.g., Tr. 935. As a practical matter, HCFA's concern for the general public welfare and the existence of jeopardy to patients should have been alleviated by Petitioner's closure.

In addition, Petitioner has consistently indicated its willingness to follow directives issued by HCFA or the State agency to overcome the deficiencies alleged by HCFA. E.g., Tr. 31 - 32; P. Ex. 24. Now that Petitioner has heard several days of testimony explaining the few pages of summaries that were provided to it during the enforcement process, Petitioner should have a better understanding of what HCFA meant and wanted. Petitioner should take them into consideration if it ever operates again under CLIA. As noted above, HCFA has the option of seeking an injunction or restraining order in court if Petitioner's activities ever pose a significant hazard to public health.

In addition, even if I were to adjudicate the issue of whether Petitioner's deficiencies in early 1993 warranted the imposition of sanctions and I found in HCFA's favor, HCFA remains the Secretary's delegate for enforcing compliance through the imposition of sanctions. For the reasons previously discussed, it would be improper for me to step outside my role of a neutral adjudicator to take on the duties of an enforcement official. Therefore, my adjudicating the allegations of deficiencies cannot result in my providing the relief sought by HCFA: revoking Petitioner's CLIA certificate. See HCFA Br. at 53.

If Petitioner resumes operation once again, HCFA or the State agency may survey it to ascertain whether deficiencies exist and what actions are warranted. If HCFA makes determinations adverse to Petitioner at that time, Petitioner then will have the opportunity to come before an administrative law judge to litigate the merits of any alleged deficiencies. HCFA will have the opportunity to prove the continuation of any pattern or practice at that time as well. Until Petitioner resumes operation and HCFA determines Petitioner's resumed operation to be out of compliance with CLIA requirements, my resources and the resources of the parties can be better utilized elsewhere.

CONCLUSION AND ORDER

Because the sanctions imposed by HCFA were not authorized by the regulations, I set them aside and order that Petitioner's CLIA certificate and approval to receive Medicare payment for services be restored to the same status they had prior to May 27, 1993.

If HCFA believes that, despite Petitioner's closure since May of 1993, HCFA needs to make determinations on new

issues (such as if or which sanctions should be imposed forthwith in lieu of those I have vacated), HCFA may file a remand motion for my consideration pursuant to 42 C.F.R. § 498.56(d).

/s/

Mimi Hwang Leahy
Administrative Law Judge