Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Parowan Medical Clinic,	)	Date: September 14, 1998
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-97-357
	)	Decision No. CR547
Health Care Financing Administration.	)	
	)	

DECISION

I decide that the Health Care Financing Administration (HCFA) was authorized to terminate Beaver City Corporation's Medicare provider agreement for the rural health clinic known as Parowan Medical Clinic (Petitioner).

PROCEDURAL BACKGROUND

HCFA notified Petitioner in a letter dated March 24, 1997, that "HCFA will terminate its agreement with Beaver City Corporation for the rural health clinic (Parowan Medical Clinic), effective April 23, 1997 (30 days from the date of this letter), due to the fact that the Parowan Medical Clinic no longer meets the requirements for participation as a provider of rural health clinic services in the Health Insurance Benefits Program for the Aged and Disabled (Medicare), established under Title XVIII of the Social Security Act, as amended." Petitioner requested a hearing in a letter dated April 14, 1997.

The record includes the following submissions: Petitioner's Brief (P. Br.), HCFA's Brief (HCFA Br.), and Petitioner's reply letter (P. R. Ltr.). Petitioner attached two exhibits (P. Ex. A and P. Ex. B, which have been remarked as P. Ex. 1 and P. Ex. 2), and HCFA attached two exhibits (HCFA Ex. 1 and HCFA Ex. 2). Neither party objected to the other party's exhibits, and I admit these exhibits into evidence. No facts of decisional significance are in dispute and, consequently, there is no need for an in-person hearing.

ISSUE

The issue is whether HCFA was authorized to terminate its Medicare provider agreement with Beaver City Corporation for the rural health clinic known as Parowan Medical Clinic.

BURDEN OF PROOF

Regarding the burden of proof, HCFA bears the burden of coming forward with evidence establishing a prima facie case that Petitioner no longer met a participation condition or requirement at issue. Once HCFA has established a prima facie case, Petitioner has the ultimate burden of persuasion: to prevail, Petitioner must prove by a preponderance of the evidence that it did meet the condition or requirement. Hillman Rehabilitation Center, DAB No. 1611 (1997) and DAB No. 1663 (1998).

APPLICABLE STATUTE AND REGULATIONS

The term "rural health clinic" is defined by the Social Security Act (Act), 42 U.S.C. § 1395x(aa)(2). The requirement pertinent to this case states:

> (2) The term "rural health clinic" means a facility which --
>
> . . . .
>
> (G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this title. . . .

Section 1861(aa)(2)(G) of the Act [42 U.S.C. § 1395x(aa)(2)(G)].

The Act's requirement that a rural health clinic "directly provides routine diagnostic services, including clinical laboratory services," is not defined by the Act. An explanation of the Act's requirement was published in the Federal Register, in the background section of "supplementary information" accompanying the 1993 amendment to 42 C.F.R. § 491.9:

> Section 1861(aa)(2)(G) of the Act requires RHCs to provide routine diagnostic services directly (that is, they are furnished at the RHC by RHC personnel), including clinical laboratory services.

58 Fed. Reg. 63,533 (1993).

Thus, the published explanation of "directly provides," with regard to laboratory services, is that "they are furnished at the RHC by RHC personnel."

The regulations require a rural health clinic to provide certain basic laboratory services as a "direct service" and permit it to provide other laboratory services "through agreements or arrangements." The pertinent regulation subsections are 42 C.F.R. §§ 491.9 (c)(2) and (d)(1)(iii), which state:

> § 491.9 **Provision of services.**
> (c) *Direct services--*
>
> . . . .
>
> (2) *Laboratory*. . . . The RHC [rural health clinic] provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient. . .
>
> (d) *Services provided through agreements or arrangements.*
>
> (1) The clinic or center has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:
>
> . . . .
>
> (iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

42 C.F.R. §§ 491.9 (c)(2) and (d)(1)(iii).

The regulations define "direct services"[1] as follows:

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[1] The definitions found in 42 C.F.R. § 491.2 contain the phrase **unless the context indicates otherwise** (emphasis added), so caution must be exercised in applying the definition.

§ 491.2 **Definitions.**

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by the clinic's staff.

42 C.F.R. § 491.2.

Thus, direct services are provided by the clinic's staff, unless the context indicates otherwise.

Clinic staff is specified by the regulations as follows:

§ 491.8 **Staffing and staff responsibilities.**

(a) *Staffing.*

(1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.

42 C.F.R. § 491.8(a) (1) and (2).

The 1993 amendment to 42 C.F.R. § 491.9 was necessary to address the impact CLIA[2] would have on RHCs. Every clinical laboratory that tested human specimens for health purposes, even a physician's office laboratory or an RHC laboratory, would require a CLIA certificate. [A CLIA certificate can be a certificate of waiver.[3]] An entity doing

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[2] CLIA stands for Clinical Laboratory Improvement Act Amendments of 1988, Public Law 100-578. CLIA revised section 353 of the Public Health Service Act (42 U.S.C. § 263a) to require all clinical laboratories that test human specimens for health purposes to meet certain requirements. Although the provisions of the Act and initial regulations pertaining to RHCs predate CLIA, the regulations were amended in response to CLIA.

[3] Laboratory tests under CLIA are categorized as "waived," those needing minimal supervision, to "high complexity." If laboratories obtain a certificate of waiver to perform only specified simple tests, they are not required to meet the standards applied to laboratories that perform moderate or high complexity tests. These specified simple tests are those that (1) are cleared by the Food and Drug Administration (FDA) for home use; (2) employ methodologies that are so simple and accurate that they render the likelihood of error negligible; or (3) pose no

only specified simple laboratory tests could be covered by a certificate of waiver; for moderate complexity or high complexity laboratory tests, other certificates would be required. When 42 C.F.R. § 491.9 was amended, the purpose was to prevent CLIA from causing RHCs to experience financial burdens and/or personnel problems that might cause them to close. The amendment, which became effective January 3, 1994, revised the range of laboratory tests that RHCs are required to provide to meet the Medicare conditions of participation. 58 Fed. Reg. at 63,534. A change was made to the basic laboratory services required, so that under the amendment, only laboratory tests classified as "waived" under CLIA were required. Id. at 63,533-34.

The 1993 amendment to 42 C.F.R. § 491.9, including the supplementary information published with the amendment in the Federal Register [58 Fed. Reg. at 63,533], responds to CLIA requirements. The "supplementary information" included in the publication of the amendment states:

> The statute provides that the RHC must provide the clinical laboratory services as prescribed in regulations. We have implemented this statutory provision through regulations at 42 CFR 491.9; that section requires RHCs to provide nine different diagnostic laboratory tests directly. The list of tests has remained unchanged since it was established in 1978 (43 FR 30529). This listing reflects tests that were commonly performed in physicians' offices. The laboratory services required under § 491.9 are performed by clinic personnel and enable the clinic to fulfill its mission to provide routine diagnostic services.

58 Fed. Reg. at 63,533.

> In this rule, we are reducing to six the number of services listed in § 491.9(c)(2) that RHCs must perform directly. We will require as a condition of participation that an RHC provide the following services:
>
> (1) Chemical examinations of urine by stick or tablet methods or both (including urine ketones);
> (2) Hemoglobin or hematocrit;
> (3) Blood glucose;
> (4) Examination of stool specimens for occult blood;
> (5) Pregnancy tests; and
> (6) Primary culturing for transmittal to a certified laboratory.

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reasonable risk of harm to the patient if the test is performed incorrectly. 58 FR 63533 (1993).

> All six of these tests are currently in the waived category under CLIA if they are performed using the specified methodology.

58 Fed. Reg. at 63,534.

The objective of the 1993 amendment was to enable RHCs to provide the required basic laboratory services, so that the RHCs would not be forced to close or be found out of compliance with the conditions of certification and face termination from the Medicare program:

> This revision will allow many RHCs that would otherwise lose their Medicare certification to remain as a source of primary medical care for Medicare beneficiaries living in medically underserved rural areas.

58 Fed. Reg. at 63,536.

Medicare covers laboratory tests performed by RHC personnel in the RHC. 58 Fed. Reg. at 63,534. HCFA is required to cancel a laboratory's approval to receive Medicare payment for its services where the laboratory's CLIA certificate is revoked. 42 C.F.R. § 493.1808(a) and § 493.1842(a)(1). Consequently, Petitioner cannot bill Medicare for any services for which laboratory service was a component, due to the cancellation of the laboratory's approval to receive Medicare payment for its services while its CLIA certificate is revoked.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner is a rural health clinic, located in Parowan, Utah.

2. Rural health clinics are required to be able to provide "directly" certain basic laboratory services, which services are essential to the immediate diagnosis and treatment of the patient. 42 U.S.C. § 1395x(aa)(2)(G); 42 C.F.R. § 491.9(c)(2).

3. "Directly provides" means "furnished at the RHC (rural health clinic) by RHC personnel." 58 Fed. Reg. at 63,533.

4. HCFA proved that Petitioner's CLIA (laboratory) certificate was revoked, effective August 18, 1996. HCFA Ex. 1.

5. Petitioner failed to prove that it was able to provide "directly" the required basic laboratory services during the five month period from August 18, 1996, when Petitioner's CLIA certificate was revoked, until January 28, 1997, the effective date of Beaver Medical Clinic Lab's "CLIA Laboratory Certificate." P. Ex. 2.

6. Due to Petitioner's failure to prove that it could provide "directly" the required basic laboratory services, from August 18, 1996 until January 28, 1997, HCFA was authorized to terminate its agreement with Beaver City Corporation for the rural health clinic known as Parowan Medical Clinic.

DISCUSSION

I. Petitioner failed to prove that it was able, from August 18, 1996 until January 28, 1997, to provide "directly" the required basic laboratory services.

HCFA revoked Petitioner's CLIA laboratory certificate, effective August 18, 1996. HCFA Ex. 1. Petitioner maintains that it has nevertheless been able to provide the required basic laboratory services through a laboratory other than the Parowan Medical Clinic Laboratory, Beaver Medical Clinic Lab. Dr. Roger Smith, a physician member of Petitioner's staff, is the Laboratory Director of Beaver Medical Clinic Lab. The CLIA Laboratory Certificate of Waiver issued to the laboratory of which Dr. Smith is the Director, Beaver Medical Clinic Lab, has an effective date of January 28, 1997, however, which is more than five months following revocation of Petitioner's CLIA certificate.

By letter dated March 24, 1997 (P. Ex. 1), HCFA notified Petitioner that, due to Petitioner's inability to provide CLIA laboratory services directly because of the lack of a valid CLIA certificate, HCFA had imposed the remedy of termination of Petitioner's participation as a Medicare provider of rural health clinic services, effective April 23, 1997. HCFA's notice letter also states that the laboratory services that an RHC is required to provide "directly," pursuant to 42 C.F.R. § 491.9(c)(2), cannot be provided through arrangement.

The revocation of Petitioner's CLIA certificate effective August 18, 1996, triggered a period during which Petitioner failed to meet the rural health clinic requirement of being able to provide CLIA laboratory services directly. The foregoing Findings of Fact and Conclusions of Law suffice to show, without further discussion, that HCFA was authorized to terminate its agreement with Beaver City Corporation for Petitioner to provide rural health clinic services.

II. The parties disagree on whether an RHC is required to have its ***own*** CLIA certificate.

HCFA's argument

HCFA maintains that the rural health clinic must have its ***own*** CLIA certificate; and, further, that the CLIA certificate must be held by the "owners of the RHC." HCFA maintains that, without having its ***own*** CLIA laboratory certificate, a rural health clinic cannot meet the "direct services" requirement of the regulation at 42 C.F.R. § 491.9(c)(2). HCFA Br. at 5. HCFA argues also that the requirement in the regulations [42 C.F.R. § 491.9(c)(2)], that "(t)he RHC provides laboratory services in accordance with part 493 of this chapter . . . ." (Part 493 of the regulations contains the Laboratory Requirements) means that the owners of the rural health clinic must hold a CLIA laboratory certificate. P. Br. at 3; HCFA Ex. 2.

Petitioner's argument

Petitioner maintains that a rural health clinic, when its CLIA certificate is revoked, can nevertheless meet the requirement of being able to provide the required basic laboratory services "directly." Despite the revocation of its CLIA laboratory certificate, asserts Petitioner, it is able to provide those laboratory services through Dr. Roger Smith, a physician member of Petitioner's staff. P. Ex. 2. Dr. Smith is the laboratory director of Beaver Medical Clinic Lab. Petitioner maintains that services provided by Dr. Smith are provided by the clinic's staff, and consequently are, by regulatory definition, "direct services." 42 C.F.R. § 491.2.

Petitioner maintains further that, because it is able to provide the required basic laboratory services at the clinic site, it satisfies the requirement for direct services. [Petitioner's physical location is 460 East Clinic Way, Parowan, Utah. P. Ex. 1. Beaver Medical Clinic Lab's physical location is 450 East Clinic Way, Parowan, Utah. P. Ex. 2. Parowan Medical Clinic Laboratory's physical location was also 450 East Clinic Way. HCFA Ex. 1.] Petitioner maintains that the distinction between "direct services" and "services provided through agreements or arrangements" is that "direct services" are provided on site at the rural health clinic, and the "services provided through agreements or arrangements" may be provided elsewhere.

Analysis of the Parties' arguments

The parties ask me to decide whether a rural health clinic, while its CLIA certificate is revoked, can nevertheless meet the requirement of being able to provide "directly" the required basic laboratory services. HCFA asserts that the only way a rural health clinic can meet the "direct services" requirement of the regulation at 42 C.F.R. § 491.9(c)(2) is to have its ***own*** CLIA certificate. Petitioner does not agree with either of HCFA's assertions, either that the RHC must hold a CLIA certificate, or that the owners of the RHC must hold a CLIA certificate. Petitioner maintains that those services must be provided on site at the RHC, by RHC staff. [Emphasis added.] P. Br. at 1-2; P. R. Ltr. at 1.

Petitioner's approach, through the Beaver Medical Clinic Lab Certificate of Waiver (P. Ex. 2), does appear to meet the objective of the Act, the availability of reliable primary care health service in medically underserved rural communities (58 FR 63533); and CLIA's objective, that human specimens be analyzed accurately and effectively. [Enforcement of CLIA is intended to protect individuals served by laboratories against substandard testing, to safeguard the public against health and safety hazards which might result from noncompliance, and to motivate laboratories to comply with CLIA requirements. 42 C.F.R. § 493.1804(a)(1) - (3).] Petitioner's approach is not expressly precluded: not by the Act, not by the regulations,[4] and, apparently, not by the Medicare provider agreement.[5]

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[4] Neither the Act nor the regulations explicitly requires a rural health clinic to have its own CLIA certificate.

[5] HCFA did not submit Beaver City Corporation's provider agreement as evidence, so I presume that the provider agreement does not specifically require Petitioner (Parowan Medical Clinic) or Beaver City Corporation to have a CLIA certificate.

HCFA maintains that the basic CLIA services required to be provided as "direct services," must be provided "in the RHC laboratory by RHC staff."[6] [Emphasis added.] HCFA Br. at 5. However, even the language of the "supplementary information" included in the publication of the 1993 amendment is not that explicit:

> The laboratory services required under § 491.9 are performed by clinic personnel and enable the clinic to fulfill its mission to provide routine diagnostic services.

58 Fed. Reg. at 63,533.

From the record before me it appears that Beaver Medical Clinic Lab is as much "at the RHC" as Parowan Medical Clinic Laboratory was. Beaver Medical Clinic Lab is not a clinic staff member, but the same was equally true for Parowan Medical Clinic Laboratory. It appears that the work of Beaver Medical Clinic Lab is performed "by RHC personnel" or " by clinic personnel" or "by RHC staff" as much as the work of Parowan Medical Clinic Laboratory was. Even though the parties have asked me to determine whether a rural health clinic, while its CLIA certificate is revoked, can nevertheless meet the requirement of being able to provide "directly" the required basic laboratory services, it is not necessary for me to do so, because I have already decided that HCFA was authorized to terminate the provider agreement (see Section I. of Discussion, above).

CONCLUSION

Due to Petitioner's failure to prove that it could provide "directly" the required basic laboratory services, from August 18, 1996 until January 28, 1997, HCFA was authorized to terminate its agreement with Beaver City Corporation for the rural health clinic known as Parowan Medical Clinic.

/s/
Jill S. Clifton
Administrative Law Judge

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[6] HCFA asserts also that the CLIA certificate must be held by the "owners of the RHC." P. Br. at 3. HCFA Ex. 2. Presumably Petitioner's owner is Beaver City Corporation, so Beaver City Corporation would be required to have a CLIA certificate under the theory that the owners of a rural health clinic must hold a CLIA certificate.