

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Tri-County Medical Center, Inc.
Docket No. A-14-26
Decision No. 2575
May 29, 2014

DECISION

Tri-County Medical Center, Inc. (TCMC), a non-profit community health center, appealed a November 8, 2013 decision by the Health Resources and Services Administration (HRSA) to terminate its Health Center Program grant under section 330 of the Public Health Service Act (PHSA), 42 U.S.C. § 254b. HRSA took this action because it found that TCMC had materially failed to comply with a grant condition requiring it to implement its quality improvement and assurance (QI/QA) plan, particularly the plan's provisions calling for periodic review of service utilization and quality. Because the record substantiates HRSA's finding that TCMC materially failed to comply with the terms and conditions of its Health Center Program grant, we conclude that HRSA lawfully terminated the grant.

Legal Background

Section 330 of the PHSA authorizes HRSA to make grants of federal funds to support non-profit "health centers" that provide care to "medically underserved" populations. 42 U.S.C. § 254b. Grants authorized by section 330 are issued and administered in accordance with the regulations in 42 C.F.R. Part 51c. As we discuss later in more detail, the statute and regulations require health centers that receive section 330 funding to take measures to ensure that patients receive high-quality health care.

In a typical "discretionary"¹ grant program (like the Health Center Program grant program), the grantor agency determines that a grantee is eligible to receive federal funds for a multi-year "project period" but awards the funds incrementally for each "budget

¹ The term "discretionary" signifies that the grantor agency may exercise judgment in selecting a grantee and setting the amount of federal funding. *Virgin Islands Dept. of Justice*, DAB No. 1067 (1989); HHS Grants Policy Statement (HHS GPS) at I-3 (available at <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

period” (usually 12 months) within the project period. *Northwest Rural Opportunities, Inc.*, DAB No. 342 (1982); HHS Grants Policy Statement (Jan. 1, 2007) (HHS GPS) at I-15 (available at <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).² The federal agency’s initial or continuing approval of a grant is communicated to the grantee in a “Notice of Award”³ that specifies the amount of federal funds available to the grantee for the upcoming budget period, the projected amount of federal funding for future budget periods, and “terms and conditions” of the grant. HHS GPS at I-33. A discretionary grant’s standard “terms and conditions” include provisions of the grant-authorizing statute and grant program’s regulations. *Id.* at i, II-1. If the grantee is a non-profit organization (like TCMC), the grant’s terms and conditions also include the uniform administrative requirements in 45 C.F.R. Part 74. *Id.*

Two sections of the uniform administrative requirements are relevant here. First, section 74.14 authorizes the grantor agency to modify a grant’s terms and conditions to include “additional requirements” – what the regulation’s title calls “special award conditions” – when the agency has reason to believe that federal funds are at risk of loss or misuse due to a grantee’s inexperience, poor performance, financial mismanagement, noncompliance with grant terms and conditions, or other circumstances.⁴ 45 C.F.R. § 74.14; HHS GPS at I-35; *Recovery Resource Center, Inc.*, DAB No. 2063, at 3 n.5 (2007). Second, section 74.62 provides that if a grantee “materially fails to comply with the terms and conditions of an award, whether stated in a Federal statute or regulation, an assurance, an application, or a notice of award,” the awarding agency may impose one or more remedies of varying severity, including termination of the award. 45 C.F.R. § 74.62(a)(3); *see also id.* § 74.61(a)(1) (stating that a federal award may be terminated in whole or part if the recipient “materially fails to comply with the terms and conditions of [the] award”).

² The HHS Grants Policy Statement contains policy and interpretive guidance regarding grant terms and conditions that are common across all HHS operating divisions. HHS GPS at i.

³ The regulations define the term “award” to mean “financial assistance that provides support or stimulation to accomplish a public purpose” and further define the term to “include grants and other agreements in the form of money or property in lieu of money, by the Federal Government to an eligible recipient.” 45 C.F.R. § 74.2.

⁴ Title 45 C.F.R. § 74.14 states that an HHS awarding agency “may impose additional requirements as needed . . . if an applicant or recipient: (1) Has a history of poor performance; (2) Is not financially stable; (3) Has a management system that does not meet the standards prescribed in this part; (4) Has not conformed to the terms and conditions of a previous award; or (5) Is not otherwise responsible.” Section 74.14(b) states that when an agency imposes any additional requirements, it must notify the recipient in writing about the nature of the additional requirements, the reason why the additional requirements are being imposed, the nature of the corrective actions needed, the time allowed for completing the corrective actions, and the method for requesting reconsideration of the additional requirements imposed.

Exercising its authority under section 74.14, HSRA has instituted a “progressive action process” to help ensure that grantees operate in compliance with grant program requirements. HSRA Ex. 7, at 2. HSRA described the progressive action process in an August 2010 Program Assistance Letter addressed to all program grantees. *Id.* at 1. Under that process, when a grantee is found to be noncompliant with one or more “grant requirements” (such as applicable provisions of section 330 and the grant program’s regulations), HSRA issues award notices with “conditions” that advise the grantee of HSRA’s noncompliance findings and, when appropriate, give the grantee timeframes in which to submit and implement a plan to achieve compliance before enforcement action is taken under 45 C.F.R. § 74.62. *Id.* at 2-3.

Case Background

The material facts of this case are not in dispute.⁵ In February 2011, HSRA approved a Health Center Program grant for TCMC with a five-year project period ending in 2015. *See* HSRA Ex. 1. HSRA’s approval of the grant was communicated to TCMC in a five-page Notice of Award for the grant’s initial budget period (February through November 2011). *Id.* The notice’s cover page states that the grant’s “terms and conditions” included section 330 of the PHSA, the grant program’s regulations, the uniform administrative requirements in 45 C.F.R. Part 74, and various other terms and conditions attached to the cover page. *Id.* at 1 (box 16).

On August 20, 2012, HSRA issued TCMC a similar Notice of Award (containing the same standard terms and conditions) for the succeeding budget period. HSRA Ex. 2. That award notice contained an attached “condition” which directed TCMC to provide within 90 days (or by November 18, 2012) a “board approved QI/QA plan *in accordance with program requirements.*” *Id.* at 2 ¶ 3 (italics added). The condition identified the relevant “program requirements” as section 330(k)(3)(C) of the PHSA and the regulations in 45 C.F.R. Part 51c which implement that statutory provision. These authorities provide that a health center receiving federal financial support under section 330 must have an “ongoing quality improvement system,” 42 U.S.C. § 254b(k)(3)(C), that provides for “[p]eriodic assessment of the appropriateness of the *utilization of services and the quality of services provided or proposed to be provided to individuals served by the center,*” 42 C.F.R. § 51c.303(c) (italics added).

The condition relating to TCMC’s QI/QA plan was included in the August 20, 2012 award notice because HSRA had found “several components missing” from the plan during a July 2012 site visit. HSRA Ex. 8, at 1. Among the missing components was a

⁵ Both parties submitted relevant documentation, but neither has questioned the truth or accuracy of the information contained in the other’s documents.

“procedure” for conducting “peer reviews” of the quality of services provided by TCMC’s medical staff. *Id.* HRSA also found during the site visit that “[u]tilization reviews” were not being performed. *Id.*

With technical assistance from HRSA, TCMC submitted an acceptable QI/QA plan by the November 2012 deadline specified in the August 20, 2012 award notice. *See* HRSA Ex. 8, at 2. HRSA then gave TCMC an opportunity to “document” that it had implemented the approved QI/QA plan, which called for (among other actions) quarterly “peer review” of patient services in accordance with a protocol specifying various dimensions of service quality. *Id.*; TCMC Ex. B (2012 QI/QA Plan at 14 & Appendix A). On January 3, 2013, HRSA issued an award notice to TCMC which included the following condition:

Health centers are expected to comply with all applicable statutory and regulatory requirements. In your most recent Notice of Award (NoA) [dated August 20, 2012], your organization was required to provide a board approved QI/QA plan in accordance with program requirements. . . . Based upon a review of the required response, HRSA has approved your plan. *Within 120 days* [of January 3, 2013 – that is, by May 3, 2013], *provide documentation that this requirement has been implemented*, per the HRSA approved, time-phased plan.

HRSA Ex. 3, at 3 (italics added). During the 120-day period specified in the January 3, 2013 award notice, HRSA provided “technical” support and other guidance to help TCMC “achiev[e] compliance with the QI/QA Program Implementation program requirement” HRSA Ex. 8, at 3.

TCMC did not provide documentation of plan implementation by the 120-day deadline specified in the January 3, 2013 award notice. *See* HRSA Ex. 8, at 3. Consequently, on May 22, 2013, HRSA issued another award notice with the following condition:

Within 60 days, provide documentation that the HRSA approved, time-phased plan has been implemented. Your organization has 60 days to address this condition. *If your organization does not adequately address this condition, the organization will be given one final 30 day opportunity.* Failure to adequately address this condition within this additional 30 day period will serve as documentation that your organization has materially failed to comply with the terms and conditions of this grant award and will result in the announcement of a competition to identify an organization that can carry out a service delivery program consistent with Federal Health

Center Program requirements. In addition, *your current project period may be shortened and include the withdrawal of support through the cancellation of all or part of the grant award before the current Project Period end date per 45 CFR 74.62(a).*

HRSA Ex. 4, at 2 (italics added).

In late July 2013, HRSA made a “Program Requirement Verification Site Visit” to TCMC in order “to assess and support the grantee’s progress” in meeting the condition imposed by the May 22, 2013 award notice. HRSA Ex. 8, at 3. As a result of that visit, and after examining documentation submitted by TCMC on July 31, 2013 – including minutes of TCMC’s Quality Improvement and Assurance Committee (QIAC) – HRSA concluded that TCMC had still not completely or satisfactorily implemented its QI/QA plan. *Id.* Among the deficiencies HRSA found were: (1) “no documentation of regular QI/QA Committee Meetings or activity”; (2) “[n]o utilization review had been conducted”; (3) “[p]eer reviews had not been conducted since 2012”; and (4) “no evidence of an annual work plan for the QI/QA Program that clearly delineates the Program’s activities for the year.” *Id.* According to HRSA’s record of the progressive action process, TCMC had received “[c]lear directives consistent with previous guidance and indicating what the grantee was required to submit to demonstrate compliance with the QI/QA implementation program” *Id.*

On September 19, 2013, HRSA issued a final award notice stating that TCMC had 30 additional days to “provide documentation that the board approved QI/QA program has been implemented” HRSA Ex. 5, at 2. The notice specified the following consequences of a failure to provide the necessary documentation:

Failure to adequately address this condition will serve as documentation that your organization has materially failed to comply with the terms and conditions of this grant award. This will result in the announcement of a competition to identify an organization that can carry out a service delivery program consistent with Federal Health Center Program requirements. In addition, your current project period may be shortened and include the withdrawal of support through the cancellation of all or part of the grant award before the current Project Period end date per 45 CFR 74.62(a).

Id. HRSA staff advised TCMC that in order to “demonstrate compliance” by the October 19, 2013 deadline, it needed to submit (among other documents) QIAC meeting minutes “discussing **quality improvement implementation** activities” in the areas of “[s]ervice utilization review” and “[q]uality of services review.” HRSA Ex. 8, at 3-4 (italics and emphasis in original).

On October 19, 2013, TCMC submitted a response that included meeting minutes of its QIAC. HRSA Ex. 8, at 4; TCMC Ex. B. HRSA judged the response to be inadequate for the following reasons:

The 30 day implementation condition submission reflects progress in planning for QI/QA Program implementation but does not demonstrate actual QI/QA implementation. The submission included a QI/QA Committee Meeting minute template that will facilitate documentation of key QI methodology elements. However, submitted QI/QA Committee Meeting minutes did not reflect QI implementation activities in the area of service utilization reviews and quality of service reviews (e.g., peer review and utilization of evidence-based guidelines). Likewise, submitted Board Meeting minutes did not reflect report-out of QI/QA Program implementation activities. This has been an issue of noncompliance discussed with the grantee since the finding at the July 13-15, 2012 site visit that has not been resolved.

HRSA Ex. 8, at 5 (emphasis in original).

Because it found that TCMC had failed to verify that its QI/QA plan had been implemented “within the requisite timeframe,” HRSA notified TCMC on November 8, 2013 that its Health Center Program grant would be terminated effective November 30, 2013. TCMC Ex. A. The termination notice stated that TCMC’s October 19, 2013 submission to HRSA was “inadequate” because it “failed to address the QI/QA Program implementation requirements in the area of *service utilization reviews and quality of service reviews* (e.g., peer review and utilization of evidence-based clinical guidelines), as required.” *Id.* at 2 (italics added).

TCMC then filed this appeal, asserting that HRSA was “incorrect in prematurely terminating” its Health Center Program grant. TCMC Brief (Br.) at 1.

Discussion

The Board is “bound by all applicable laws and regulations.” 45 C.F.R. § 16.14. As indicated, applicable regulations authorize a grantor agency to terminate a grant if the grantee “materially fails to comply” with the grant’s “terms and conditions.” *Id.* § 74.62(a)(3).

Uncontested evidence in the record demonstrates that TCMC materially failed to comply with terms and conditions of its Health Center Program grant. The award notices issued for the grant indicate that its terms and conditions included section 330(k)(3)(C) of the PHSA, which requires a health center to have an “ongoing quality improvement system,” as well as 45 C.F.R. § 51c.303(c), which specifies required elements of that system. *See,*

e.g., HRSA Ex. 1, at 1 (Box 16) (stating that the grant’s terms and conditions included section 330 and the relevant grant program regulations). In addition, beginning in August 2012, the award notices included special conditions that expressly addressed TCMC’s compliance with these quality requirements. Quoting 45 C.F.R. § 51c.303(c)(2), the special conditions stated that TCMC’s quality improvement system needed to provide for “periodic assessment” of (1) the “appropriateness of the utilization of services” and (2) the “quality of services provided or proposed to be provided” to patients. *See, e.g.*, HRSA Ex. 2, at 2 ¶ 3. The special conditions also imposed deadlines for (1) submitting a QI/QA plan for performing the required periodic assessments and (2) furnishing documentation verifying that the approved QI/QA plan had been “implemented.” *Id.*; HRSA Ex. 3, at 3 ¶ 6; HRSA Ex. 4, at 2 ¶ 1.

HRSA’s progressive action record shows that although TCMC in late 2012 submitted a QI/QA plan that called for periodic assessment of service utilization and quality, TCMC failed to demonstrate that it had implemented the plan as of October 19, 2013, more than nine months after it was first notified by HRSA in the January 3, 2013 award notice that it needed to submit documentation of plan implementation. *See* HRSA Ex. 2, at 2 ¶ 3; HRSA Ex. 3, at 3 ¶ 6; HRSA Ex. 8, at 3-6. Even before January 2013, the grant program regulations put TCMC on notice of its obligation, as a recipient of section 330 funding, to have an ongoing quality improvement system that provides for periodic assessments of service utilization and quality. 42 C.F.R. § 51c.303(c)(2) (indicating that the requirement to conduct utilization and quality assessments applies to a “health center supported under this subpart”).⁶

In its appeal brief, TCMC does not dispute several key facts that are apparent from the record. For example, TCMC does not deny that the terms and conditions of its Health Center Program grant required it to implement provisions of its QI/QA plan relating to service utilization and quality, such as the provision calling for quarterly peer review. Nor does TCMC dispute that it had not yet implemented, or adequately implemented, those provisions as of January 2013, when HRSA first directed it to provide (within 120 days) documentation of plan implementation. TCMC also does not question the reported results of HRSA’s July 2013 site visit, which found (among other things) that TCMC had not performed peer review during 2013 or conducted “utilization reviews.” In addition, TCMC does not contend that it lacked sufficient time – or adequate notice of what corrective action was required – to implement its QI/QA plan and achieve material compliance with the grant terms and conditions at issue.

⁶ Section 51c.303(c)(2) states these periodic assessments “shall: (i) [b]e conducted by physicians or by other licensed health professionals under the supervision of physicians; (ii) [b]e based on the systematic collection and evaluation of patient records; and (iii) [i]dentify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.”

TCMC contends that the QIAC meeting minutes it submitted to HRSA on October 19, 2013 were evidence of material compliance with the grant's terms and conditions. TCMC Br. at 1. According to TCMC, those minutes "describ[e] . . . implementation of the QI/QA Plan." *Id.* Apart from that general assertion, TCMC does not discuss the content of the QIAC minutes or address the specific deficiency cited by HRSA as the reason for its termination decision – namely, the failure to demonstrate that it was conducting periodic reviews of service utilization and quality. *See* TCMC Ex. A at 2. As indicated, HRSA found that the QIAC minutes submitted on October 19, 2013 "did *not* reflect QI implementation activities in the areas of areas of service utilization review and quality of service reviews (e.g., peer review and utilization of evidence-based clinical guidelines)." HRSA Ex. 8, at 5 (*italics and emphasis added*). TCMC does not point to anything – and we see nothing – in the minutes which undercuts that finding.

TCMC contends that it has appointed a new chief medical officer (CMO) who "is implementing [the] current QI/QA plan." TCMC Br. at 1. In support of that contention, TCMC produced minutes of a December 17, 2013 meeting of its board of directors. TCMC Ex. D. According to those minutes, the board voted to offer the CMO position to an individual who had earlier agreed to accept the position if offered. *Id.* However, the board minutes do not say that the new CMO was already on the job, nor do they indicate that he or any other qualified employee had recently initiated utilization or quality reviews of TCMC's medical services. Furthermore, because the grant conditions which TCMC violated (and whose validity TCMC does not dispute) imposed compliance deadlines that expired prior to HRSA's decision to terminate the grant, any corrective action taken by TCMC *after termination*, such as the hiring of a new CMO, is irrelevant. *See, e.g., Vance Warren Comprehensive Health Plan*, DAB No. 2180, at 16 (2108) (holding that a grantee's post-termination actions to improve its grant-funded program were "not relevant").

Finally, TCMC asserts that it "has put in place a new credentials and privileges policy and plan." TCMC Br. at 2. Like the hiring of its new CMO, this action also occurred after HRSA terminated the grant and is insufficient for that reason. Moreover, TCMC does not explain how its adoption of the credentials and privileges policy is relevant to HRSA's finding that it failed to implement the provisions of its QI/QA plan relating to service utilization and quality.

In sum, the grant's terms and conditions expressly required TCMC to comply with its obligation under the PHSA to conduct periodic reviews of service utilization and quality. The terms and conditions also required TCMC to achieve compliance within generous timeframes whose combined length totaled more than nine months. Despite technical assistance from HRSA, TCMC failed to achieve compliance within the required timeframes. These circumstances adequately support HRSA's conclusion that TCMC materially failed to comply with terms and conditions of its Health Center Program grant. *Cf. Tuscarora Tribe of North Carolina*, DAB No. 1835, at 2, 8-11 (2002) (holding that

failure to comply with a special award condition requiring the grantee to meet an essential grant objective within 90 days was a “material” failure within the meaning of section 74.62(a)); *Partnership for Youth & Community Empowerment*, DAB No. 2036, at 16 (2010) (upholding the grantor agency’s decision to deny continuation funding for a grantee that failed to “timely and sufficiently complete corrective actions,” despite a six-month effort to help the grantee to address its fiscal and other program-related deficiencies).

Conclusion

Because TCMC materially failed to comply with the terms and conditions of grant number H80CS00095 under section 330 of the PHSA, the Board affirms HRSA’s November 8, 2013 decision to terminate that grant.

_____/s/
Judith A. Ballard

_____/s/
Leslie A. Sussan

_____/s/
Sheila Ann Hegy
Presiding Board Member