Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Texas Tech Physician Associates Docket No. A-14-5 Decision No. 2671 December 22, 2015

DECISION

Texas Tech Physician Associates (Texas Tech) appeals a September 5, 2013 decision by the Centers for Medicare & Medicaid Services (CMS) that Texas Tech must return \$7,988,526 in fees that it received from CMS during its participation in a Medicare demonstration project that tested a pay-for-performance contracting model and intervention strategies for managing the care of high-cost Medicare fee-for-service beneficiaries. The project was conceived and operated by a consortium that included Texas Tech under a "Demonstration Agreement" with CMS. The project's basic goal was to reduce the costs of providing care to those beneficiaries while improving the quality of care and provider and beneficiary satisfaction with care.

The Demonstration Agreement between CMS and Texas Tech called for CMS to pay Texas Tech monthly "care management" fees based on the number, or some portion of the number, of Medicare fee-for-service beneficiaries assigned to the demonstration project's "intervention group" – the group of beneficiaries that received the project's services. The Demonstration Agreement also required Texas Tech to refund some or all of the care management fees in the event that the project failed to achieve a specified level of Medicare cost savings. In addition, the Demonstration Agreement provided that CMS would determine whether any savings were achieved by comparing the Medicare costs of the intervention group to the Medicare costs of a "comparison group" – that is, a group similar to the intervention group except that its members did not receive the project's services. (We sometimes refer to the intervention and comparison groups as the "study groups.")

Texas Tech began operating its demonstration project in April 2006. The project was terminated early, effective July 1, 2007, at Texas Tech's request. CMS then determined, based on a comparison of the study groups' Medicare costs, that the project had failed to achieve the level of Medicare savings required under the Demonstration Agreement. Based on that determination, CMS demanded that Texas Tech refund \$7,988,526 in care management fees that it had received during the project's period of operation.

Texas Tech timely appealed CMS's action to the Board. Shortly afterward, Texas Tech moved to dismiss the appeal, arguing that the Demonstration Agreement was a "procurement contract" covered by the Contract Disputes Act of 1978, 41 U.S.C. § 7101 *et seq.*, and thus the proper administrative forum for the dispute was not the Board but the Civilian Board of Contract Appeals. By ruling issued on May 5, 2014, the Board Chair denied the motion to dismiss. The Board Chair held that the Demonstration Agreement was not a procurement contract but, rather, a "grant agreement" as defined in the Federal Grant and Cooperative Agreement Act of 1977 (FGCAA), 31 U.S.C. § 6301 *et seq.* Accordingly, the Board Chair concluded that the Board was authorized to resolve the parties' dispute in accordance with its regulations in 45 C.F.R. Part 16.¹ After the Board Chair issued her jurisdictional ruling, the parties submitted legal argument and evidence concerning the merits of the dispute.

Urging the Board to resolve the dispute based on common law contract theories, Texas Tech contends that CMS breached an obligation under the Demonstration Agreement to select an appropriate comparison group for its demonstration project. Texas Tech further contends that this alleged "breach of contract" (along with other common law contract claims and defenses) relieves it of any obligation to refund care management fees.

For the reasons discussed below, we conclude that Texas Tech's common law contract law theories are inapplicable to the parties' dispute and that the Demonstration Agreement's terms and conditions obligate Texas Tech to return care management fees of \$7,988,526 to the federal government.

I. <u>Background</u>

Section 402(a) of the Social Security Amendments of 1967, 42 U.S.C. § 1395b-1(a), authorizes the Department of Health and Human Services (HHS) to conduct "experiments and demonstration projects" to test methods of healthcare financing that may promote efficient and economical delivery of healthcare services to Medicare beneficiaries. Exercising that statutory authority, CMS in 2004 initiated a Medicare demonstration program called Care Management for High Cost Beneficiaries (CMHCB). Texas Tech Exhibit (TT Ex.) 1. The purpose of the CMHCB program was to test models to improve the "care coordination" (or "care management") of high-cost Medicare feefor-service beneficiaries. *Id.* at 1-2. CMS solicited proposals from "care management organizations" (CMOs) willing to test their care coordination models as part of the demonstration program. *Id.*; CMS Ex. 18, at 3, ¶ 7.

¹ The Board Chair's May 5, 2014 ruling is made a part of the Board's decision as Appendix A.

In an October 2004 solicitation for project proposals, CMS outlined the goals of the CMHCB demonstration, the methods that CMS expected to use to identify Medicare beneficiaries who might benefit from an approved project, minimum project design requirements, and criteria (such as clinical quality and cost) for evaluating a project's "effectiveness." TT Ex. 1. The solicitation indicated that, for each approved project, CMS would select an appropriate "target population" of Medicare beneficiaries, then "randomize individual eligible beneficiaries [from the target population] into intervention and control groups," with randomization being used "to ensure comparability [of the two groups] on factors that could affect performance improvement and overall health care costs." Id. at 5. In the event that a project's care management model precluded randomization of the target population (as it did in this case), CMS proposed to select a "matched population of eligible beneficiaries for the control group." Id. at 5-6. A project's effectiveness, the solicitation said, would be measured by comparing outcomes for the intervention group with outcomes for the corresponding control group. Id. at 16. (Outcomes for the control group would be treated as representing what the outcomes for the intervention group would have been in the absence of the demonstration project.)

CMS's solicitation advised CMOs that a project selected for the demonstration could charge the federal government "care management fees" (on a per-beneficiary-per-month basis) to help defray project-related expenses. TT Ex. 1, at 2, 12. However, CMS cautioned that, in order to maintain the CMHCB program's budget neutrality, retention of care management fees would be contingent on, among other things, whether the project met a Medicare cost savings target. *Id.* at 25. The solicitation stated that –

[e]ach organization [selected for the CMHCB demonstration program] will be required to guarantee that the total of Medicare claims and . . . care management fees for beneficiaries in the intervention group will be no more than 95 percent of the amount that total Medicare claims payments would have been absent [the demonstration project], as measured by claims for the corresponding control group over a 3-year period

Id. at 14. In other words, a CMO would be required to guarantee that the Medicare costs of the project's intervention group (which included care management fees paid to the CMO) would be five percent less than the Medicare costs of the project's comparison group.

CMS's solicitation further indicated a CMO would be required to refund care management fees in the event they were not offset by Medicare cost savings achieved by the project: ... [I]n the event that 5 percent net savings is not achieved over the 3-year program window, the awardee will be required to refund to the government the amount of excess expenditures made under [the demonstration] up to the full amount of any care management fees paid to the awardee.... Also, we may require organizations to make fee refunds to the government based on interim performance monitoring results or we may specify in agreements some other mechanism to limit our exposure, but the final financial settlement will be based on 3-year program performance.

Id. at 14-15.

In January 2005, Texas Tech – as part of a consortium with Texas Tech University Health Sciences Center (TTUHSC) and TrailBlazer Health Enterprises, LLC (TrailBlazer) – filed an application to participate in the CMHCB program. TT Ex. 2. Texas Tech proposed to use multi-disciplinary care managers to improve physician-patient relationships and coordinate patient care – with the goal of reducing emergency room visits and hospitalizations and encouraging and enabling Medicare beneficiaries to take an active role in managing their illnesses. *Id.* at iii-iv, 6-14. The proposed project, which Texas Tech planned to implement across a 48-county area, was called Texas Senior Trails. *Id.* at ii. (Henceforth, we use the name "Texas Tech" to refer interchangeably to the project's consortium, its constituent members, or the demonstration project itself.)

CMS approved Texas Tech's proposed project and the projects of five other CMOs. TT Ex. 3. In January 2006, Texas Tech entered into the Demonstration Agreement with CMS to carry out Texas Senior Trails. TT Ex. 5; CMS Ex. 6. The agreement specified a three-year "award period" (the period during which Texas Senior Trails would operate) commencing on the date requested by Texas Tech (which was April 1, 2006). TT Ex. 5, at 2, ¶ 4; CMS Ex. 9. As proposed by Texas Tech, CMS agreed to pay "per member per month" (*i.e.*, per-beneficiary-per-month) care management fees during the award period. TT Ex. 5, at 3, ¶ 11.

The Demonstration Agreement's "terms and conditions" include "policies and procedures" found in various "CMS Operational Protocols," which were attached as appendices to the agreement. *Id.* at 2, ¶ 3. One of the protocols, called the Population Protocol, states that Texas Tech was responsible for delivering care management (under its approved model) to an "intervention group" of Medicare beneficiaries that would be assigned to Texas Senior Trails at the start of the project and selected in accordance with the protocol's procedures, methods, and criteria. *Id.* at 7, ¶ 1.1. The Population Protocol further states that the "impact" of Texas Tech's project on the intervention group would be "evaluated against a **comparison group** selected either by randomization where feasible or by a matched control cohort." *Id.* (emphasis in original).

Another protocol, called the Evaluation Protocol, states that an "independent evaluator" under contract with CMS would "evaluate the experience of the intervention group . . . compared to the relevant comparison group" and help CMS "design[] features for a suitable comparison group." *Id.* at 28, ¶ 5.1. As noted, Texas Tech's care management model required the use of a "matched control cohort" in lieu of a control group defined by random selection. Concerning that study element, the Evaluation Protocol states:

For a matched control cohort, the [independent] evaluator will specify the approach to be used in identifying such cohort. For each site that is not randomized, attention will be given to ensuring the matched control cohort represents an appropriate comparison group that is specific to the intervention model. [Texas Tech] will have the opportunity to review and agree to the approach that is proposed by the evaluator and CMS. CMS and [Texas Tech] will mutually agree on the criteria and methodology used to select the relevant comparison group pursuant to a memorandum from the evaluation contractor documenting these methods and written documentation from [Texas Tech] stating its agreement with such memorandum.

Id. RTI International (RTI) was the CMHCB demonstration program's independent evaluator. A second CMS contractor, Actuarial Research Corporation (ARC), was also involved in implementing and monitoring the progress of the program and in performing a post-termination financial reconciliation of the program outcomes.

Consistent with CMS's solicitation, the Demonstration Agreement, together with an appended Financial Letter of Agreement, provides that Texas Tech would be "financially responsible" for any failure by the project to achieve "5% net savings over the three-year demonstration as defined by [the agreement's] Financial Protocol" and that Texas Tech had pledged its "full assets to cover any losses from its participation in the demonstration up to but not exceeding the total CMS payments [*i.e.*, care management fees paid] to [Texas Tech] under the demonstration []." Id. at 5 (¶ 20), 35 (emphasis omitted). The Demonstration Agreement also states that Texas Tech had "agree[d]" to a financial "reconciliation" methodology, described in the Financial Protocol, for determining the amount of Medicare savings achieved and any resulting liability to repay care management fees. Id. at 4, ¶ 12. In general, that methodology called for "comparing the intervention group's aggregated cost of care plus the fee paid to [Texas Tech] with a target cost of care based on the experience of a comparison group." Id. at 19, ¶ 4.1; see also id. at 19-26, ¶¶ 4.2, 4.5-4.13 (specifying data, methods, and formulae to be used to measure Medicare savings achieved by the project and calculate Texas Tech's repayment liability).

In the event of Texas Tech's early "withdrawal" from, or "termination" of its participation in, the project, the Demonstration Agreement provided that financial reconciliation would "follow the process outlined in the . . . Financial Protocol . . . for the period that [Texas Tech] participated in the demonstration." *Id.* at 5, ¶ 18 (emphasis omitted); *see also id.* at 26, ¶ 4.13. Section 4.13 of the Financial Protocol explains:

If [Texas Tech] chooses to terminate its participation before the end of the planned 36-month demonstration period, then the final reconciliation will be made within 12 months of the termination date. *Early program termination does not relieve [Texas Tech] of an obligation to meet its savings guarantees or to refund [care management] fees* up to the full amount of . . . fees received. . . . If termination is at [Texas Tech's] request, any refund necessary to achieve required savings will be determined on the same basis as a [Texas Tech] termination at the end of three years.

If CMS terminates [the demonstration project] early or in the event that [Texas Tech] and CMS mutually agree to terminate the program, then the savings guarantee will be calculated on a pro rata basis related to CMO projections for savings in the period of CMO operations that has elapsed as of the termination date. . . .

Id. at 26 (emphasis added). Under the reconciliation methodology specified in the Financial Protocol, the "savings guarantee," or level of "required savings," was no less than the amount of care management fees paid to Texas Tech during the project's period of operation.²

REQUIRED SAVINGS (in dollars) = $FEE_{Total} + [NS\% x ME(C)]$, where

FEE_{Total} = total care management fees paid;

NS% = the applicable "net savings" percentage (which was five percent for projects operated for 31-36 months or some lesser percentage for projects operated for shorter periods, as specified in section 4.13 of the Financial Protocol); and

ME(**C**) = the amount of the comparison group's Medicare costs during the demonstration project's operation.

² The Financial Protocol instructed CMS to calculate required savings by applying the following formula:

TT Ex. 5, at 24-25 (¶¶ 4.9-4.11) and 26 (¶ 4.13). The Financial Protocol also included "shared savings" provisions for additional payments to be made in the event net savings higher than 5 percent were achieved. *Id.* at 26-27, ¶ 4.14.

Correspondence, memoranda, and other documents submitted by the parties indicate that during the five months leading up to the April 1, 2006 start date of Texas Senior Trails, Texas Tech worked collaboratively with CMS and its contractors to develop mutually acceptable criteria and methods to define and select the project's study groups.³ The parties' deliberations and negotiations concerning the study groups are described in detail in the affidavit of David M. Bott, Ph.D., a CMS Supervisory Social Science Research Analyst with expertise in research and evaluation methods who oversaw the evaluation of the CMHCB demonstration projects. *See* CMS Ex. 18, at 1 (¶ 3), 2 (¶ 5), 3 (¶ 7), 5-9 (¶¶ 9-11).

In accordance with the Evaluation Protocol, CMS's independent evaluator, RTI, proposed an approach to defining and selecting the project's study groups. In part, that approach called for Medicare beneficiaries eligible for the project's services to be assigned to (or identified with) physician group practices (PGPs) – either a Texas Tech-affiliated PGP if the beneficiary was a member of the intervention group, or a similar non-Texas Tech-affiliated PGP if the beneficiary "loyalty." *See* CMS Ex. 15; TT Ex. 12. Loyalty in this context refers to how much of a beneficiary's healthcare is obtained from the assigned PGP during the period of interest. *See* CMS Ex. 15, at 2, 4. There was concern that loyalty (or attachment) to a PGP might differentially influence the amount of Medicare costs incurred (or the growth rate of such costs), biasing the results of the intervention in one direction or the other.⁴

³ See CMS Ex. 4 (January 2006 memorandum from Texas Tech to CMS identifying "several areas of question, concern or update" concerning the project's intervention group); CMS Ex. 8, at 1 (indicating that CMS was awaiting data from Texas Tech to help it define the comparison group); CMS Ex. 11 (CMS contractor ARC's March 14, 2006 memorandum setting out the methodology for selecting the starting intervention population "based on criteria set forth by Texas Tech"); CMS Ex. 12 (Texas Tech's March 23, 2006 memorandum stating that Texas Tech accepts ARC's methodology as discussed in its March 14, 2006 memorandum); TT Ex. 17, at 4 (step 4) and 6 (step 8) (discussing the selection of the intervention group); see also CMS Ex. 18 (Bott Affidavit), at 3, ¶ 7.g (stating that CMS, its contractors, and CMOs participated in "regular meetings" in order to "identify parameters of intervention and comparison populations" and discuss other issues relating to the CMOs' projects).

⁴ An intervention group that was more loyal to its assigned (Texas Tech-affiliated) group practices than the comparison group was to its assigned practices might use comparatively more health care services, "thereby creating a bias against the CMO." CMS Ex. 15, at 4. On the other hand, loyalty might serve to "reduce[] costs through the ability of the CMO to provide preventive and early intervention care, and to reduce fragmentation and redundancy in care, in which case the actual comparison would be biased in the CMO's favor." *Id.*

In late November 2005, RTI provided Texas Tech with a memorandum describing criteria and "recommended procedures" for creating the comparison group, including statistical procedures intended to ensure that "baseline" Medicare costs for both intervention and comparison groups were comparable. CMS Ex. 18, at 7, ¶ 10.c; TT Ex. 12. The November 2005 memorandum also elicited input from Texas Tech. TT Ex. 12, at 2. RTI asked Texas Tech, for example, whether it was "feasible to draw a comparison group within your intervention targeted geographic area" and, if not, to suggest "alternative areas." *Id.* (question 1). RTI also asked Texas Tech to comment on the PGP-based approach to defining the study groups. *Id.* (question 2). In addition, RTI asked Texas Tech to identify any factors, other than "cost equivalency," that it thought important to ensure "comparability between the intervention and comparison groups." *Id.* (question 3).

Between November 2005 and early April 2006, Texas Tech expressed various concerns about RTI's proposed criteria and methods, prompting RTI to "propose successive alterations." CMS Ex. 4; CMS Ex. 18, at 3-4 (¶ 7.g), 5-7 (¶ 9), 7-8 (¶ 10.d-.g), 8-9 (¶ 10.k-.l). On April 4, 2006, RTI issued a revised criteria-and-methods memorandum, one that apparently incorporated the changes made in response to Texas Tech's concerns. TT Ex. 18, at 8, ¶ 10.k; CMS Ex. 21. The April 4, 2006 memorandum indicates that CMS and its contractors identified a comparison group using procedures that "parallel[ed] the procedures used to identify beneficiaries in the intervention group." CMS Ex. 21, at 1. The memorandum explains that a "loyalty algorithm" was used to identify a pool of Medicare beneficiaries who were associated with non-Texas Techaffiliated PGPs and whose group-practice loyalty was comparable to that of the intervention group. Id. at 3-4. The beneficiaries in that pool were eligible for the comparison group if they resided in the 48-county area served by Texas Senior Trails, had either high Medicare costs (during a 12-month baseline period), or high disease severity (as measured by Hierarchical Conditions Category (HCC) risk scores), and met certain other "inclusion" or "exclusion" criteria. Id. at 2, 5. Beneficiaries meeting these threshold criteria were then selected for the comparison group by matching them to intervention group beneficiaries along five "payment quintiles" (Medicare cost strata), with the objective being "to select a group of comparison beneficiaries whose baseline [Medicare] costs [were] equivalent to those in the intervention group." Id. at 4. "After matching on the basis of the 5 cost strata," CMS identified a comparison group whose baseline per-beneficiary Medicare costs were \$1,733 per month, 4.5 percent lower than the intervention group's baseline Medicare costs of \$1,814 per beneficiary. Id.

The parties discussed the April 4, 2006 memorandum in an April 13, 2006 conference call, during which Texas Tech raised additional concerns. TT Ex. 18, at 8-9, ¶ 10.1. Texas Tech also asked for – and on April 18, 2006 CMS produced – "additional descriptive statistics on key health status and payment variables for the comparison and

intervention samples." *Id.*; CMS Ex. 22. On April 24, 2006, Texas Tech notified CMS of its "acceptance of [the] analysis and methodology for selecting the comparison population for the Texas Senior Trails Project" as set out in RTI's April 4, 2006 memorandum. CMS Ex. 14.

As noted, Texas Tech began operating its project on April 1, 2006. The first six months of the project were known as the "outreach" phase, a period during which interventiongroup members were contacted to obtain their consent to receive the project's care management services. From April through September 2006, Texas Tech received monthly care management fees for each member of the intervention group. TT Ex. 14, at 12. Afterward, Texas Tech received care management fees only for those beneficiaries who consented to participate and only during the periods of participation. *Id.*

During December 2006, Texas Tech discussed with CMS whether it could obtain from TrailBlazer, its consortium partner, Medicare claims information concerning the intervention group and a "pseudo" comparison group. TT Ex. 22. (In addition to being Texas Tech's partner, TrailBlazer was, and still is, a Medicare administrative contractor and thus a custodian of Medicare claims information. TT Ex. 2, at ii.) CMS advised Texas Tech that it was not entitled to obtain Medicare claims data for a pseudo comparison group. TT Ex. 22. CMS also advised Texas Tech that it could not obtain claims data from TrailBlazer concerning the intervention group until it submitted a "Data Sharing Agreement" and CMS approved the agreement. *Id.* Texas Tech asserts that it sent CMS a draft Data Sharing Agreement (or Data Use Agreement) for TrailBlazer's Medicare claims information but that CMS did not approve the agreement until May 2007. TT Ex. 10, at 4, ¶ 9.

Meanwhile, on February 22, 2007, ARC reported preliminary financial results for Texas Senior Trails based on Medicare claims data from the project's first six months (April 1 through September 30, 2006). TT Ex. 14, at 1. ARC found that, without accounting for two adjustments mentioned in the next two sentences, the intervention group's Medicare costs during the outreach period were 14 percent higher than Medicare costs for the comparison group. *Id.* at 5. To that finding ARC applied a 5.8 percent "baseline adjustment" in order to account for the fact that, during a one-year "base period" prior to the start of the project (a base period different from the one used to match the study groups), the intervention group's Medicare costs were 5.8 percent higher than the

comparison group's Medicare costs.⁵ *Id.* at 6; *see also* CMS Ex. 18, at 10, ¶ 13.a. Factoring in the baseline adjustment, and a separate adjustment for outliers, ARC calculated that the intervention group's Medicare costs during the project's first six months were seven percent higher than the comparison group's Medicare costs. TT Ex. 14, at 6, 11 (Table 6). ARC noted that the "financial results for services incurred by members of the intervention group and comparison group" were "not complete." *Id.* at 1. ARC also commented that its findings covered only the six-month period during which Texas Tech was engaged in contacting and recruiting Medicare beneficiaries (from the intervention group) to participate in its care management program, and that it was therefore "likely that the full impact of Texas Tech's [care management] program [was] not reflected in the operational data to date." *Id.*

On March 7, 2007, Texas Tech, CMS, and CMS's contractors held a telephone conference to discuss the findings in ARC's report. TT Ex. 18. Notes of the conference (evidently prepared by Texas Tech) reflect "TST [Texas Senior Trails] concern" about data from September 2004 through September 2006 that "[did] not show parallel rates of [Medicare] claims and utilization between the intervention group and the comparison group":

... At the beginning, ... about a 4% adjustment [was needed] to make the groups equivalent (9/1/04 through 8/31/05 data); true adjustment using 4/1/05 through 3/31/06 data returns a 5.8% adjustment necessary; *first 6 months monitoring report shows a 14% differential* between the two groups, despite minimal interventions having been employed during this time (enrollment and assessment activities)....

⁵ The Demonstration Agreement's Financial Protocol required CMS to make the baseline adjustment. TT Ex. 5, at 24, \P 4.9. Dr. Bott explained the adjustment's purpose:

Once the demonstration began, it would be impossible to determine if the intervention population costs changed because of the TST program or some other factors. Therefore, the baseline period was used to compare differences in total costs between the two. The assumption made in the [Demonstration Agreement's] terms and conditions, was that the difference observed in the baseline would continue throughout the demonstration period even if the intervention never occurred. In other words, after the total intervention and comparison group costs were summed, the comparison group's expenditures were multiplied by 1.058 before the difference between the two groups was assessed....

CMS Ex. 18, at 10, ¶ 13.b.; *see also id.* at 10, ¶ 13.a (stating that the baseline period against which the project's financial performance was measured was from April 1, 2005 through March 31, 2006). Dr. Bott further explained that the ratio of 1.058, *i.e.*, the ratio of expenditures in the intervention population compared to the comparison group, meant that the intervention group had 5.8 percent higher expenditures than the comparison group during the baseline period. Stated differently, during the baseline period, for every dollar spent caring for a comparison group beneficiary, \$1.058 was spent caring for an intervention group beneficiary. *Id.* at 10, ¶ 13.a.

Id. (emphasis added). The conference notes indicate that the parties discussed population characteristics that may have contributed to the reported Medicare cost disparity and that Texas Tech was advised by CMS to request "further analyses" in writing. *Id.*

Between March and May 2007, CMS and its contractors analyzed data and reviewed analyses provided by Texas Tech in order to understand the source of the cost disparity reported by ARC. *See* TT Ex. 15, at 2; TT Ex. 21, at 2-3. Among other things, CMS attempted to measure the effect of removing certain types of beneficiaries or claims from the cost calculations.⁶ CMS concluded that the "overall analyses showed an insignificant [Medicare cost] differential as compared to the . . . results" of ARC's February 2007 report and that "[n]o single factor in the analyses explained the differential in the report." CMS Ex. 15, at 2.

In a May 18, 2007 memorandum addressed to CMS, Texas Tech continued to express concern that the comparison group was not a "validly matched control," citing the "widening differences in Per Beneficiary Per Month (PBPM) costs" between the baseline and outreach periods. TT Ex. 20, at 1. Texas Tech stated that it "was confident when the original project proposal was submitted and the contract to participate in the [CMHCB] demonstration was accepted, that the objectives of the demonstration could be met when compared to a matched Comparison Group." *Id.* Texas Tech further stated that "[d]espite [the] concerns [it] voiced at the time of the Comparison Group selection discussions, [it] was assured by CMS and RTI that the methods used should result in comparable populations for the purposes of the demonstration."⁷ *Id.*

TT Ex. 15, at 2; CMS Ex. 1, at 8.

⁶ An April 16, 2008 CMS letter, a copy of which was submitted by both parties, summarized the efforts made between March and May 2007 to understand the reason(s) for the "disparity" in Medicare costs between the intervention and comparison groups:

The selection of analyses performed was agreed upon with TST as pertinent. The multiple analyses included a cost comparison to determine a true-up to set the same date of eligibility for intervention and control; a cost comparison after true-up as if hospice claims costs were removed; and an analysis of the Hierarchical Conditions Category scores of risk trend over time and cost comparison after removing beneficiaries who died or were in nursing homes and skilled nursing facilities. In addition, TST presented a Diagnosis Related Group (DRG) analysis on base DRG factors for Medicare Disproportionate Share (DSH) and Independent Medical Education (IME) showing costs disproportionately high for intervention vs. control. . . .

⁷ Texas Tech stated in its May 18, 2007 memorandum that it had voiced its concerns about the comparability of the study groups "throughout the term of the demonstration to CMS personnel at numerous levels," and that its concerns had been "documented in a memo to CMS on March 12, 2006." TT Ex. 20, at 1. Neither party submitted a copy of the March 12, 2006 memorandum for the record.

Texas Tech's May 18, 2007 memorandum presented a statistical analysis of various demographic and other characteristics of the selected study groups. *Id.* at 3-11. Texas Tech stated in the memorandum that the statistical analysis showed that "differences exist on multiple significant levels between" the intervention and comparison groups and that the differences collectively explained the Medicare "cost and utilization differentials" between the groups. Id. at 1, 3, 11; see also TT Ex. 10, at 9-10, ¶ 17. The "only possible conclusion" to be drawn from that analysis, said Texas Tech, was that "[t]he Comparison Group [was] not properly matched to the Intervention Group on several impactful dimensions." TT Ex. 20, at 11. Accordingly, Texas Tech asked CMS to "choose a new and different Comparison Group that is matched on important factors such as age, disability status, HCC distribution, diagnoses, nursing home status, and zip code of residence, as well as the high cost factor." Id. (italics omitted). (Texas Tech stated that "[l]oyalty to other groups was not one of the factors [it] found important when the original Comparison Group was chosen, and it need not be a factor in choosing an appropriately matched group now." Id. (italics omitted).) Texas Tech also asked CMS to extend the demonstration period by at least five months – from April 1 through August 31, 2009 – to compensate it for time devoted to "finding solutions" for the study groups' "cost differences," which it characterized as a "mortal threat to the continuation of the demonstration." Id. at 12.

Texas Tech suggested in the May 18, 2007 memorandum that the application of statistical methods, in lieu of selecting an entirely new comparison group, might suffice to correct what it regarded as significant health, service utilization, and other differences between the study groups but that "test[ing] of baseline timeframe data for [the] Comparison Group would be necessary . . . to assure that the sample bias that is currently observed had indeed been adequately addressed." *Id.* Texas Tech commented that "[a] major obstacle" to the alternative approach was "the fact that [it] does not have access to Comparison Group [Medicare] claims data prior to April 1, 2006, making appropriate adjustment testing impossible." *Id.* at 1. According to Texas Tech, either of its proposed solutions – selecting an entirely new comparison group, or statistically aligning the existing study groups – would "require extensive work by all parties, and adequate time to allow TST to properly move forward" *Id.* at 13.

In a May 31, 2007 memorandum, CMS responded that "producing a new Comparison Group for the [Texas Senior Trails] demonstration [was] not feasible, and [that] an extension of program operations [was] not within current authority." TT Ex. 21. CMS also stated:

CMS has investigated the disparity in costs and utilization reflected in [ARC's February 22, 2007] report. These analyses fail to provide any reasonable adjustments that could produce a match between the Intervention and Control Groups throughout baseline periods that mitigated disparities during the first 6 months of program operations.

In conclusion, CMS will not modify the Texas Senior Trails Intervention and Comparison Group populations as proposed by Texas Senior Trails.

Id.

On June 1, 2007, Texas Tech sent CMS a letter which states:

This letter relates to joint recognition on the part of CMS and Texas Tech Physician Associates (TTPA) that it is necessary to end Demonstration Agreement No. 95-W-00182/6. Like CMS, we regret that it has become necessary to terminate the program, but we concur with CMS that this step has become necessary due to concerns about the validity and viability of the demonstration....

The underlying need for this decision is the finding that there has not [been] a comparable match between the costs and utilization patterns of our TST intervention group and those of the comparison group against which our performance was to be measured since the inception of the demonstration. As no solution has been found that can rectify the disparities, as discussed in our telephone conference this afternoon, TTPA concurs with CMS that no option remains beyond termination of the demonstration.

CMS Ex. 1, at 1.

On June 28, 2007, CMS acknowledged what it called Texas Tech's "formal notice to withdraw" from the CMHCB program and advised Texas Tech that a "[f]inal financial reconciliation" would be performed in accordance with the Demonstration Agreement's Financial Protocol. *Id.* at 2.

CMS (through its contractor, ARC) performed the final reconciliation and in July 2008 issued a report of its findings. CMS Ex. 16. CMS found that Texas Tech had received \$7,988,526 in care management fees during the life of its demonstration project. *Id.* at 4. CMS further found that the Demonstration Agreement required Texas Senior Trails to achieve Medicare savings of \$10 million in order for Texas Tech to avoid full or partial repayment of care management fees. *Id.* In other words, CMS found that the project's Medicare costs (including care management fees) needed to be approximately \$10 million less than the comparison group's Medicare costs in order to avoid repayment liability. *Id.* CMS calculated that the intervention group's Medicare costs were actually \$6.79 million *higher* than the comparison group's costs, resulting in a total "savings shortfall" of \$16.79 million. *Id.* Because the savings shortfall exceeded the amount of care management fees it had received. *Id. at* 4; CMS Ex. 1, at 16.

After withdrawing from the demonstration, Texas Tech asked a consulting firm, Solucia Consulting, to investigate the reasons for the Medicare cost disparity between the study groups. TT Ex. 10, at 5, ¶ 11; CMS Ex. 18, at 11, ¶ 13.c. Solucia issued a report in October 2008. TT Ex. 16. Based on an analysis of *non-project-related* Medicare claims data, Solucia identified two main concerns that, in its view, required further study by CMS. The first concern, mirroring the one expressed in Texas Tech's May 18, 2007 memorandum, was that differences in the health status and socio-demographic profile of intervention and comparison group members may have resulted in the groups having systematically different Medicare cost trends. *Id.* at 3 (urging that CMS perform analysis "to verify that the [cost] trend of the comparison group is an adequate proxy for the trend of the intervention group by looking at historical comparisons"). The second concern was that bias may have been introduced into the study by the fact that the intervention group "had a much larger percentage of members who died (14.4%) than the control group (10.9%)." *Id.* at 5. Solucia's report offered various recommendations about how these (and other related) issues should be studied.

Using "actual TST data," RTI evaluated Solucia's concerns and presented its findings to CMS in November 2008. CMS Ex. 17. RTI "confirmed that the intervention group became more expensive over the demonstration period compared to the comparison group during the baseline period and during the demonstration period." CMS Ex. 18, at 11, ¶ 13.e.; *see also* CMS Ex. 17, at 2 (finding that "PBPM costs for Texas Tech beneficiaries increased 8.7 percentage points faster than in the comparison group"). RTI also acknowledged that there were inter-group "differences in the frequencies" of some socio-demographic characteristics (such as mortality). CMS Ex. 18, at 11-12, ¶ 13.f; *see also* CMS Ex. 17, at 8. However, RTI found that those differences "were not of sufficient magnitude and impact in the TST populations and thus [could not] explain the observed [Medicare cost] differences shown in ARC's final reconciliation report, nor did they account for all the differences in the RTI model."⁸ CMS Ex. 18, at 12, ¶ 13.g; *see also* CMS Ex. 17, at 11. In short, RTI concluded "that group differences in these beneficiary characteristics cannot account for the estimated Texas Tech intervention effect of high, not lower, cost growth." CMS Ex. 17, at 11.

CMS Ex. 18, at 11-12, ¶ 13.f.

⁸ Dr. Bott explained that the "magnitude of the impact" of a group difference was "dependent upon the relative numbers of beneficiaries" in each group with the characteristic of interest, rather than on the relative "frequency" of that characteristic's occurrence in each population:

For example, a large impact for a particular characteristic, e.g., institutionalized versus community-based, may be observed in a model explaining expenditures for beneficiaries, but if there are relatively few institutionalized beneficiaries in either group, even large differences in [the] proportion of beneficiaries with that characteristic, e.g., double the number in one group, may reflect small actual counts, e.g., 10 versus 5 beneficiaries respectively, and thus have a minimal impact on the estimates of total expenditures that involve thousands of beneficiaries in each group.

On March 6, 2009, CMS demanded that Texas Tech refund the \$7,988,526 in care management fees paid under its demonstration project, asserting that Texas Tech was obligated to return "100 percent of fees paid" because it "chose to withdraw early from the demonstration." CMS Ex. 1, at 16. Texas Tech resisted the demand, asserting that "CMS's failure to perform its obligation to provide a matched Comparison Group renders a legitimate comparison between the Intervention Group and Comparison Group impossible, thereby excusing TTPA from having to repay administrative fees." *Id.* at 14; CMS Ex. 3, at 1. Texas Tech also asked CMS to perform additional analysis (namely, a "detailed mortality analysis") and produce "comprehensive" Medicare claims data on the study groups in order to enable Solucia to make a "proper assessment of the information given to the [Texas Senior Trails] program." CMS Ex. 3.

CMS responded to these requests on April 3, 2009:

CMS is unable to comply with your request for claims data regarding the TST program. We agreed to have RTI perform additional analysis of factors that TST representatives suggested as potentially significant influences on the intervention and comparison groups' per-beneficiary-per-month (PBPM) estimates. As indicated in the analysis, there was no significant difference that would explain the large disparity between the groups during the program term.

CMS has provided TST with the data referenced in the Terms and Conditions of the demonstration agreement. As we have previously communicated, CMS worked collaboratively with TST to develop the comparison population and provided additional analyses resulting in a new comparison group methodology sent to TST from RTI on April 4, 2006, to determine any avoidable differences between the intervention and comparison groups PBPM [per-beneficiary-per month Medicare costs]. The methodology for selection of the comparison population was collaborative and iterative and was accepted by TST and CMS. At this time no further data on the comparison group will be released....

TT Ex. 13, at 1.

CMS renewed its repayment demand in a September 5, 2013 letter. TT Ex. 9. CMS stated that its "demand letter, in combination with the Final Reconciliation Report," represented its "final decision" in the matter. *Id.* at 2.

II. <u>Discussion</u>

As noted in this decision's introduction, Texas Tech asks us to resolve its dispute with CMS by applying common law contract doctrines. *See* Texas Tech's Appeal, Statement of Facts and Argument and Authorities (TT Br.). We conclude, for the reasons set out in part A of this section, that those doctrines are inapplicable and that our task is limited to deciding whether the terms and conditions of the Demonstration Agreement obligate Texas Tech to refund care management fees given the circumstances of its participation and withdrawal from the CMHCB demonstration.

In part B, we hold that because Texas Tech proceeded with its demonstration project based on its agreement to the methods and criteria for selecting the study groups, the Demonstration Agreement required the project to achieve \$10 million in Medicare savings and also required Texas Tech to refund care management fees to make up any savings shortfall. In addition, we find that Texas Senior Trails did not achieve any required Medicare savings, thereby obligating Texas Tech to refund all of the care management fees it received to operate the demonstration project.

In part C, we consider but reject Texas Tech's contentions that CMS was obligated under the Demonstration Agreement to select a "comparable" comparison group and that CMS was precluded from recouping care management fees because it failed to fulfill that presumed obligation.

In parts D through F, we briefly consider certain factual contentions – *e.g.*, that differences between the study groups invalidated the demonstration project, that CMS failed to share Medicare claims data and other information, and that CMS failed to cooperate with Texas Tech to ensure successful completion of the project – that underlie Texas Tech's contract law claims. We review those contentions only to determine whether they provide grounds for relief under the terms and conditions of the Demonstration Agreement, not for the purpose of deciding whether they support Texas Tech's common law contract theories because, as we state herein, those theories are inapplicable to the dispute between Texas Tech and CMS. In general, Texas Tech's factual contentions are irrelevant or immaterial because the Demonstration Agreement does not make CMS's (or its contractors') performance a condition for enforcing Texas Tech's Medicare savings guarantee. In any event, the contentions are largely unsubstantiated by the evidence by record.

Finally, in part G, we consider but reject Texas Tech's equitable estoppel claim.

A. Common law contract theories are inapplicable in deciding Texas Tech's rights and obligations under its Demonstration Agreement.

Texas Tech asserts that it should be excused from complying with any refund obligation because CMS breached certain "contractual" obligations created by the Demonstration Agreement.⁹ TT Br. at 6-8. In addition to alleging a breach of contract, Texas asserts various other contract law claims or defenses, including breach of an implied covenant of good faith and fair dealing, unilateral and mutual mistake, and impossibility. *Id.* at 9-13. Texas Tech further suggests that an appropriate remedy in these circumstances would be "reformation" of the Demonstration Agreement "to provide that . . . repayment [of care management fees] will not be required if implementation of the methodology did not result in a 'comparable' Comparison Group based on scientific standards." *Id.* at 10-11. CMS responds, and we agree, that Texas Tech's analytical framework is incompatible with the Board Chair's determination that the Demonstration Agreement is a grant agreement.

While it is true that a federal grant may have characteristics of a contract,¹⁰ such as terms which impose mutual and legally enforceable obligations, the analogy of a grant to a contract is imperfect. Traditional contract elements of mutual intent and bilateral bargaining are often absent when a federal grantee receives financial assistance subject to conditions dictated by federal law or policy:

Rather than a voluntary agreement negotiated between two parties, a grant-in-aid program . . . is an exercise by the federal government of its authority under the spending power to bring about certain public policy goals. The government acts by inducing a state or private party to cooperate with the federal policy by conditioning receipt of federal aid upon compliance by the recipient with federal statutory and administrative directives. The 'conditions' of this arrangement are not the result of a negotiated agreement between the parties but rather are provided by the statute under which the program is administered. Determination of statutory intent, therefore, is of more relevance to the interpretation of these conditions than is an inquiry into the intent of the two parties at the moment of the initial agreement. . . .

⁹ In order to recover for breach of contract, a party must allege and establish: (1) a valid contract between the parties; (2) an obligation or duty arising out of the contract; (3) a breach of that duty; and (4) damages caused by the breach. *San Carlos Irrigation & Drainage Dist. v. United States*, 877 F.2d 957, 959 (Fed. Cir. 1989); *Hunn v. Dan Wilson Homes, Inc.*, 789 F.3d 573, 579 (5th Cir. 2015) (setting out the elements of a common law breach-of-contract claim under Texas law).

¹⁰ *Cf. Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981) (holding that grantauthorizing legislation enacted pursuant to Congress's spending power is "much in the nature of contract," and that "if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously").

American Hospital Assoc. v. Schweiker, 721 F.2d 170, 182-83 (7th Cir. 1983) (citation omitted), *cert. denied*, 466 U.S. 958 (1984).

For these reasons, courts have held that straightforward or wholesale application of common law contract doctrines is inappropriate in determining a party's rights and obligations under a federal grant. American Hospital Assoc., 721 F.2d at 183 (stating that the "contract analogy [to federal grants] has only limited application"). In Bennett v. Kentucky Department of Education, a case before the Supreme Court, the state of Kentucky argued that a federal-state grant agreement was in the nature of a contract, and, for that reason, ambiguities concerning the state's obligations under the agreement should be resolved against the party which drafted it (namely, the federal government). 470 U.S. at 656, 666 (1985). The Court rejected the proposition that "ambiguities in the requirements [of the grant] should invariably be resolved against the Federal Government as the drafter of the grant agreement." Id. at 669. Although it agreed that the relevant grant agreement had a "contractual aspect," the Court held that the agreement "[could not] be viewed in the same manner as a bilateral contract governing a discrete transaction" because "[u]nlike normal contractual undertakings, federal grant programs originate in and remain governed by statutory provisions expressing the judgment of Congress concerning desirable public policy." Id.

Lower courts have also recognized limitations on applying contract law doctrines to disputes involving federal grants. *See*, *e.g.*, *Md. Dept. of Human Resources v. Dept. of Health & Human Servs.*, 762 F.2d 406, 408-09 (1985) (holding that the "impossibility of performance" doctrine "relates to commercial contracts and not to grant in aid programs"); *American Hospital Assoc.*, 721 F.2d at 182-83 (rejecting an argument that regulations had impaired the contractual rights of hospitals under a federal grant program, and stating that "the relationship between the government and the hospitals here cannot be wholly captured by the term 'contract' and the analysis traditionally associated with that term"); and *cf. United States v. Vanhorn*, 20 F.3d 104, 111-12 (1994) (affirming a district court's refusal to entertain contract law defenses raised by the recipient of a National Health Service Corps scholarship who had failed to fulfill certain conditions of the scholarship specified in signed written agreements with HHS, stating that the agreements "were all governed by statute and did not create a contractual relationship separate from that statute," and further noting that the underlying "statutory scheme . . . [was] more analogous to" federal grant-in-aid programs).

The Board has also held that contract law doctrines do not dictate its analysis or resolution of disputes involving federal grants. In *New York State Department of Social Services*, the Board, while acknowledging that "there are some ways in which a grant is like a contract," rejected a grantee's request to overturn a grant disallowance based on the contract law doctrine of substantial performance. DAB No. 1358, at 23 (1992). And in *Iowa Department of Human Services*, a case involving Medicaid (a mandatory grant

program), the Board declined to apply the contract remedy of reformation to resolve a dispute concerning the terms of Iowa's state plan, noting that the reformation remedy "was developed largely for commercial contracts and does not directly apply here." DAB No. 1248, at 16 (1991).

There are also practical obstacles to analyzing the dispute as if it involved an ordinary contract. A breach of contract claim would, if sustained, ordinarily lead to a consideration of the non-breaching party's "damages." However, Texas Tech identifies no authority under which damages could be awarded at all under the governing statutes or regulations, much less by the Board. Similarly, the imposition of equitable contract remedies (such as reformation) is unavailable in Board proceedings. *See Camden County Council on Econ. Opportunity*, DAB No. 881, at 7-8 (1987) ("The Board is bound by all applicable laws, and cannot invent equitable remedies without a basis in law."); *The Children's Center, Inc.*, DAB No. 2506, at 8 (2013) ("The Board is not authorized to reverse a disallowance based on equity.").

Texas Tech asserts that "[t]he Board does utilize the common law of contracts when appropriate." Reply Br. at 3. In recognition of the contractual aspects of a grant or cooperative agreement, the Board may, in appropriate circumstances, consider principles of contract interpretation (together with applicable statutes, regulations, and agency policy statements and evidence of the parties' dealings) to help it construe and apply grant terms whose meaning is unclear or ambiguous. But we are unaware of any case in which the Board resolved a grant-related dispute based on the merits of common law contract claims or defenses (such as breach of contract or mistake) or by imposing contract law remedies that were not expressly authorized by statute or regulation or by the grant's terms and conditions.¹¹

Texas Tech does not assert, or show, that the Board has done so. Texas Tech cites *Emory University*, DAB No. 9 (1975) (incorrectly cited by Texas Tech as DAB No. 14); *California Department of Social Services*, DAB No. 410 (1983); and *Mississippi Division of Medicaid*, DAB No. 1305 (1992). Reply Br. at 3-4. In none of these decisions did the Board resolve the parties' dispute on the basis of contract law theories.

¹¹ Contract claims and defenses are the province of the Civilian Board of Contract Appeals, which hears disputes arising under express or implied contracts involving various federal agencies, including HHS. 48 C.F.R. Part 333, subpart 333.2 (indicating the Secretary of HHS has designated the Civilian Board of Contract Appeals as the authorized body to hear and determine contract disputes for the Department); *see also Humanics Associates*, DAB No. 860, at 11 (1987) ("[W]e are not bound by Board of Contract Appeals decisions, even though they decide issues concerning contract provisions containing the same wording as grants provisions; special considerations may apply in grants administration which do not apply to procurement contracts"). As explained earlier, the grant agreement at issue here is properly within the Board's bailiwick, rather than that of the Civilian Board of Contract Appeals.

In *Emory University*, the Board reversed a disallowance of the interest component of the acquisition costs of computer equipment, stating that "[f]ull allowance of the challenged cost item carries out an agreement plainly made by the program, relied on in good faith by the grantee" DAB No. 9, at 4. The Board found that the auditors had been "evidently unaware" of the program's "express approval" of the arrangement at issue. *Id.* This case does not parallel Texas Tech's situation and, in any event, represents nothing more than the Board's recognizing agreed terms of a grant, not application of common law contract principles.

California Department of Social Services involved the state agency's dispute of the Commissioner of Social Security's decision concerning certain supplementary payments by the state of California to recipients of supplemental security income in accordance with a federal-state agreement under which the Social Security Administration (SSA) agreed to administer the payments under California's State Supplement Program. It is true, as Texas Tech points out (Reply Br. at 3), that the Board mentioned "the contract principle of mitigation of damages" but the Board did so only in passing and within the context of its analysis of whether the SSA properly computed the payments for certain classes of state supplementary payment recipients. DAB No. 410, at 17-18. This reference does not establish that the Board relied on common law contract principles to resolve the dispute. The mere fact that the Board may refer to a contracts law concept in the course of deciding a dispute under the applicable federal statutes and regulations does not mean the Board is applying common law contracts law.

As for *Mississippi Division of Medicaid*, a dispute involving the disallowance by the Health Care Financing Administration (HCFA), CMS's predecessor, of federal financial participation claimed by a state Medicaid agency for non-emergency transportation costs, the Board discussed estoppel, finding that the state Medicaid agency failed to substantiate the elements of estoppel but also noting that "estoppel is not available against the government on the same terms as against private parties, because different considerations come into play." DAB No. 1305, at 4. Estoppel, or the inapplicability thereof, is a general legal concept not limited to common law contracts law.

Texas Tech also cites *Guaynabo Hospice Care, Inc.*, DAB CR374 (1995). Reply Br. at 3. *Guaynabo* was a decision issued by an Administrative Law Judge (ALJ). We have no record that it was appealed to the Board. *Guaynabo* therefore may not be cited as an example of a decision in which the Board has either applied or recognized the applicability of common law contract principles. Even if *Guaynabo* had the status of precedent, which it does not since it was not a Board decision, *Guaynabo* would be inapplicable because it involved a dispute between HCFA and a hospice providing care to Medicare provider agreements and Medicare (and non-Medicare) program grants are

governed by entirely different federal statutes and regulations. Moreover, the entire decision involved the ALJ's application of the federal statutes and regulations governing provider agreements and HCFA's bases for terminating them, not common law of contracts. A Medicare provider agreement is entirely a creation of federal statutes and regulations, and the ALJ's passing analogy to contracts does not change that.

Texas Tech also questions whether CMS has any authority to demand repayment unless the Demonstration Agreement is found to be a contract. Reply Br. at 4. In fact, CMS has such authority, irrespective of whether the Demonstration Agreement created a contractual relationship.

The federal government has inherent authority to enforce valid conditions imposed on a grantee's receipt of federal funds. *See United States v. Miami Univ.*, 294 F.3d 797, 808 (6th Cir. 2002) (federal government has inherent power to sue to enforce conditions imposed on the recipients of federal grants); *United States v. Marion County School Dist.*, 625 F.2d 607, 609 (5th Cir. 1980) ("As the Supreme Court has long recognized, the United States may attach conditions to a grant of federal assistance, the recipient of the grant is obligated to perform the conditions, and the United States has an inherent right to sue for enforcement of the recipient's obligation in court."), *cert. denied*, 451 U.S. 910 (1981).

In addition, the regulations in 45 C.F.R. Part 74 authorize CMS to enforce the conditions of the Demonstration Agreement.¹² In particular, section 74.62 authorizes the awarding HHS agency to take various enforcement actions, including disallowance of costs, when the recipient "materially fails to comply with the *terms and conditions* of an award" (emphasis added). In addition, section 74.73(a) authorizes the HHS awarding agency to initiate debt collection actions to recover "[a]ny funds paid to a recipient [of an award] in excess of the amount to which the recipient is finally determined to be entitled under the *terms and conditions* of the award" (emphasis added).

In this case, CMS, exercising its authority in 45 C.F.R. Part 74, issued a final written decision which states that the "terms" of Texas Tech's award, as set forth in the Demonstration Agreement, require Texas Tech to refund \$7,988,526 to the federal government and further indicates that this amount constitutes a "debt" to the federal government. As the Board Chair's jurisdictional ruling explains, the Board is authorized

¹² During the period at issue here, the Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations in 45 C.F.R. Part 74 (Oct. 1, 2004) applied to HHS "awards" issued to those types of organizations. *See* 45 C.F.R. § 74.1 (Oct. 1, 2004). Consistent with the FGCAA's definitions of "grant agreement" and "cooperative agreement," the term "award" is defined in the Part 74 regulations to include "grants and other agreements" under which the award "recipient" receives "financial assistance . . . to accomplish a public purpose." *Id.* § 74.2.

by its regulations to review CMS's final written decision. Because that decision explicitly identifies the terms of the Demonstration Agreement as the grounds for CMS's repayment demand, our task, simply put, is to determine whether the agreement's "terms and conditions" – considered as a whole and in light of relevant facts and applicable statutes and regulations – require Texas Tech to comply with the repayment demand. *Cf. N.J. Dept. of the Human Servs.*, DAB No. 120, at 3 (1980) (noting that the Board's function is to review the appealable agency decision "based on the applicable statutes and regulations"); *Institute of Technology Development v. Brown*, 63 F.3d 445, 449 (5th Cir. 1995) (stating that while the federal demonstration grant at issue had a "contractual aspect," in that it specified terms that were binding on both grantor and grantee, the parties' dispute would be resolved by "examin[ing] the actual, binding Grant Agreements," including the agreement's "incorporated documents," as well as the "legislative history underlying the grants, and the Study ordered by Congress prior to awarding these funds").

B. The Demonstration Agreement required Texas Senior Trails to achieve Medicare savings of \$10 million or refund care management fees to make up any savings shortfall.

The Demonstration Agreement states that Texas Tech's participation in the CMHCB program was governed by the agreement's "terms and conditions." TT Ex. 5, at 1. Those terms and conditions expressly called for Texas Tech and CMS to "mutually agree" upon the criteria and methods for selecting the project's intervention and comparison groups. *Id.* at 3 (¶ 7) and 28 (¶ 5.1).

Nothing in the Demonstration Agreement required Texas Tech to operate its project if the parties failed to reach consensus on how to define and select the study groups. If the parties could not agree, then Texas Tech was free to withdraw from the CMHCB demonstration (prior to the project's start date) without penalty. But in the event the parties reached such agreement and Texas Tech proceeded to operate Texas Senior Trails on that basis, the Demonstration Agreement required the project to achieve Medicare cost savings for *any* period of operation. *See* TT Ex. 5, at 19 (¶ 4.1), 26 (¶¶ 4.12, 4.13).¹³ The agreement also informed Texas Tech that CMS would conduct "reconciliation" – a comparison of the Medicare costs incurred by the intervention and comparison groups "over the months of CMO [Texas Senior Trails'] operation" – to determine whether the project had achieved required savings. *Id.* at 21, 23-26 (¶¶ 4.6, 4.8-4.11). In addition, the

¹³ In the event that termination occurred during the six-month outreach period, the Demonstration Agreement did not require Texas Senior Trails to achieve cost savings relative to the intervention group, only savings sufficient to offset the amount of care management fees paid. *See* TT Ex. 5, at 26, \P 4.13.

Demonstration Agreement expressly required Texas Tech to refund care management fees as necessary to meet the "savings guarantee," even in the event of early termination. *Id.* at 26, ¶ 4.13 (stating that "[e]arly program termination does not relieve [Texas Tech] of an obligation to meet its savings guarantees or to refund [care management] fees").

In sum, the Demonstration Agreement provides if Texas Tech operated Texas Senior Trails for any period, as it did beginning April 1, 2006: (1) the project needed to achieve Medicare savings during its period of operation; (2) after project termination, CMS would calculate the project's required Medicare savings, and any savings shortfall, by comparing the study groups' Medicare costs; and (3) Texas Tech would assume financial liability, up to the amount of care management fees received, for failure to achieve required savings during the project's operating period.

As the background narrative shows, Texas Tech and CMS mutually agreed on the criteria and methods for selecting the study groups. Texas Tech then operated its demonstration project for 15 months. In doing so, Texas Tech assumed the obligation under the Demonstration Agreement to achieve Medicare savings during the project's period of operation or to repay care management fees as necessary to eliminate or reduce a savings shortfall.

CMS calculated, upon final reconciliation, that Texas Senior Trails was required to achieve Medicare savings of \$10 million during its operating period but that the project achieved no cost savings during that period. Texas Tech alleges no deviation by CMS from the Demonstration Agreement's reconciliation methodology in calculating the amount of required savings or the intervention group's actual savings (relative to the comparison group). Because Texas Senior Trails failed to achieve any of the required \$10 million in Medicare savings, Texas Tech is obligated to refund all of its \$7,988,526 in care management fees to offset the savings shortfall.

C. The Demonstration Agreement did not make CMS unilaterally responsible for selecting "comparable" study groups.

Texas Tech suggests that the Demonstration Agreement imposed upon CMS a unilateral obligation to "ensure" that the project's comparison group was "comparable" to the intervention group. TT Br. at 6 (\P 2), 7-8 (\P 7); Reply Br. at 8 (alleging that CMS "represented that the comparison group . . . would <u>ensure</u> comparability"). In addition, Texas Tech alleges that CMS (and its contractors) failed to meet that presumed obligation. *Id.* at 6. Texas Tech therefore contends that it has no obligation to refund care management fees.

This argument has no support in the Demonstration Agreement's text. The provision of the agreement governing the selection of a comparison group is paragraph 5.1 of the Evaluation Protocol. Nothing in that paragraph indicates that CMS promised or guaranteed study group comparability. Paragraph 5.1 indicates only that CMS's independent evaluator (RTI) would propose an "approach" for identifying a "matched control cohort," then give Texas Tech an opportunity to review and agree with the proposed approach. TT Ex. 5, at 28. Texas Tech does not allege that the independent evaluator failed to carry out those obligations.

Texas Tech implies that the seventh sentence of paragraph 5.1 of the Evaluation Protocol should be read as requiring CMS to "ensure" – or guarantee – a viable comparison group. *See* Reply Br. at 8. The seventh sentence states that when random selection of the control group is infeasible, "attention will be given to *ensuring* that the matched control cohort represents an appropriate comparison group that is specific to the intervention model." TT Ex. 5, at 28, ¶ 5.1 (italics added).

On its face, the statement only asserts that the parties will give "attention" to ensuring an "appropriate comparison group," not that either party guaranteed to ensure that the resulting group would prove comparable. Furthermore, that sentence must be read in concert with the surrounding sentences. The immediately preceding sentence states that the evaluation contractor would specify an "approach" for Texas Tech to "review." Id. The sentence which immediately follows states that Texas Tech would have the opportunity to "review and agree" with the "proposed" approach." Id. Considered in that context, the word "ensuring" merely indicates that CMS's contractor would propose criteria and methods *designed or intended* to result in the selection of a suitable comparison group (one "specific to the intervention model"). The parties would then, in paragraph 5.1's words, have to "mutually agree on the criteria and methodology used to select the relevant comparison group," language signaling the likely need for the parties to exchange views and negotiate changes to the "proposed approach." Id. Read as a whole, paragraph 5.1 does not require one party or the other to achieve a specific result; rather, the paragraph describes a process leading to the parties' mutual agreement on how to achieve that result (namely, the selection of an appropriate comparison group). Far from making one party the guarantor of a particular outcome, the Demonstration Agreement made *both parties* responsible for selecting an equivalent comparison group. Texas Tech has not proffered any evidence that the parties intended the agreement to convey a different meaning.

Texas Tech's argument is untenable for another reason: nothing in the Demonstration Agreement states that Texas Tech's obligation to achieve Medicare savings and to refund care management fees to offset any savings shortfall is contingent on the quality of the agreed-upon criteria and methods for selecting the study groups, shortcomings in the study's design and implementation, or Texas Tech's retrospective (post-selection) judgment concerning the usefulness of the selected comparison group. The agreement's Financial Protocol plainly indicates that, for <u>any</u> period of project operation, CMS would perform the financial reconciliation to determine Texas Tech's liability to refund care management fees, using the Medicare costs of the comparison group selected for the project as the benchmark for measuring required Medicare cost savings. *See* TT Ex. 5, at 21-26, ¶ 4.6 (stating that "CMS will reconcile the total payments that have been paid to the CMO with the actual savings achieved") and ¶¶ 4.9-4.11 (specifying formulae for calculating "required savings" for financial reconciliation based in part on "Medicare expenditures over the months of CMO operation for the comparison group"). The agreement further indicates that a "refund will be owed" to CMS in the event a project's "actual [Medicare] savings" is less than "required savings" during the period of operation. *Id.* at 26, ¶ 4.12. Texas Tech does not point to a relevant express condition on CMS's right to enforce the Medicare savings guarantee in these circumstances, nor does Texas Tech argue that such a condition is implied by the Demonstration Agreement's express terms.

If any implication can be drawn, it is that Texas Tech assumed the risk that it might fail to recognize flaws in the study's design or implementation and thereby jeopardize its ability to achieve cost savings and retain its fees. Like other CMOs in the CMHCB program, Texas Tech had concerns from the outset about whether the selection criteria and methodology proposed by RTI would produce a sufficiently comparable comparison group. CMS Ex. 18, at 3-4 (\P 7.g), 5-6 (\P 9), 7-8 (\P 10.e). In his affidavit, Dr. Bott indicated that CMS worked closely and diligently with Texas Tech to allay those concerns. *Id.* at 3-4 (\P 7.g), 5-9 (\P 9-10). Not all of Texas Tech's concerns were addressed to its satisfaction. *Id.* at 6, \P 9.a. However, the parties agreed, as Dr. Bott said, that, while a "perfect comparison population was not achievable within the given limits," the selection criteria and methodology accepted by Texas Tech (and described in RTI's April 4, 2006 memorandum) "addressed all significant concerns" and provided the "best chance of a fair evaluation of the TST program[.]" *Id.* at 3-4 (\P 7.g).

This unrebutted narrative strongly suggests that when Texas Tech initiated its project in April 2006, it knew that the agreed-upon selection criteria and methodology might, despite the parties' best efforts, produce a comparison group that was not equivalent to the intervention group on some population characteristics that might influence the study's results. Texas Tech proceeded despite its concerns, aware that the Demonstration Agreement placed its care management fees "at risk" in the event that its project could not be shown to have achieved Medicare savings. That risk was spelled out not only in the Demonstration Agreement but in CMS's project solicitation. CMS advised Texas Tech in the solicitation that it would have to "guarantee" the required Medicare savings. TT Ex. 1, at 25. As noted, Texas Tech's sphere of responsibility under the Demonstration group. In

these circumstances, Texas Tech could not reasonably have failed to understand (1) that it had assumed the financial risks associated with shortcomings in study design and implementation and (2) that its repayment liability would be determined using costs of a comparison group whose definition and selection it had agreed to in advance.

D. Texas Tech does not substantiate its claim that study group differences invalidated the demonstration study's results.

In her declaration, Texas Tech's Project Director Lorri Velten asserts that the differences between the study groups – "bias elements," she calls them – "invalidate the result of the Texas Tech demonstration" and that "[t]here are *too many differences* in the composition of the groups to determine what causes the [Medicare cost] disparity between the Intervention and Comparison Group." TT Ex. 10, at 7, ¶ 13.c (italics added). We understand the assertions to mean that the study groups were so dissimilar from the outset of the project that CMS could not, with *any* reasonable degree of confidence, draw conclusions about the project's effectiveness.

Ms. Velten's assertions are, for reasons mentioned earlier, immaterial. Nothing in the Demonstration Agreement makes the enforceability of the refund requirement contingent, in whole or part, on the comparability of the intervention and comparison groups, or on the extent to which valid conclusions can be drawn about the effectiveness of Texas Tech's care management model. The Demonstration Agreement's Financial Protocol calls for CMS to calculate the study groups' Medicare costs, to apply specific formulae to measure the intervention group's "required savings," and then to calculate any savings shortfall. That protocol does not require CMS to supplement these calculations with causal explanations for the observed cost differences.

In any event, Ms. Velten's opinion about the validity of the study's cost comparisons is entitled to little weight. Ms. Velten is not a statistician. She does not purport to have expertise in study design or program evaluation, and her declaration was not offered as expert opinion. She also did not cite or expressly rely on any statistical analysis to support her opinion or explain how it can be squared with RTI's unrebutted posttermination analysis, which concluded "that group differences in [certain] beneficiary characteristics cannot account for the estimated Texas Tech intervention effect of higher, not lower, cost growth." CMS Ex. 17, at 11; *see also* TT Ex. 10, at 6-7, ¶ 13; CMS Ex. 18, at 11-12, ¶ 13.f. Texas Tech's appeal brief points to the October 1, 2008 report of its "expert" (Solucia) (TT Ex. 16), but Texas Tech does not tell us whether or how Solucia's post-termination analysis supports Ms. Velten's opinion or point to evidence that any observed disparity in costs between the intervention and comparison groups was attributable to flaws in the design or composition of the two groups. In short, Ms. Velten's opinion that imbalances in the study groups entirely precluded reasonable estimates of the project's efficacy is unconvincing as well as irrelevant.

E. Texas Tech's allegations that CMS improperly denied it access to Medicare claims data are irrelevant and unsubstantiated.

Texas Tech alleges that during the course of its demonstration project, CMS denied – or unreasonably delayed – timely access to Medicare claims data (and other information). TT Br. at 3 (¶ 7), 5 (¶ 13), and 7 (¶ 6); Reply Br. at 9 (¶ 7). Because it lacked access to this data, says Texas Tech, it was denied a meaningful opportunity to evaluate "any historical analysis provided by CMS" or to "approve or test the independent evaluator's <u>implementation</u>" of the methodology used to select the comparison group." TT Br. at 3 (¶ 7) and 4 (¶ 12) (emphasis in original). And because it was allegedly denied those opportunities, Texas Tech claims that it was forced to "rely on the representations of CMS and its agents that the Comparison Group was 'comparable." *Id.* at 3, ¶ 7.

This line of argument is foreclosed by our previously stated holding that enforcement of the Demonstration Agreement's Medicare savings guarantee is not contingent on the merits of any claim that the demonstration study was flawed (either in design or execution) or that CMS failed to perform obligations other than those relating to post-termination reconciliation. In short, the allegations that CMS improperly withheld data are legally irrelevant.

The allegations are also factually unsubstantiated or fail to demonstrate a violation of the Demonstration Agreement. The allegations stem from Texas Tech's communication with CMS in late 2006 about access to Medicare claims information in the custody of TrailBlazer, its consortium partner and a Medicare contractor.¹⁴ According to a December 2006 email, Texas Tech requested Medicare data from TrailBlazer to "create [its] own pseudo comparison group." TT Ex. 22, at 1 (unnumbered). CMS notified Texas Tech that obtaining such information was "not permissible," a position that Texas Tech does not challenge in this appeal. *Id*.

The December 2006 email also indicates that Texas Tech asked CMS for access to TrailBlazer's Medicare claims data on the intervention group. TT Ex. 22, at 1 (unnumbered). In response to that request, CMS stated that, "[w]hile Trailblazer is part of the consortium of the Texas Senior Trails, the [existing] DUA [Data Use Agreement] [that Texas Tech] signed with CMS does not cover the provision of additional claims data to you from Trailblazer" and that Texas Tech would need to submit, for CMS's approval, another DUA covering the newly requested data. *Id.* CMS further advised Texas Tech that "any new DUA that may be signed between you and Trailblazer would only allow the provision of data on your intervention group" and that "no data exchange on beneficiaries outside of this group [would be] permitted." *Id.*

¹⁴ Texas Tech also suggests that CMS improperly refused to comply with its *post-termination* requests for data. *See* TT Br. at 3 (*citing* TT Exhibit 13, a 2009 letter in which CMS denied a request for claims data concerning Texas Senior Trails). The Demonstration Agreement imposed no obligation on CMS to provide data to Texas Tech after its project was terminated.

Texas Tech asserts that its demonstration project proposal "reflected that it planned to use the claims data of TrailBlazer . . . in analyses and targeting" and that this planned use was "incorporated" by reference in paragraph one of the Demonstration Agreement. TT Br. at 5, ¶ 13. For these reasons, Texas Tech implies that TrailBlazer's Medicare claims data – which it calls its "own data" – should have been freely accessible without a DUA. *Id.*; *see also* TT Ex. 10, at 4, ¶ 9 (referring to CMS's December 2006 insistence on a DUA for the TrailBlazer data as "newly required").

To the contrary, Texas Tech was not free to obtain and use TrailBlazer's Medicare claims data as it pleased. Such data is generally protected from unauthorized use or disclosure by the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act (HIPAA), the latter of which safeguards the privacy and security of "individually identifiable health information." *See* Pub. L. No. 104-191, 101 Stat. 1936. Regulations that implement HIPAA provide that a "covered entity" – a term that includes a "health plan," which in turn is defined to include Medicare Parts A and B (*see* 45 C.F.R. § 160.103) – may disclose protected information to a "business associate"¹⁵ of that entity "only if the covered entity obtains satisfactory assurance, *in the form of a data use agreement* that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes." 45 C.F.R. § 164.514(e)(3), (e)(4) (italics added) .

CMS's solicitation for the CMHCB program advised Texas Tech that it "must comply with all applicable law . . . including but not limited to privacy laws and the Health Insurance Portability and Accountability Act[.]" TT Ex. 1, at 12. Furthermore, the Demonstration Agreement's Data Protocol expressly implemented the statutory and regulatory privacy protections by requiring Texas Tech, as a CMS (Medicare) "business associate," to sign a DUA allowing the release of "individually identifiable health information (specifically, CMS-Medicare fee-for-service claims and eligibility data) for demonstration enrollment and monitoring purposes."¹⁶ TT Ex. 5, at 16, ¶ 3.1. CMS therefore acted in accordance with the Demonstration Agreement in requiring Texas Tech to sign a DUA covering TrailBlazer's claims data.

 $^{^{15}}$ A "business associate" is defined in regulations as a person who, "[0]n behalf of [a] covered entity or of an organized health care arrangement . . ., but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information" 45 C.F.R. § 160.103.

¹⁶ In its May 18, 2007 memorandum, Texas Tech complained that the DUA requirement was "not brought to its attention until the 9th month of operations." TT Ex. 20, at 11. However, the provisions we have just quoted show that Texas Tech was on notice of that requirement from the date it signed the Demonstration Agreement.

F. Texas Tech's other allegations of CMS nonperformance are irrelevant and also unsubstantiated.

Texas Tech contends that CMS:

- possessed, but failed to disclose, "vital knowledge . . . of relevant and important characteristics of the beneficiaries in the Comparison Group that did, or should have, alerted [an] organization[] with the expertise of CMS (and claimed by RTI) that the Comparison Group beneficiaries were not 'comparable' to the Intervention Group" (TT Br. at 9-10);
- failed to "provide a meaningful analysis of the Comparison and Intervention groups" (*id.* at 8 (¶ 7)); and
- "failed to cooperate" and otherwise make reasonable efforts to "resolve the disparities" between the study groups (*id.* at 8 (\P 8)).¹⁷

These allegations of deficient "performance" by CMS are in essence more attempts to have this case decided under contract law principles, an approach we have rejected since this case must be decided under grants law. Under that law, we must look to the terms of the Demonstration Agreement, and Texas Tech does not point to any term or condition of the Demonstration Agreement that would excuse its repayment obligation on these (or other similar) grounds.

Furthermore, Texas Tech's allegations are unsubstantiated. Concerning the allegation that CMS failed to disclose "vital knowledge" about the comparison group, Texas Tech does not specify the information that CMS failed to disclose, much less indicate how the alleged non-disclosure violated the Demonstration Agreement. In addition, we see no evidence that, either before or during the operation of Texas Senior Trails, CMS failed to respond to a request for information apart from denying access to certain Medicare claims data, as discussed above, about the comparison group. As our case background shows, CMS responded promptly to Texas Tech's April 2006 request for health, payment, and other information about the comparison group. CMS Ex. 18, at 8-9, ¶ 10.1; CMS Ex. 22.

¹⁷ In support of this allegation, Texas Tech's Project Director asserts that, after ARC issued its report on the project's six-month results, "CMS failed to make . . . appropriate and requested adjustments" to the calculation of baseline Medicare costs. TT Ex. 10, at 7-9, \P 15-16.

Texas Tech's claim that CMS failed to "provide a meaningful analysis of the Comparison and Intervention groups" is unaccompanied by any further explanation and is thus too vague to merit a response. As for Texas Tech's claim that CMS "failed to cooperate" and otherwise make reasonable efforts to "resolve the disparities" between the study groups, the Demonstration Agreement did not require CMS to accept Texas Tech's judgment that the selected comparison group was substantially flawed or to agree to Texas Tech's proposed alterations.¹⁸ The agreement also contained no guarantee that the project, once begun (based on the agreed-upon criteria and methods for selecting the study groups), would be completed under Texas Tech's preferred conditions. *See* TT Br. at 8, ¶ 8.

Finally, Texas Tech suggests that shortcomings in the study deprived it of an opportunity to demonstrate the effectiveness of its care management model. It asserts that its "consideration" for providing health care to members of the intervention group was CMS's agreement to pay care management fees. Reply Br. at 7. Texas Tech suggests that it is being penalized because of the study's flaws. *Id.* at 12.

Texas Tech misunderstands the nature of its involvement in the demonstration. The CMHCB program's objective was not to confer a bargained-for benefit on Texas Tech in the form of care management fees. Rather, as the Board Chair stated in her jurisdictional ruling, the program served the distinctly public purpose of generating data that might improve the quality and cost-effectiveness of Medicare-covered services. The program also required CMS to achieve that purpose by budget neutral means – means that included the Medicare savings guarantee and other provisions in the Demonstration Agreement's Financial Protocol. No "penalty" is being exacted: CMS merely seeks to enforce the Demonstration Agreement according to its terms and conditions.

G. The Board lacks authority to waive Texas Tech's financial liability based on the estoppel doctrine.

Texas Tech contends that the estoppel doctrine bars CMS's demand for repayment. TT Br. at 11, ¶ 15. "The doctrine of equitable estoppel precludes a party from establishing an essential element of its claim because of that party's misrepresentations, on which the opposing party relied to its detriment." *N.Y. State Dept. of Social Servs.*, DAB No. 449, at 23 (1983), *aff'd*, *N.Y. State Dep't of Social Servs.* v. *Bowen*, 648 F. Supp. 850 (D. D.C. 1986), *aff'd*, 835 F.2d 360 (D.C. Cir. 1987).

¹⁸ In support of its claim of bad faith or insufficient cooperation by CMS, Texas Tech alleges that CMS's reliance on RTI to evaluate its concerns or suggestions about the comparison group "was a clear conflict of interest" because "it was RTI that designed and made the selection of beneficiaries in the Intervention Group" and because "[a]ny 'cause' [that RTI] would find for the disparity [between the intervention and comparison groups] would be an adverse reflection on its own work." TT Br. at 9, ¶ 11. This allegation is wholly unsupported. RTI's role in the demonstration is clearly spelled out in the Demonstration Agreement. See, e.g., TT Ex. 5, at 28, ¶ 5.1. Texas Tech accepted that role when it signed the agreement. We also see no reason why RTI would have been at fault if the process agreed on by both parties resulted in unforeseen discrepancies between the groups.

Relying on previously discussed factual allegations, Texas Tech asserts that estoppel is appropriate in this case because CMS "(a) design[ed] and utiliz[ed] a Comparison Group when it knew or should have known that the Comparison Group was not comparable based on RTI's use (or at least access through CMS) of actual, historical Medicare claims data for both the Comparison and Intervention Groups; (b) presumably fail[ed] to test the two groups for comparability utilizing its access to actual claims data; (c) den[ied] Texas Tech access to actual claims data for the Comparison Group to evaluate the Comparison Group or use for treatment of the Intervention Group; (d) den[ied] Texas Tech access to its <u>own</u> claims data (though TrailBlazer) by delaying approval of the Data Use Agreement until it was too late to be of benefit; and (e) fail[ed] to provide its own analysis (as required by the Demonstration Agreement) that was adequate for either party to forecast the disparities subsequently reported." *Id.* at 12 (emphasis in original).

Texas Tech's estoppel argument assumes that the fault for what it perceives to be the demonstration project's failure lies with CMS, an assumption that, as our earlier discussion makes clear, is not supported by the record or grants law precepts. In any event, the Board has long held that estoppel does not lie against the government in the same way as against private parties. "It is well-established that the government cannot be estopped absent, at a minimum, a showing that the traditional requirements for estoppel are present (i.e., a factual misrepresentation by the government, reasonable reliance on the misrepresentation by the party seeking estoppel, and harm or detriment to that party as a result of the reliance) and that the government's employees or agents engaged in 'affirmative misconduct.''' *Bright Beginnings for Kittias County*, DAB No. 2623, at 8 (2015) (internal quotation marks omitted) (*citing*, among other decisions, *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 421 (1990)). A party asserting estoppel against the federal government has the burden to show that these elements are present. *N.Y. State Dept. of Social Servs.* at 23 n.10.

Texas Tech does not contend, much less demonstrate, that its allegations (which we have already shown to be unfounded) amount to "misrepresentation" or "affirmative misconduct" or that the other requisite elements for estoppel are present. Moreover, the Board lacks the authority to grant relief based on an equitable remedy or defense (such as estoppel). *Cf. Municipality of Santa Isabel,* DAB No. 2230, at 11 (2009) (noting that "the Board has no authority to waive a disallowance based on equitable principles"); *The Children's Center* at 8 (same).

Conclusion

We uphold CMS's decision that Texas Tech is obligated under the terms and conditions of its January 20, 2006 Demonstration Agreement (number 95-W-00182/6) to refund \$7,988,526 to the federal government.

> Leslie A. Sussan /s/

/s/

Sheila Ann Hegy

/s/

Susan S. Yim Presiding Board Member