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Comptroller General
of the United States

United States Government Accountability Office
Washington, DC 20548

Decision

Matter of: ARKRAY USA, Inc.

File: B-408981.4

Date: March 5, 2014

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Donna Lee Yesner, Esq., and Stephen E. Ruscus, Esq., Morgan, Lewis & Bockius LLP, for Abbott Diabetes Care Sales Corporation, the intervenor.
David S. Hurt, Esq., Jennifer Hesch, Esq., and David Smith, Esq., Department of Defense, and Maura C. Brown, Esq., Department of Veterans Affairs, for the agencies.
Pedro E. Briones, Esq., and Guy R. Pietrovito, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Protest of the establishment of a blanket purchase agreement by the Department of Defense for self-monitoring blood glucose test strips for the TRICARE uniform formulary is dismissed as untimely, where the solicitation is patently ambiguous with respect to whether the awardee's glucometer must be on the vendor's Federal Supply Schedule contract and the protester did not protest the ambiguity prior to the time set for receipt of quotations.

DECISION

ARKRAY USA, Inc., of Edina, Minnesota, protests the Department of Defense's (DOD) establishment of a blanket purchase agreement (BPA) with Abbott Diabetes Care Sales Corporation, of Alameda, California, for self-monitoring blood glucose system test strips for inclusion on the TRICARE uniform formulary.[1] ARKRAY contends that Abbott's blood glucose meters--which the vendor must provide to

[1] TRICARE, which is managed by the Defense Health Agency, is a comprehensive managed healthcare program for active duty personnel, National Guard and Reserve servicemembers, and retirees, as well as their dependents and/or survivors. 32 C.F.R. § 199.17 (2013); www.tricare.mil/tma.

TRICARE beneficiaries free of charge under the terms of the BPA--are not on Abbott's Federal Supply Schedule (FSS) contract or compliant with the Trade Agreements Act (TAA).

We dismiss the protest, because the protester's arguments are an untimely challenge to patent ambiguities in the solicitation.

BACKGROUND

The uniform formulary is the approved list of pharmaceutical agents that must, by law, be available to eligible beneficiaries under the TRICARE pharmacy benefits program. 10 U.S.C. § 1074g(a)(2)(E) (2006). Under the program, pharmaceutical agents are available through a tiered cost-sharing (or co-payment) structure based on whether an agent is considered generic, formulary, or nonformulary, and the "point of service" that dispenses the agent--a military treatment facility, TRICARE's national mail-order pharmacy, or a participating retail pharmacy. 32 C.F.R. §§ 199.21(h)-(j). Selection of pharmaceutical agents for the formulary triggers significant procurements of those agents and reduces (or, if dispensed at a military treatment facility, eliminates) the co-payment for beneficiaries. See id. § 199.21(i); see, e.g., Merck & Co., Inc., B-295888, May 13, 2005, 2005 CPD ¶ 98 at 10.

Pharmaceutical agents are selected for the formulary (which is reviewed quarterly) based on their clinical and cost effectiveness, as determined by a Pharmaceutical and Therapeutics (P&T) Committee of military healthcare providers and pharmacists.[2] 10 U.S.C. §§ 1074g(a)(2)(A)-(D), (b). The selection and review process is complex and typically begins at DOD's Pharmacoeconomic Center, which collects and analyzes clinical information, gathers pricing and cost data, and provides administrative support to the P&T Committee. Agency Report (AR) at 4-7. A Beneficiary Advisory Panel (BAP), comprised of representatives of TRICARE beneficiaries, contractors, and providers, reviews and comments on any proposed changes to the formulary. 10 U.S.C. § 1074g(c). The Director of the Defense Health Agency makes final formulary decisions, considering both the P&T Committee's recommendations and the BAP's comments. Id. §§ (a)(2)(A)-(D), (c).

Self-monitoring blood glucose systems (SMBGS) were last reviewed, as a therapeutic class, in 2008; new SMBGS test strips were reviewed, individually,

[2] Pharmaceutical agent is defined to include drugs, biological products, and medical devices under the regulatory authority of the Food and Drug Administration (FDA). 10 U.S.C. § 1074g(g)(2). Pharmaceutical agents that are similar in chemical structure, pharmacological effect, and/or clinical use are grouped as a therapeutic class. 32 C.F.R. § 199.21(b)(2). As relevant here, FDA regulates self-monitoring blood glucose system test strips and glucometers as class II medical devices. See 21 C.F.R. § 862.1345 (2013).

in 2009 and 2011.[3] AR, Tab 14, May 2013 P&T Comm. Clinical Effectiveness Review, at 5. Three types of Abbott test strips and two types of ARKRAY test strips are on the current formulary.[4] AR, Tab 15, May 2013 P&T Comm. Handout, SMBG Test Strips/Meters, at 1, 6. All SMBGS formulary vendors, including Abbott and ARKRAY, provide their glucometers free of charge to TRICARE patients that use the firms' test strips. See AR, Tab 14, May 2013 P&T Comm. Clinical Effectiveness Review, at 10.

In March 2013, the Defense Health Agency announced (on its website, www.pec.ha.osd.mil) that it would conduct a new SMBGS class review. See AR, Tab 2, P&T Comm. Meeting Notice. The notice identified each brand of test strip that would be reviewed and provided historical data on the number of each brand dispensed by each TRICARE point of service, and overall. AR, Tab 6, SMBGS Class Description; Tab 7, SMBGS Test Strip Utilization. After issuing the notice, DOD's Pharmacoeconomic Center gathered clinical data through industry meetings, manufacturer demonstrations, examination of test strips and glucometers, and medical literature reviews. See generally AR, DOD/Vendor Emails, Tabs 41-58, 83-99, 103-9. The agency also requested price discounts from FSS vendors for any of their brands of test strips listed in the notice.[5] See AR, Tab 6, SMBGS Class Description, at 5; Contracting Officer's (CO) Statement at 3.

On May 15, the P&T Committee reviewed SMBGS clinical data presented by the agency's Pharmacoeconomic Center, and conducted an initial clinical effectiveness review. See AR, Tab 16, May 2013 P&T Comm. Decision Paper & Minutes, at 6, 19; Tab 14, May 2013 P&T Comm. Clinical Effectiveness Review. After examining over 100 brands of test strips (and their corresponding glucometers), the committee recommended a number of minimum requirements for formulary test strips and recommended that vendors be required to provide TAA-compliant glucometers to

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[3] DOD includes SMBGS test strips and other "consumable" medical devices on the formulary; glucometers are not included on the formulary. AR at 2.

[4] One of Abbott's three formulary test strips is on the basic core formulary (BCF), which is the mandatory minimum list of pharmaceutical agents that all military treatment facilities must stock. Fifty percent of TRICARE beneficiaries who use test strips, currently use Abbott test strips; less than 4 percent use ARKRAY and certain other brands of strips combined. AR at 16.

[5] Pharmaceutical manufacturers' drug prices with the federal government may not exceed 76 percent of the manufacturer's average nonfederal drug prices, and those drugs must be made available through FSS contracts for procurement by specified agencies, including DOD. See 38 U.S.C. § 8126. The Department of Veterans Affairs (VA), under a delegation from the General Services Administration, manages FSS healthcare contracts, including, as here, contracts under FSS Group 65, Medical, Dental, and Veterinary Equipment and Supplies. See www.fss.va.gov.

TRICARE beneficiaries free of charge.[6] See AR, Tab 16, May 2013 P&T Comm. Decision Paper & Minutes, at 6-7, 19; Tab 14, May 2013 P&T Comm. Clinical Effectiveness Review, at 19-24. The committee established a pool of seven potential formulary candidates, including Abbott and ARKRAY, based on four factors: (1) test strip brands dispensed over the past 3 years; (2) availability at all points of service; (3) TAA compliance; and (4) compliance with existing and newly proposed technical criteria. AR, Tab 14, May 2013 P&T Comm. Clinical Effectiveness Review, at 19-24, 91.

Solicitation

On July 13, the agency posted a solicitation for the "Class: Self Monitoring Blood Glucose Systems" on DOD's Pharmacoeconomic Center website, and announced that the P&T Committee would conduct a class review in August. AR, Tab 3, Class Review Notice & Solicitation Templates, at 1-2. Vendors were invited to submit quotations for a uniform formulary blanket purchase agreement (UF BPA) for pharmaceutical agents in the class under review, and the website provided a "UF BPA Template" that vendors would use to submit their quotations.[7] Id.

The solicitation instructs vendors to submit quotations for pharmaceutical agents, lower than or equal to the vendor's FSS prices, using an included appendix (or schedule). See AR, Tab 4, BPA Template, at 1, 3. Vendors were informed that their quotations "must include all National Drug Codes (NDCs)[8] available for purchase by the Government and on the Company's FSS contract for quoted form and strength[,]" and that the vendor must have an "existing FSS contract for any pharmaceutical agent(s) quoted." Id. at 3.

In pertinent part, the solicitation also states:

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[6] The TAA generally requires that "end products" be acquired from the U.S. or designated countries, and applies to FSS contracts. See 19 U.S.C. § 2512(a)(1)(A) (2006); see also www.gsa.gov/portal/content/200369#taa; www.fss.va.gov/faqs/tradeAgreements.asp. The Defense Federal Acquisition Regulation Supplement (DFARS) also requires that products purchased under FSS 65 comply with the TAA. DFARS § 225.401-70.

[7] A separate template was provided for a Voluntary Agreement for Retail Refunds (VARR), which sets the rate at which a manufacturer refunds the government for test strips dispensed at participating retail pharmacies. AR, Tab 5, VARR Template, at 1-2.

[8] Under the Drug Listing Act of 1972, 21 U.S.C. § 360, manufacturers must register their drugs and medical devices with the FDA, which assigns the product a unique, universal identifying number. See www.fda.gov/drugs/informationondrugs/ucm142438.htm.

> The Company must submit a complete UF BPA price quote for each NDC [National Drug Code] that applies to the Company's pharmaceutical agent(s) in a given drug class.
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> * * * * *
>
> **Suite**: Each manufacturer will be allowed to designate what strips are in their group of strips known as a suite. Only one bid submission per manufacturer will be allowed. All strips within a suite must have the same price. The government will accept the entire suite, or not at all. All NDCs within the suite must have a permanent FSS. If NDCs are included that do not have a permanent FSS then the entire bid will be considered non-responsive and returned to the bidder.
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> * * * * *
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> 1. General Requirements
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> ● Test Strips
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> -- Must be available at all 3 Points of Service
> -- Must be Trade Agreements Act-compliant
>
> ● Meters
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> -- Manufacturer must have a process to supply meters to beneficiaries at no cost.
> -- Must be Trade Agreements Act-compliant

AR, Tab 8, BPA Appendix, at 1 (emphasis in original). The solicitation also identifies specific, minimum technical requirements, most of which relate to glucometers, including blood glucose results in 10 seconds or less, memory of 250 readings or more, large visual display, and downloading and data management capability.[9]

Using charts provided in the appendix, vendors were requested to identify the NDC, drug name, strength, dosage form, and package size for each NDC in the vendor's

[9] See generally Home Blood Sugar Testing, National Library of Medicine, National Institutes of Health, www.nlm.nih.gov/medlineplus/ency/patientinstructions/000324.htm (describing how SMBGS test strips and glucometers function).

proposed suite, and to provide their price per test strip. Id. at 2-3. Narrative technical quotations were not solicited. Vendors are also advised that, if recommended by the P&T Committee and approved by the Director, their quoted price would be incorporated into a BPA, which will remain in effect until the drug class is reevaluated and any resultant formulary change implemented, or until the BPA was terminated. AR, Tab 4, BPA Template, at 1-2.

Evaluation and Selection

The agency received quotations from five vendors, including from ARKRAY and Abbott, by the July 25 submission deadline. CO's Statement at 7. ARKRAY proposed one test strip and Abbott proposed three test strips. AR, Tab 10, ARKRAY Quotation, at 7; Tab 12, Abbott Quotation, at 7. Both vendors identified their respective test strips by NDC; neither vendor's quotation identified or submitted prices for a glucometer.

The P&T Committee determined that Abbott's test strips were the most cost effective, and recommended that they be the only test strips on the formulary. See AR, Tab 24, Aug. 2013 P&T Comm. Decision Paper & Minutes, at 3-6, 16-18. ARKRAY's and the other vendors' test strips were recommended for non-formulary status. Id. On September 19, the Beneficiary Advisory Panel (BAP) met to review the P&T Committee's determinations (which were made public on that date) and to hear public comments on the P&T Committee's formulary recommendations.[10] AR at 17; Tab 26, BAP Agenda, at 1-2. The BAP agreed with the P&T Committee's recommendation that only Abbott test strips should be included on the formulary. See AR, Tab 29, Sept. 19, 2013 BAP Minutes, at 3-8.

On September 27, ARKRAY protested to our Office (B-408981), challenging the agency's selection of Abbott's test strips. On September 30, ARKRAY withdrew its protest after being informed by DOD that a final formulary decision had not been made.

On November 7, the Director of the Defense Health Agency approved the P&T Committee's and BAP's formulary recommendations. AR at 17. On November 12, the agency established a BPA with Abbott, with an effective date of May 7, 2014. This protest followed notification of the agency's decision.

DISCUSSION

[10] The BAP, which is subject to the Federal Advisory Committee Act, 5 U.S.C. App. 2, published a meeting notice in the Federal Register one month earlier. 78 Fed. Reg. 50,049 (Aug. 16, 2013). The protester attended the meeting. Protest, 1st Declaration of ARKRAY Vice Pres., Consumer Health Div., at 13.

ARKRAY contends that the agency should have rejected Abbott's quotation, because Abbott's glucometer is not listed on the firm's FSS contract, which, the protester argues, was required by the solicitation.[11] See Protest at 3-4, 9. The protester further argues that the agency is procuring both test strips and glucometers with this solicitation. In this regard, ARKRAY contends that glucometers were "central" to the P&T Committee's class review of SMBG "systems" and the committee's clinical effectiveness determinations and recommendations. Protester's Comments at 9-11. The protester notes that the solicitation stated minimum technical requirements for the glucometers, and in this respect points out that the Contracting Officer views those requirements as having been included in the solicitation so that vendors could calculate their test strip prices accordingly. See id. at 10-11, citing, inter alia, CO's Statement at 7.

DOD responds that it evaluated test strips for clinical and cost effectiveness, and selected Abbott's test strips, according to applicable statutes and regulations, and according to the terms of the solicitation. AR at 20. The agency contends that vendors' glucometers were not required to be on the firms' FSS contracts, where glucometers are not included on the formulary, the agency will not be placing orders for glucometers, and the solicitation did not include glucometers in its definition of "suites." Id. at 14. DOD contends that the solicitation is "clear" that only pharmaceutical agents quoted must be on the FSS contract, and that the "plain language" of the solicitation only requests that vendors provide prices for test strips. Id. at 21-22.

We find, as explained in detail below, that the solicitation is patently ambiguous with respect to whether glucometers were required to be included on a vendor's FSS contract, and that ARKRAY'S protest in this regard is untimely.

Our Bid Protest Regulations contain strict rules requiring timely submission of protests. Under these rules, protests based upon alleged improprieties in a solicitation which are apparent prior to the time set for receipt of proposals must be filed prior to that time. 4 C.F.R. § 21.2(a)(1) (2013). Where a patent ambiguity is not challenged prior to submission of solicitation responses, we will not consider subsequent untimely arguments asserting the protester's own interpretation of the ambiguous provisions. Marine Group Boat Works, LLC, B-404277, B-404277.2, Jan. 19, 2011, 2011 CPD ¶ 23 at 4; Kellogg Brown & Root, Inc., B-291769, B-291769.2, Mar. 24, 2003, 2003 CPD ¶ 96 at 8; Bank of Am., B-287608, B-287608.2, July 26, 2001, 2001 CPD ¶ 137 at 10. An offeror or vendor that

[11] We requested the VA's views here because it administers FSS Group 65 contracts. The VA confirmed that Abbott's glucometer is not listed on its FSS contract, but did not address whether glucometers should be viewed as part of this procurement. VA Email to GAO, Feb. 13, 2014. The protester concedes that Abbott's test strips are on its FSS contract. Protest at 7.

chooses to compete under a patently ambiguous solicitation does so at its own peril, and cannot later complain when the agency proceeds in a way inconsistent with one of the possible interpretations. Wackenhut Servs., Inc., B-276012.2, Sept. 1, 1998, 98-2 CPD ¶ 75 at 5.

The solicitation contains a number of contradictory instructions that render the solicitation facially ambiguous. On the one hand, the solicitation states that vendors "must submit a complete price [quotation] for each NDC that applies to the Company's pharmaceutical agent(s) in a given drug class[,]" and "must include all [NDCs] available for purchase by the Government and on the Company's FSS contract for the quoted form and strength."[12] AR, Tab 4, BPA Template, at 3; Tab 8, BPA Appendix, at 1. As we discuss above, the terms NDC, pharmaceutical agent, and class, have statutory and regulatory definitions (see supra nn. 2, 8) that, as relevant here, appear to include both SMBGS test strips and glucometers. By employing terms that appear to include both test strips and glucometers, this aspect of the solicitation indicates that glucose strips and glucometers must be on the vendor's FSS contracts.

On the other hand, as the agency urges, the solicitation only requests prices for test strips, as a "suite," and in that regard states that all NDCs within the suite must be on the firm's FSS's contract. AR, Tab 8, BPA Appendix, at 1. The solicitation's definition of "suite" does not appear to include glucometers, and in this respect the solicitation's charts only include blocks for vendors to fill in the name, NDCs, and price for test strips, not glucometers. See id. at 2-3. Significantly, the only provisions in the solicitation that expressly address glucometers state only that vendors "must have a process to supply meters to beneficiaries at no cost" and that they must be TAA-compliant. See id. at 1. Moreover, as the agency argues, the solicitation describes a process under which the agency will not order glucometers under the BPA. Thus, the solicitation also reasonably indicates that the glucometers would not be required to be on the vendor's FSS contract.

The record here also indicates that, at the time that ARKRAY prepared and submitted its quotation, the protester interpreted the solicitation as not requiring that glucometers be listed on its FSS contract--contrary to the position it now takes. The protester provided a declaration from ARKRAY's Vice President stating that ARKRAY was prepared to quote a price for a particular test strip model, but "specifically decided" that it could not include that test strip in its suite of test strips,

[12] Inexplicably, the agency does not provide a template tailored to medical devices, even though the agency acknowledges that medical devices are included on the formulary. AR at 2. The protester complains (but did not timely protest) that the solicitation's generalized, "bare-bones" template requires strength and dosage information that is not applicable to SMBGS test strips. See Protester's Comments at 11.

"because the [corresponding] meter was not TAA-compliant at the time ARKRAY made its offer." Protester's Comments, 2nd Declaration of ARKRAY Vice Pres., Consumer Health Div., ¶¶ 4-5, 17. This suggests that the protester decided not to quote a particular test strip--not because its glucometer was not on ARKRAY's FSS contract--but because the glucometer was not TAA-compliant.[13] A firm may not compete under a patently ambiguous solicitation and then complain when the agency proceeds in a way inconsistent with one of the possible interpretations. Rather, the firm has an affirmative obligation to seek clarification prior to the first due date for responding to the solicitation following introduction of the ambiguity into the solicitation. 4 C.F.R. § 21.2(a)(1); see Dix Corp., B-293964, July 13, 2004, 2004 CPD ¶ 143 at 3; Gartner Inc., B-408933.2, B-408933.3, Feb. 12, 2014, 2014 CPD ¶ 67 at 3.

The protest is dismissed.[14]

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[13] Insofar as the protester questions whether Abbott's glucometers were TAA-compliant at the time that it submitted its quotation, the protest has no merit. As the agency points out, during the P&T Committee's clinical and cost effectiveness evaluations, Abbott informed the agency that the glucometer that it will provide is manufactured in Singapore, a TAA-designated nation. See AR at 21-22; see, e.g., Klinge Corp., B-309930.2, Feb. 13, 2008, 2008 CPD ¶ 102 at 5 (protest denied where agency reasonably relied on awardee's representation that its proposed system would be manufactured in Singapore, a TAA nation).

[14] In its comments on the agency report, ARKRAY also challenges the agency's cost effectiveness determination. See Protester's Comments at 13-15. We also dismiss these arguments as untimely because they were not raised within 10 days of when the protester learned of the basis for protest. 4 C.F.R. § 21.2(a)(2).