#### IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Stanton-Negley Drug Company, : t/d/b/a Stanton-Negley Legend Drug, :

Petitioner

.

v. : No. 1797 C.D. 2007

Argued: February 12, 2008

Department of Public Welfare,

Respondent

BEFORE: HONORABLE DORIS A. SMITH-RIBNER, Judge

HONORABLE ROCHELLE S. FRIEDMAN, Judge HONORABLE JAMES R. KELLEY, Senior Judge

OPINION BY JUDGE FRIEDMAN FILED: February 28, 2008

Stanton-Negley Drug Company, t/d/b/a Stanton-Negley Legend Drug (Stanton-Negley) petitions for review of the August 20, 2007, final determination of Glenn E. Williams (Director), Director, Bureau of Administrative Services, Department of Public Welfare (DPW), which denied Stanton-Negley's bid protest¹ and determined that DPW's request for proposals (RFP) No. 31-06, relating to the planned implementation of its Specialty Pharmacy Drug Program, was not improper or contrary to law.

<sup>&</sup>lt;sup>1</sup> Stanton-Negley filed its bid protest pursuant to section 1711.1(a) of the Commonwealth Procurement Code, which gives a bidder or offeror, a prospective bidder or offeror or a prospective contractor aggrieved in connection with the solicitation or award of an agency contract the right to protest in writing to the head of the purchasing agency. 62 Pa. C.S. §1711.1(a).

On October 5, 2006, DPW issued RFP No. 31-06 on behalf of the Office of Medical Assistance (MA) Programs (OMAP),<sup>2</sup> seeking to select two contractors to assist in developing, implementing and operating a Specialty Pharmacy Drug Program (Project).<sup>3</sup> (RFP No. 31-06, §I-2.) The selected contractors will serve as DPW's preferred providers of specialty pharmacy drugs and related services for some 800,000 MA recipients residing in forty-two counties who do not have risk-based mandatory managed care but currently receive their health care in the fee-for-service delivery system.<sup>4</sup> (RFP No. 31-06, §§I-4, IV-

<sup>&</sup>lt;sup>2</sup> The MA Programs are cooperative federal-state programs administered under Title XIX of the Social Security Act (SSA), 42 U.S.C. §§1396-1396v, and Article IV of the Public Welfare Code, Act of June 13, 1967, P.L. 31, *as amended*, 62 P.S. §§401-493, through which the federal government provides funds to enable states to make MA available to indigent, elderly and disabled individuals. Section 1901 of the SSA, 42 U.S.C. §1396.

<sup>&</sup>lt;sup>3</sup> Specialty pharmacy drugs are drugs that require a set of services for access not typically provided in a traditional outpatient pharmacy setting. They are generally biotechnical in nature and include, but are not limited to, drugs that are: injectables; infusibles; environmentally sensitive and require special handling; typically administered on a long term basis to treat chronic diseases; either self-administered in the home or provider-administered in the home, clinic or physician's office; usually high cost; and associated with complex dosing regimens, frequently requiring patient education, monitoring and clinical supports. (RFP No. 31-06, §§I-4, IV-2, Appendix J.)

<sup>&</sup>lt;sup>4</sup> In Pennsylvania, MA recipients obtain services through either the fee-for-service or the managed care delivery system. In the fee-for-service system, recipients have been able to obtain covered services from any provider enrolled in the MA program, and DPW pays the provider directly. In the managed care system, DPW contracts with, and pays, licensed Managed Care Organizations (MCOs) for covered services. DPW administers a mandatory managed care program in twenty-five counties. Moreover, voluntary enrollment with an MCO is available in twenty-six of the forty-two fee-for-service counties. The Project does not affect those covered under either the mandatory or voluntary managed care delivery systems. In addition, approximately thirty-four percent of fee-for-service recipients are dual eligibles, i.e., eligible under the MA Program and Medicare, and they are exempt from participation in the Project. (RFP No. 31-06, §IV-2(a).)

1(a).) The Project was proposed to address the needs of the increasing number of MA recipients being prescribed such drugs and to provide the specialized services required to administer those drugs more efficiently and safely. DPW intended to adopt selective contracting with a limited number of preferred providers as a strategy to improve care for recipients and to cost-effectively manage the clinical and administrative complexities of specialty pharmacy drugs.<sup>5</sup> (RFP No. 31-06, §§I-4, IV-1; N.T. at 104, 106, 139-41.)

Under the current fee-for-service system, any pharmacy enrolled in DPW's MA Program can dispense and administer drugs, including specialty pharmacy drugs, to MA recipients. (S.R. at 251b, 253b.) However, following implementation of the Project, affected MA recipients who are prescribed any of the specialty pharmacy drugs listed in RFP No. 31-06 will be required to secure those drugs through the Project from one of DPW's two preferred providers. (RFP

(RFP No. 31-06, §§I-4, IV-1.)

<sup>&</sup>lt;sup>5</sup> Specifically, DPW is initiating the Project to achieve the following objectives:

<sup>(1)</sup> to implement and operate an efficient and effective Specialty Pharmacy Drug Program as an alternative to the traditional fee-forservice model;

<sup>(2)</sup> to offer MA recipients a choice of specialty pharmacy preferred providers;

<sup>(3)</sup> to provide a reliable and convenient dispensing and delivery system for providers and MA recipients that facilitates care in clinically appropriate settings;

<sup>(4)</sup> to provide a clinical support system designed to optimize therapy management, care coordination, and patient compliance; and

<sup>(5)</sup> to provide cost-effective services through an accountable Specialty Pharmacy Drug Program.

No. 31-06, §IV-2(a).) Moreover, although current providers need no accreditation to dispense specialty pharmacy drugs, RFP No. 31-06 includes a requirement that selected contractors have and maintain accreditation from the Joint Commission on Accreditation of Healthcare Organizations, the Community Health Accreditation Program or the Compliance Team.<sup>6</sup> (RFP No. 31-06, §IV-2.1(a).)

Stanton-Negley is a drug company that has been operating a pharmacy in Pittsburgh for over forty years. Stanton-Negley participates in the Medicare and MA Programs and has been serving MA recipients in terms of both routine pharmacy needs and specialty pharmacy needs throughout the course of its existence. In 2006, Stanton-Negley billed approximately 2.2 million dollars for services rendered to MA recipients, approximately \$600,000 of which related directly to specialty pharmacy drugs. (S.R. at 166b-67b, 171b.) At the time RFP No. 31-06 was issued on October 5, 2006, Stanton-Negley lacked the accreditation required to submit a proposal, and, because the accreditation process takes between eight to fifteen months, it was impossible for Stanton-Negley, or any non-accredited pharmacy, to obtain accreditation before proposal submissions for the Project were due on November 9, 2006. However, DPW did receive seven proposals in response to RFP No. 31-06.

 $<sup>^{6}</sup>$  RFP No. 31-06 subsequently was amended to include an additional accrediting entity. (S.R. at 323b.)

<sup>&</sup>lt;sup>7</sup> The first public notice of the accreditation requirement was made when a draft of RFP No. 31-06 was published in June 2006. (S.R. at 311b.) However, even then, accreditation could not have been obtained by a non-accredited entity in time to submit a bid on or before the due date for submission on November 9, 2006.

On November 3, 2006, Stanton-Negley filed a written protest against RFP No. 31-06 and the Project it sought to implement, asserting seventeen different grounds for protest. (S.R. at 1b-4b.) Initially, DPW dismissed Stanton-Negley's protest as untimely; however, Commonwealth Court reinstated Stanton-Negley's protest and remanded the matter to DPW for a determination on the merits. *Stanton-Negley Drug Co. v. Department of Public Welfare*, 926 A.2d 554 (Pa. Cmwlth. 2007) (*Stanton-Negley I*). Thereafter, responses to Stanton-Negley's protest were submitted by OMAP and two offerors. (S.R. at 10b-22b, 68b-84b, 85b-94b.) Along with its response, OMAP submitted the federal waiver approval issued by the Secretary of the Department of Health and Human Services (HHS), (S.R. at 23b-24b), which was a pre-requisite for implementation of the proposed Project. Section 1915(b)(4) of the Social Security Act (SSA), 42 U.S.C. §1396n(b)(4).

<sup>&</sup>lt;sup>8</sup> According to Stanton-Negley: DPW failed to seek or receive an approved federal waiver prior to issuing RFP No. 31-06; DPW is unable to qualify for such a waiver because RFP No. 31-06 and the Project would have a negative impact on access to needed medications, quality of care and costs; DPW failed to perform an internal, independent evaluation on the viability of the Project prior to issuing RFP No. 31-06; RFP No. 31-06 fails to comply with applicable statutes and regulations concerning procurement of services by a state agency; RFP No. 31-06 discriminates against certain pharmacies currently providing MA services in that the criteria set forth in RFP No. 31-06 requires inclusion of services and care that far exceeds those required of MA providers under the current system; RFP No. 31-06 is contrary to pending state legislation; RFP No. 31-06 violates federal and state antitrust statutes and the Antibid-Rigging Act, 62 Pa. C.S. §§4501-4509; RFP No. 31-06 contains no preference for in-state offerors; and RFP No. 31-06 and the proposed Project violate the equal protection rights of MA beneficiaries by creating different classes of service based solely on county of residence. (S.R. at 1b-4b.)

<sup>&</sup>lt;sup>9</sup> To qualify for federal funding, DPW must administer its MA Program in conformity with federal requirements. Section 1902 of the SSA, 42 U.S.C. §1396a. Under section 1902(a)(23) of the SSA, 42 U.S.C. §1396a(a)(23), a state must provide MA recipients with the freedom to receive services from any qualified provider of those services. However, to provide the flexibility needed for states to try new or different approaches to the efficient and cost-(Footnote continued on next page...)

On July 20, 2007, Stanton-Negley submitted its reply to the responses and raised an additional ground for protest, alleging that RFP No. 31-06 violates its due process and equal protection rights by adversely affecting its rights to practice its profession and operate its business. (S.R. at 112b-28b.) As an attachment to its reply, Stanton-Negley provided a copy of the transcript of a December 19, 2006, Commonwealth Court hearing held in connection with other litigation involving Stanton-Negley; the testimony from that hearing directly related to the issues raised in the bid protest. (S.R. at 95b-391b.) Stanton-Negley also requested that a hearing be held regarding its protest.

# (continued...)

effective delivery of health care services, federal law permits the waiver of certain requirements, including limiting an MA recipient's choice of providers. Section 1915(b)(4) of the SSA, 42 U.S.C. §1396n(b)(4); 42 C.F.R §§430.25(a) and (c)(iv). Because, under the Project, DPW plans to limit an MA recipient's choice to only two providers of specialty pharmacy drugs, DPW requested a waiver from HHS. The requirements for this type of waiver are set forth in federal regulations at 42 C.F.R. §§430.25 and 431.55, and a waiver is granted only if HHS determines that the proposed provision of services is "cost-effective and efficient and not inconsistent with the purposes of [Title XIX]." Section 1915(b) of the SSA, 42 U.S.C. §1396n(b). DPW received federal approval of its waiver request in December of 2006. (S.R. at 23b-24b.)

<sup>10</sup> On November 8, 2006, Stanton-Negley filed a petition for preliminary injunction and a complaint, both in this court's original jurisdiction. The December 19, 2006, hearing was held in conjunction with the petition for preliminary injunction. Following that hearing, a Judge of this court preliminarily enjoined DPW from interfering with Stanton-Negley's participation in "specialty service" during the pendency of the proceedings on Stanton-Negley's complaint, but denied Stanton-Negley's request for preliminary injunction in all other respects. In the complaint, Stanton-Negley sought a declaration that RFP No. 31-06 and/or the Project were unlawful and sought to enjoin DPW from implementing the Project. This court sustained DPW's preliminary objections to the complaint based on a lack of jurisdiction and dismissed the complaint. *Stanton-Negley Drug Co. v. Department of Public Welfare*, 927 A.2d 671 (Pa. Cmwlth. 2007). Stanton-Negley's appeal from that decision is pending before our supreme court; in addition, Stanton-Negley has a pending federal lawsuit relating to the Project.

On August 20, 2007, the Director issued a final adjudication. After determining that a hearing on the matter was unnecessary,<sup>11</sup> the Director addressed and rejected each of Stanton-Negley's grounds for protest. Accordingly, the Director determined that RFP No. 31-06 was not contrary to law, and he denied Stanton-Negley's bid protest. Stanton-Negley now petitions this court for review of that order.<sup>12</sup>

Stanton-Negley argues that DPW's denial of Stanton-Negley's bid protest was arbitrary and capricious, constituted an abuse of discretion or was contrary to law because RFP No. 31-06: (a) violates Stanton-Negley's rights to due process and equal protection; (b) violates the Commonwealth's policy regarding the engagement of and assistance to small and disadvantaged businesses; (c) violates the Antibid-Rigging Act; and/or (d) violates provisions of the SSA relating to an MA recipient's freedom of choice and access to care, as set forth in 42 U.S.C. §§1396(a)(23)(A) and 1396(a)(30)(A). We will discuss these claims seriatim.

Stanton-Negley first argues that RFP No. 31-06 substantially impairs its ability to practice its profession and operate its business, in violation of its equal protection and due process rights. However, before considering the merits of this

<sup>&</sup>lt;sup>11</sup> Stanton-Negley does not challenge this determination on appeal.

<sup>&</sup>lt;sup>12</sup> The Procurement Code sets forth the scope and standard of review in an appeal from a determination denying a bid protest. Section 1711.1(i) provides, "The court shall hear the appeal, without a jury, on the record of determination certified by the purchasing agency. The court shall affirm the determination of the purchasing agency unless it finds from the record that the determination is arbitrary and capricious, an abuse of discretion or is contrary to law." 62 Pa. C.S. § 1711.1(i)

argument, we must address DPW's contention that Stanton-Negley has waived consideration of these particular issues by failing to raise them in its November 3, 2006, protest.

According to DPW, Stanton-Negley, as a prospective bidder, was required to raise all grounds on which it based its protest prior to November 9, 2006, the date set for proposal receipt under RFP No. 31-06. 62 Pa. C.S. §1711.1(b); *Stanton-Negley I*. Here, Stanton-Negley raised the issue of due process and equal protection violations *for the first time* in its July 20, 2007, reply, well after the required date. Because a protesting party waives consideration of any grounds for protest not raised in a timely manner, DPW asserts that Stanton-Negley has waived its right to have these belated constitutional claims considered. *Common Sense Adoption Services v. Department of Public Welfare*, 799 A.2d 225 (Pa. Cmwlth. 2002) (finding certain issues were waived by the protesting party since they were not raised in a timely manner).

DPW is correct that a prospective bidder is deemed to have waived consideration of any protest not timely raised. 62 Pa. C.S. §1711.1(b). DPW also is correct that, in ruling that Stanton-Negley's November 3, 2006, protest was timely, our court explained that Stanton-Negley "had *until the proposal receipt date*, which was November 9, 2006, to file its protest." *Stanton-Negley I*, 926 A.2d at 557 (emphasis added); *see also, MSG Group, Inc. v. Department of Public Welfare*, 902 A.2d 613 (Pa. Cmwlth. 2006) (affirming the denial of a bid protest as untimely because of protestor's failure to file by the bid closing date). However, section 1711.1(b) of the Procurement Code, which contains the time limitations for

filing a bid protest, provides, in relevant part, that a prospective bidder or offeror must file its protest with the head of the purchasing agency "*prior to the bid opening time or the proposal receipt date.*" 62 Pa. C.S §1711.1(b) (emphasis added). Because there is no indication that Stanton-Negley raised its constitutional challenge to RFP No. 31-06 after bid opening time, we conclude that Stanton-Negley did not waive its due process and equal protection claims.<sup>13</sup>

#### Due process

For due process rights to attach, there first must be a deprivation of a property right or other similar interest that is constitutionally protected. *Ohio Casualty Insurance Co. v. Insurance Department of the Commonwealth of Pennsylvania*, 585 A.2d 1160 (Pa. Cmwlth. 1991). According to Stanton-Negley, all persons within the Commonwealth have a protected interest in the practice of their profession and business, which triggers the protective mechanism of procedural due process where such livelihood is adversely affected. Here, the owners of Stanton-Negley maintain that, as a result of RFP No. 31-06, they have been substantially deprived of their right to pursue their livelihood and practice their profession as pharmacists without being afforded the required due process.

Focusing on the accreditation requirement in RFP No. 31-06, Stanton-Negley asserts that DPW was fully aware that accreditation was not required of

<sup>&</sup>lt;sup>13</sup> We also note that of the seventeen grounds raised in Stanton-Negley's November 3, 2006, protest, numbers 5, 8, 9, 10, and 16 set forth many of the same arguments that Stanton-Negley raises in its later challenge to RFP No. 31-06 on grounds that it violated Stanton-Negley's rights to due process and equal protection. (S.R. at 2b-4b.)

existing providers of specialty pharmacy drugs and that the accreditation process was lengthy; nevertheless, DPW included this precondition in RFP No. 31-06, without providing sufficient turn-around time to allow non-accredited providers to comply and submit a proposal before the imposed deadline. An owner of Stanton-Negley explained the impact that RFP No. 31-06 would have on his business, stating that the inability to provide specialty pharmacy drugs covered by the Project not only would mean an annual loss of \$600,000 in revenue for Stanton-Negley but also would have a collateral impact on other revenues because MA recipients of specialty pharmacy drugs in the counties covered by RFP No. 31-06 likely would seek *all* their drug needs from one source, i.e., the preferred providers chosen under RFP No. 31-06. Stanton-Negley asserts that if DPW had provided adequate and timely notice of this Project requirement, Stanton-Negley would have obtained the required accreditation and submitted a bid in response to RFP No. 31-06. Thus, according to Stanton-Negley, DPW's failure to make a timely disclosure of the accreditation requirement violated due process by depriving Stanton-Negley's owners of the ability to conduct their business and profession in the manner they had established and with patients they had served prior to the issuance of RFP No. 31-06 and the Project it seeks to implement. We disagree.

Contrary to Stanton-Negley's position, it has no protected property right to full participation in the MA Program. *Rite Aid of Pennsylvania, Inc. v. Houstoun*, 998 F. Supp. 522 (E.D. Pa. 1997) (holding that an agreement between the Commonwealth and a provider of prescription drugs for the Medicaid Program does not involve the "extreme dependence" necessary to support a due process claim). Further, Stanton-Negley has no protected property interest in receiving a

specific dollar amount from participation in the MA Program. See Ohio Casualty (holding that an insurer has no property right to charge a specific rate ad infinitum and, therefore, there is no denial of due process in a statutorily mandated rate reduction); Rite Aid (holding that, where a provider of prescription drugs was not terminated as a participant in a Medicaid Program, a lowering of its reimbursement rates for those drugs did not violate protected rights). Finally, Stanton-Negley has no protected property right to submit a bid in response to an RFP. See Durkee Lumber Co., Inc. v. Department of Conservation and Natural Resources, 903 A.2d 593 (Pa. Cmwlth. 2006) (holding that a denial of a bid protest without holding a hearing did not deprive a disappointed bidder of any property rights because there is no legitimate claim of entitlement to a government contract unless the contract actually is awarded). Although Stanton-Negley undoubtedly is correct that it will lose substantial revenue upon implementation of the Project, it cannot claim a violation of due process where, as here, it has no protected interest in these funds. Moreover, it is clear that neither RFP No. 31-06 nor implementation of the Project prevents Stanton-Negley from pursuing its livelihood and operating its business.<sup>14</sup>

<sup>14</sup> As the Director correctly observed, the Project will apply only to the MA Program and not any other third party payer, so Stanton-Negley is free to provide its full range of services, including specialty pharmacy drugs, to all individuals other than MA recipients. In addition, the Project is limited in scope, and Stanton-Negley is free to provide any drugs or services to MA recipients who do not reside in the designated forty-two county area or to those MA recipients within the designated area who are dual eligibles or enrolled in a voluntary managed care plan. In addition, Stanton-Negley can provide any MA recipients with drugs that are outside the limited group of specialty pharmacy drugs covered by the Project. For this reason, the cases cited by Stanton-Negley are distinguishable and do not support the claim that Stanton-Negley essentially has been deprived of its right to pursue its profession and operate its business. *See Nixon v. Commonwealth*, 576 Pa. 385, 839 A.2d 277 (2003) (involving a *lifetime disqualification* of certain persons from employment in elder care); *Soja v. Pennsylvania State Police*, 500 Pa. 188, 455 A.2d 613 (1982) (involving *dismissal* from the police force); *Roche v. State Board of* (Footnote continued on next page...)

Finally, even if Stanton-Negley had a protected property interest, DPW afforded Stanton-Negley all the process that was due by complying with the Procurement Code's requirements pertaining to notice and submission of proposals. The Procurement Code requires that public notice of an RFP be given in the same manner as prescribed for invitations for bid. 62 Pa. C.S. §513(c). "Adequate public notice of the invitation for bids shall be given a reasonable time prior to the date set for the opening of bids." 62 Pa. C.S. §512(c). Thus, DPW is required only to give adequate public notice of the solicitation; that is, a reasonable time for proposal preparation.<sup>15</sup> There is no requirement that DPW provide a sufficient amount of time for all potential offerors to undertake the steps necessary to qualify as offerors under the particular terms of the RFP. Here, DPW provided more than thirty calendar days from the issuance of RFP No. 31-06 on October 5, 2006, until proposal submission on November 9, 2006. The fact that DPW received seven proposals in response to RFP 31-06, which is more than DPW typically receives in response to an RFP, (S.R. at 333b-34b), indicates that DPW did provide a reasonable amount of time for the preparation of proposals and, therefore, complied with Procurement Code procedure.

## **Equal Protection**

(continued...)

Funeral Directors, 437 A.2d 797 (Pa. Cmwlth. 1981) (involving revocation of a license to practice as a funeral director).

<sup>&</sup>lt;sup>15</sup> The DGS Field Procurement Handbook states that state agencies should provide a reasonable time for offerors to prepare their proposals. (DGS Field Procurement Handbook, Chapter 6.A.3).

Stanton-Negley also argues that its right to engage in a particular occupation or business, which is guaranteed by the equal protection clauses of the U.S. and Pennsylvania Constitutions, will be violated as a result of RFP No. 31-06. This right has been identified as an important, but not fundamental, constitutional right subject to the rational basis test. That is, a state may not deprive an individual of that right unless it can be shown that such deprivation is reasonably related to the state interest that is sought to be protected. *Warren County Human Services v. State Civil Service Commission (Roberts)*, 844 A.2d 70 (Pa. Cmwlth.), appeal denied, 581 Pa. 687, 863 A.2d 1152 (2004). According to Stanton-Negley, under the record here, no such showing can be made.

Specifically, Stanton-Negley contends that RFP No. 31-06 is directed solely at large providers of specialty drugs and was drafted in a fashion that effectively insures elimination of existing providers in the Project. Stanton-Negley asserts that because of the required accreditation, the short turn-around between the issuance of the RFP and the time that bids would have to be submitted, and the inclusion of services not customarily offered by community pharmacies and far in excess of those required of pharmacies currently in the program, RFP No. 31-06 discriminates against smaller community pharmacies such as Stanton-Negley. Further, Stanton-Negley contends that there is no showing that such deprivation is reasonably related to the state interest sought to be advanced, i.e., improved service and/or reduced costs. In this regard, Stanton-Negley contends that DPW has advanced no evidence to demonstrate that the quality of care or service that recipients were receiving under the current system was unacceptable or that anticipated cost savings will be realized. Indeed, according to Stanton-Negley, by

restricting available providers to just two, DPW almost guarantees inferior care for MA recipients and cost increases rather than cost savings.<sup>16</sup> Again, we disagree.

Initially, as with its due process claim, Stanton-Negley has failed to show that DPW deprived it of its right to engage in its profession or business. Moreover, even assuming such a deprivation, RFP No. 31-06's requirement of accreditation and inclusion of services in excess of what had been required previously satisfies the rational basis level of scrutiny.

With its argument on criteria requirements, Stanton-Negley would have this court presume that DPW could only justify including an accreditation requirement in the RFP, as well as any other criteria beyond those customarily offered by current MA providers, if DPW first established significant problems with the existing levels of care and services. Stanton-Negley is correct that the criteria in RFP No. 31-06 includes a level of services and care that far exceed any requirements under the current system; however, the fact that Stanton-Negley is incapable of meeting these higher standards does not affect the validity of RFP No. 31-06. In fact, Stanton-Negley ignores the fact that DPW was attempting to improve on the status quo. As the Director observed, in light of the Project's objectives to improve quality and access, DPW necessarily would have to include requirements and services that exceed those for current providers of specialty pharmacy drugs.

<sup>&</sup>lt;sup>16</sup> Stanton-Negley contends that cost savings could be addressed more successfully by adjusting the payments made for the drugs in question, without disrupting the existing program, which was working well in terms of service and care rendered.

Moreover, section 513 of the Procurement Code, which governs a state agency's issuance of an RFP, provides no rigid, detailed procedure or strict requirements for the RFP process, but preserves a great deal of agency discretion, including discretion to determine agency needs in preparation of RFP requirements. 62 Pa. C.S. §513. An agency is not required to issue an RFP with terms and conditions that all entities in a particular field can meet, and Stanton-Negley cites no authority holding to the contrary. Further, as the individual challenging RFP No. 31-06, Stanton-Negley has the burden of demonstrating that DPW abused its discretion. *See A. Pickett Construction, Inc. v. Luzerne County Convention Center Authority*, 738 A.2d 20 (Pa. Cmwlth. 1999). This it has failed to do.

There is no basis to conclude that the criteria in RFP No. 31-06 were adopted with the purpose of excluding certain providers or that DPW decided on criteria for the Project in an arbitrary or capricious manner. To the contrary, the record contains evidence that DPW engaged in significant research and outreach concerning the Project and RFP No. 31-06.<sup>17</sup> Stanton-Negley does not dispute this but, instead, merely indicates that, as a non-accredited community pharmacy with an exceptional reputation for delivery and service, it can provide service superior

<sup>&</sup>lt;sup>17</sup> Suzanne Love, the individual responsible for drafting RFP No. 31-06, testified that the RFP development process included research and outreach, not only to interested stakeholders but to the general public. (S.R. at 298b-302b, 311b-19b.) Further, DPW not only conducted such research and outreach, it evaluated and reacted to the information and comments it received. (S.R. at 263b-65b, 316b-18b, 323b.) In relation to the accreditation requirement, DPW decided to include this requirement as a means to ensure quality of care. (S.R. at 309b-11b.)

to that from a large accredited drug company.<sup>18</sup> Finally, we note that in granting a waiver to DPW, HHS was required to consider the Project's effect on MA recipients' access to services and the quality of services being provided, 42 U.S.C. \$1396n(b)(4); 42 C.F.R. \$431.55(b)(2), and by granting the waiver, HHS determined that restricting the MA recipients' freedom of choice of providers was warranted.

For similar reasons, Stanton-Negley's contention that the cost savings to be realized by the Project will not be realized also must fail. Stanton-Negley claims that prices inevitably will increase due to a lack of competition; however, the record contains evidence to the contrary. (S.R. at 90b.) Moreover, any discussion regarding cost savings is purely speculative because the contract has not been awarded yet, and Stanton-Negley is not privy to the pricing offered by the offerors. Finally, the federal waiver approval process requires documentation and consideration of the cost effectiveness of a waiver program. 42 U.S.C. §1396n(b); 42 C.F.R. §431.55. In approving DPW's waiver request, the federal government found, contrary to Stanton-Negley's contention, that DPW proposed a cost-effective program. However, even assuming that DPW may be incorrect as to cost savings to be achieved through implementation of the Project, or that DPW may have been able to achieve savings in other ways, this does not mean that issuance of RFP No. 31-06 was contrary to law.

<sup>&</sup>lt;sup>18</sup> Although Stanton-Negley's expert indicated that the accreditation requirement in RFP No. 31-06 was "interesting" and may tend to exclude community pharmacies from submitting proposals, (S.R. at 215b-16b), this does not necessarily make the inclusion of such criterion improper.

For all these reasons, the Director did not err in determining that Stanton-Negley failed to establish that RFP No. 31-06 violates its rights to due process and equal protection.

Stanton-Negley also argues that RFP No. 31-06 violates the Commonwealth's policy regarding the engagement of and assistance to small and disadvantaged businesses. <sup>19</sup> Initially, we note that, in the captioned section of its brief devoted to this issue, (Stanton-Negley's brief at 33-35), Stanton-Negley cites no legal authority or presents any evidence to support its argument; indeed, beyond the caption's assertion that RFP No. 31-06 violates this policy, there is no discussion of the issue at all. Instead, Stanton-Negley merely recites various unrelated facts and opinions already provided elsewhere in its brief. The only statement even arguably pertinent to this matter is Stanton-Negley's repetition of the opinion expressed by its expert witness, Dr. Kreling, that RFP No. 31-06 is directed at large providers of specialty drugs and did not intend to include existing providers as potential offerors. Such opinion, by itself, clearly is insufficient evidence to support Stanton-Negley's claim.

In fact, Stanton-Negley is unable to show that RFP No. 31-06 violates Commonwealth policy applicable to small and disadvantaged businesses because it does not. Under the Procurement Code, the Commonwealth Department of General Services (DGS) is charged with the duty of implementing the

<sup>&</sup>lt;sup>19</sup> This issue also was first raised in Stanton-Negley's July 20, 2007, reply.

Commonwealth's policy of assisting small and disadvantaged businesses. 62 Pa. C.S. §2101. In relation to competitive procurements through the RFP process, state agencies are required to include small and disadvantaged business participation as an evaluation criterion for an RFP. Participation by a small and disadvantaged business may be as a prime contractor, as part of a joint venture or as a subcontractor. (DGS Field Procurement Handbook, Chapter 21.C.) RFP No. 31-06 addresses participation of small and disadvantaged businesses in four sections of the RFP, (RFP No. 31-06, §§I-13, II-8, III-4, IV-6), and includes participation of such businesses as one of its evaluation criteria. (RFP No. 31-06, §III-4; S.R. at 329b-30b, 333b.) Because RFP No. 31-06 fully complies with requirements of Commonwealth policy regarding small and disadvantaged businesses, DPW did not err in denying Stanton-Negley's protest on this ground.

Next, Stanton-Negley argues that RFP No. 31-06 violates the Antibid-Rigging Act, set forth at 62 Pa. C.S. §§4501-4509. In making this argument, Stanton-Negley again makes no reference to specific provisions of the Antibid-Rigging Act that allegedly were violated, nor does it present evidence of any specific action by DPW, or any offeror, to support its assertion that there was such a violation. Instead, Stanton-Negley speaks generally of the questionable nature of RFP No. 31-06 due to the unnecessary accreditation requirement, the short turn around time and the lack of evidence that prior services were unacceptable. On this basis, Stanton-Negley asserts that RFP No. 31-06 includes criteria for selection of successful offerors specifically designed to exclude existing providers that are smaller community pharmacies, such as Stanton-Negley, and insure that only

certain pre-selected large providers can satisfy the criteria.<sup>20</sup> Such an assertion is insufficient to show that RFP No. 31-06 violates the Antibid-Rigging Act. In fact, for several reasons, there is no such violation.

First, as evident from the language used, the Antibid-Rigging Act applies only to actions of bidders or prospective bidders, *not* to governmental agencies. The Antibid-Rigging Act makes it "unlawful for any *person* to conspire, collude or combine with another in order to commit or attempt to commit *bid-rigging*" *re*lating to a contract or subcontract with a government agency. 62 Pa. C.S. §4503(a). (Emphasis added.) The Antibid-Rigging Act defines "bid-rigging" as:

The concerted activity of two or more persons to determine in advance the winning bidder of a contract let or to be let for competitive bidding by a government agency. The term includes, but is not limited to, any one or more of the following:

- (1) Agreeing to sell items or services at the same price.
- (2) Agreeing to submit identical bids.
- (3) Agreeing to rotate bids.
- (4) Agreeing to share profits with a contractor who does not submit the low bid.
- (5) Submitting prearranged bids, agreed-upon higher or lower bids or other complementary bids.
- (6) Agreeing to set up territories to restrict competition.
- (7) Agreeing not to submit bids.

<sup>20</sup> To the extent that Stanton-Negley claims that all smaller pharmacies are necessarily excluded from the bid process, we must disagree. RFP No. 31-06 allows for, and even encourages, offerors to use subcontractors to perform some of the services required. Thus, even if a smaller pharmacy, such as Stanton-Negley, could not satisfy all the criteria in RFP No. 31-06 directly, it could do so by entering subcontract agreements.

62 Pa. C.S. §4502. This list of prohibited activities clearly is directed at "persons" submitting bids in response to a government contract, not the contracting governmental agency. Indeed, the Antibid-Rigging Act defines "person" as "[a]n individual, corporation or partnership or any other entity capable of submitting a bid to the Commonwealth." *Id.* Moreover, private entities, such as Stanton-Negley, cannot assert alleged violations of the Antibid-Rigging Act. 62 Pa. C.S. §§4504 and 4508.

In addition, even assuming that the actions of a governmental entity are within the scope of the Antibid-Rigging Act, in order to violate that Act, the entity must conspire, collude or combine with another person in its bid-rigging activities. 62 Pa. C.S. §4503(a). Stanton-Negley fails to offer any information that indicates any such conspiracy, collusion or combination occurred. In fact, the record here supports a contrary conclusion. DPW received seven proposals in response to RFP No. 31-06, an amount that is more than typically received by DPW. (S.R. at 333b-34b.) Moreover, Suzanne Love, the person responsible for designing the Project and drafting RFP No. 31-06, testified concerning the open and public process used to solicit public input as an aid to developing RFP No. 31-06, as well as the posting of a draft RFP so that prospective offerors could avoid any future bid problems. As the Director correctly observed, this activity is inconsistent with the development of an RFP under which only pre-selected offerors will qualify.

Finally, Stanton-Negley argues that RFP No. 31-06 violates 42 U.S.C. §§1396(a)(23)(A) and 1396a(a)(30)(A). Stanton-Negley notes that, pursuant to RFP No. 31-06, MA recipients that are prescribed one or more specialty pharmacy drugs covered by the Project would be required to secure their drugs from one of two of DPW's preferred providers. According to Stanton-Negley, this limitation violates federal law concerning MA recipients' freedom of choice and access to care, 42 U.S.C. §§1396a(a)(23) and 1396a(a)(30).<sup>21</sup> However, even assuming that Stanton-Negley is able to make a claim regarding alleged violations of these provisions, it cannot prevail. On December 14, 2006, DPW received HHS approval of its waiver request for the Project, permitting DPW to restrict MA recipients covered by the Project to two providers of specialty pharmacy drugs.<sup>22</sup> Thus, RFP No. 31-06 cannot be found to violate these federal provisions.

<sup>&</sup>lt;sup>21</sup> Section 1902(a)(23) of the SSA, 42 U.S.C. §1396a(a)(23) provides, in relevant part, that a state MA Program must provide any individual eligible for MA assistance the opportunity to obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required, that undertakes to provide him with such services. Section 1902(a)(30) of the SSA, 42 U.S.C. §1396a(a)(30) provides, in relevant part, that a state MA Program must provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

<sup>&</sup>lt;sup>22</sup> To the extent that Stanton-Negley is attempting to privately enforce these provisions of the SSA on behalf of the MA recipients, it lacks standing to do so. In addition, to the extent that Stanton-Negley is appealing the grant of the waiver, this is not the proper forum in which to do so.

Accordingly, because Stanton-Negley has failed to identify any provision of the Procurement Code that has been violated by DPW in the solicitation process, we must affirm.

ROCHELLE S. FRIEDMAN, Judge

#### IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Stanton-Negley Drug Company, : t/d/b/a Stanton-Negley Legend Drug, :

Petitioner

.

v. : No. 1797 C.D. 2007

:

Department of Public Welfare,

Respondent

## ORDER

AND NOW, this 28th day of February, 2008, the final determination of the Department of Public Welfare, dated August 20, 2007, is hereby affirmed.

ROCHELLE S. FRIEDMAN, Judge