

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Key Medical Supply, Inc.,
a Minnesota Corporation,

Civil No. 12-752 (DWF/JJG)

Plaintiff,

v.

ORDER

Kathleen Sebelius, Secretary of the
United States Department of Health and
Human Services, in her official capacity;
and Marilyn Tavenner, Acting Administrator
of the Centers for Medicare and Medicaid
Services, in her official capacity,

Defendants.

Samuel D. Orbovich, Esq., and Lousene M. Hoppe, Esq., Fredrikson & Byron, PA, counsel
for Plaintiffs.

Friedrich A. P. Seikert, Assistant United States Attorney, United States Attorney's Office,
counsel for Defendants.

INTRODUCTION

This matter is before the Court on a Motion for Temporary Restraining Order brought by Plaintiff Key Medical Supply, Inc. (Doc. No. 2.) For the reasons stated on the record at the hearing on this matter, as well as the reasons set forth below, the Court denies Plaintiff's motion.

BACKGROUND

The facts and legal issues involved in this case are complex, as evidenced by Plaintiff's 223-paragraph Complaint. (Doc. No. 1.) For purposes of this motion, the Court only briefly summarizes the relevant facts and issues involved. Plaintiff is a vendor of medical supplies and equipment, including enteral nutritional supplies. (Compl. ¶¶ 11, 12.) Enteral nutrition refers to "tube feeding." In particular, Plaintiff supplies Low-Profile Enteral Gastric Tubes, which are tubes that are custom-sized to fit each user's body.¹ (Compl. ¶ 57.) Plaintiff provides equipment and supplies to patients who reside in their homes and are covered by insurance plans, including Medicare and Medicaid, and the Minnesota Home & Community Based Waiver Program. (*Id.* ¶¶ 12, 13.) A substantial percentage of Plaintiff's clientele are persons with developmental and other disabilities.² (*Id.* ¶ 15.)

Defendant Kathleen Sebelius is the Secretary of the United States Department of Health and Human Services. (*Id.* ¶ 18.) In that capacity, Defendant Sebelius is charged with the responsibility to administer and oversee the Medicare and Medicaid programs. (*Id.*) Defendant Sebelius administers the Medicare and Medicaid programs through the

¹ Conventional tubes have long and protruding external tubes, which Plaintiff alleges are clinically inappropriate for some patients. (Compl. ¶¶ 51, 52.) Plaintiff's counsel demonstrated the relevant Low-Profile Enteral Gastric Tubes at oral argument.

² Plaintiff's counsel stated at oral argument that Plaintiff has approximately 5,000 clients. According to the Complaint, more than 80% of those clients are persons with developmental and other disabilities. (*Id.* ¶ 15.)

Centers for Medicare and Medicaid Services (“CMS”). (*Id.*) Defendant Marilyn Tavenner is the Acting Administrator of CMS. (*Id.* ¶ 19.)

In this action, Plaintiff alleges that Defendants are implementing a Medicare Competitive Bidding Program in a way that is inconsistent with their governing enabling legislation, the Medicare Prescription Drug Improvement Act of 2003, 42 U.S.C. § 1395w-3 (the “MMA”), and that Defendants’ current and historic fee for Low-Profile Enteral Gastric Tubes, supplies, and nutritional formula is incompatible with Defendants’ Competitive Bidding Program, such that no bona fide bid for these items is possible. (*Id.* ¶¶ 5, 6.) As a result, Plaintiff asserts that Defendants’ actions will end Plaintiff’s enteral-related Medicare business and its ability to provide Low-Profile Enteral Gastric Tubes and related supplies for its clients with developmental and other disabilities.³ (*Id.* ¶ 8.) Plaintiff also alleges that its deadline to submit a bid to the Medicare Competitive Bidding Program is March 30, 2012. (*Id.* ¶ 16.)

³ Plaintiff asserts that Medicare will pay \$35.39 for each Low-Profile Enteral Tube, but that the approved amount is about 500%-937% below Plaintiff’s acquisition price for those products. (Doc. No. 6, Reinhart Decl. ¶¶ 7-8.) Plaintiff also asserts that Medicare will not pay additional amounts for the extension tubes needed to deliver the nutritional formula through the tubes and limits the number of reimbursable tubes to one tube every three months. (Doc. No. 4 at 7; Doc. No. 5, Anderson Decl. ¶ 12-14.)

By comparison, Plaintiff submits that the Minnesota Department of Human Services (“DHS”) authorizes a higher reimbursement rate for these same Low-Profile Enteral Tubes. In particular, Plaintiff asserts that Medicaid will pay \$138.60 to \$530.29 for items that Medicare will pay only \$35.39, and recognizes that some persons may need up to two tubes per month. (Doc. No. 4 at 7.)

In its Complaint, Plaintiff asserts the following causes of action: Counts One and Two—Violation of the Administrative Procedures Act, 5 U.S.C. §§ 701-606; Count Three—Violation of United States Constitution Taking Clause; Count Four—Violation of the United States Constitution Equal Protection Clause; Count Five—Violation of the United States Constitution Due Process Clause. (Doc. No. 1.) For purposes of the present motion, Plaintiff seeks an order: enjoining Defendants from implementing the Medicare Competitive Bidding Program for all Enteral Nutrients, Equipment and Supplies; enjoining Defendants from accepting bids for such Enteral Nutrients, Equipment and Supplies; and enjoining Defendants from extending their Competitive Bidding Program to persons who are dually-eligible for both Medicare and Medicaid.

Defendants oppose Plaintiff's motion. Defendants point out that Congress enacted the MMA in an effort to combat waste, fraud, and abuse. Defendants also point out that as part of the MMA, Congress enacted the Medicare Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"). Further, Defendants submit evidence, via the declaration of Michael P. Keane, the Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding in the CMS, that Round 1 of the DMEPOS Competitive Bidding Program took place in 2009, and contracts were awarded and became effective in November 2010 and January 2011, respectively. (Doc. No. 12, Keane Decl. ¶ 4.) In addition, Defendants submit evidence that the following timeline for Round 2 of the DMEPOS Competitive Bidding Program is in effect:

11/30/2011

The Centers for Medicare & Medicaid Services (CMS) announces bidding timeline, begins bidder education program

12/5/2011

Registration for user IDs and passwords begins

12/22/2011

Authorized Officials are strongly encouraged to register no later than this date

1/30/2012

CMS opens 60-day bid window for Round 2 and National Mail-order Competitions

2/9/2012

Registration closes

2/29/2012

Covered Document Review Date for bidders to submit financial documents

3/30/2012

60-day bid window closes

Fall 2012

CMS announces single payment amounts, begins contracting process

Spring 2013

CMS begins supplier, referral agent, and beneficiary education campaign

July 1, 2013

Implementation of Medicare DMEPOS Competitive Bidding Program Round 2 and National Mail-order Competition contracts and prices

(Doc. No. 13, Siekert Decl. ¶ 3, Ex. A.) CMS announced the second round of competitive bidding on August 19, 2011 via a posting on its website, through its listserv, and via a press release. (Keane Decl. ¶ 7.) On November 30, 2011, CMS announced that the bidding window for the second round would close on March 30, 2012. (*Id.* ¶ 9.)

DISCUSSION

Under Eighth Circuit precedent, a temporary restraining order may be granted only if the moving party can demonstrate: (1) a likelihood of success on the merits; (2) that the movant will suffer irreparable harm absent the restraining order; (3) that the balance of harms favors the movant; and (4) that the public interest favors the movant. *See Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981); *S.B. McLaughlin & Co., Ltd. v. Tudor Oaks Condominium Project*, 877 F.2d 707, 708 (8th Cir. 1989). In each case, the factors must be balanced to determine whether they tilt toward or away from granting injunctive relief. *See West Pub. Co. v. Mead Data Cent., Inc.*, 799 F.2d 1219, 1222 (8th Cir. 1986). The party requesting the injunctive relief bears the “complete burden” of proving all of the factors listed above. *Gelco Corp. v. Coniston Partners*, 811 F.2d 414, 418 (8th Cir. 1987).

As a threshold matter, the Court determines that Plaintiff has not demonstrated that it will suffer irreparable harm absent an order prohibiting Defendants from closing the bidding period for Enteral Equipment and Supplies on Friday, March 30, 2012. Plaintiff claims that the status quo will change when the bidding window closes on March 30, 2012 because the only bid allowed for Low-Profile Enteral Gastric Tubes will be \$35.39 or less,⁴ and that any bid (submitted by Plaintiff or any other party) will not be bona fide because

⁴ Plaintiff also submits that the only bids allowed for the specialty nutritional formulas are priced below their available acquisition price.

the relevant products cannot be supplied for that price.⁵ Plaintiff asserts that before it submits such a bid, it is required to certify that its bid is bona fide and that it, and others, will be bound by their non-bona fide bids going forward. Defendants, however, assert that if Plaintiff is correct, and some systemic problem exists for Round 2 DMEPOS Competitive Bidding, then competitive bidding will necessarily fail for this segment, and CMS would not enter into contracts and the fee schedule currently in place would remain for those items. (Keane Decl. ¶ 11.) Defendants also represented at oral argument that they will “do a searching inquiry” of their client regarding the situation in Minnesota as alleged by Plaintiff. Defendants further maintain that the Court will have ample opportunity in the ordinary course of litigation to resolve these issues, particularly because the suppliers will not be reimbursed under Round 2 DMEPOS Competitive Bidding until July 1, 2013.⁶

⁵ A bid may be determined to not be a bona fide bid because the payment is too low to be sustainable. (Keane Decl. ¶ 11.)

⁶ The Court notes that Plaintiff’s present motion is complicated by the fact that the parties have entirely different descriptions of the status quo, and both concede that one party must, necessarily, be entirely incorrect in its description. Plaintiff claims that: [T]he status quo of this convoluted, inter-dependent system of dual coverage by Medicare and Medicaid has enabled Plaintiff [] to supply dually-eligible persons with developmental and other disabilities with Low-Profile Enteral Tubes, equipment, and supplies for over fourteen years. If Medicaid funding were eliminated, and [Plaintiff] or other vendors were forced to rely solely on Medicare funding to pay for Low-Profile Enteral supplies and nutritional items, these products would vanish from the disabled marketplace because vendors cannot financially sustain providing items that initially cost over \$100 to \$330 for a flat fee of \$35.39.

(Footnote Continued on Next Page)

Considering Defendants' representation that the current fee schedule for the relevant products will remain in place in the event that a systemic problem does exist for Round 2 DMEPOS Competitive Bidding, the Court concludes that an injunction is not warranted. The Court is satisfied that it will have the opportunity to address and resolve the merits of Plaintiffs' claims in the ordinary course of litigation. To this end, the Court respectfully directs the parties to agree to an expedited schedule to bring summary judgment motions.⁷

Finally, the Court notes that the evidence submitted by Defendants suggests that Plaintiff knew that CMS intended to include Low-Profile Gastric Enteral Access feeding tubes, supplies, and specialty nutrition formula in Round 2 DMEPOS Competitive Bidding and about the corresponding fee schedule reimbursement rates for such items since August 2011. Yet, Plaintiff delayed in initiating this lawsuit until days before the March 30

(Footnote Continued From Previous Page)

(Doc. No. 4 at 8.) Defendants, on the other hand, claim that CMS is monitoring contract performance under the first round of competitive bidding, and that to date it is unaware of any access problems or adverse health outcomes as a result of competitive bidding for enteral nutrition products, including to Medicare beneficiaries who are also eligible for Medicaid. (Doc. No. 11 at 6; Keane Decl. ¶ 6.) Nor are Defendants aware of any complaints from beneficiaries, suppliers, or States, regarding enteral nutrition products to those beneficiaries who are eligible for both Medicare and Medicaid. (Keane Decl. ¶ 6.)

⁷ Not surprisingly, the parties also have very different positions on the effect that an injunction would have at this point in the litigation. Plaintiff asserts that the injunction could apply only to a small piece of Defendants' competitive bidding program in Minnesota; Defendants assert that an injunction would shut down the entire program nation-wide. At this point in the litigation, the Court has insufficient evidence to fairly consider the balance of harm.

deadline that Plaintiff asserts will alter the status quo. Although Plaintiff's delay is not the sole reason for the Court's denial of Plaintiff's motion today, this delay alone would be a sufficient reason to deny Plaintiff's present motion. *Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc.*, 182 F.3d 598, 603 (8th Cir. 1999). Having considered the relevant *Dataphase* factors, the Court denies Plaintiff's motion.

ORDER

Based on the files, records, and proceedings herein, and for the reasons stated above, **IT IS ORDERED** that:

1. Key Medical Supply, Inc.'s Motion for Temporary Restraining Order (Doc. No. [2]) is respectfully **DENIED**.
2. Consistent with the Court's remarks off the bench at the hearing on this matter, the Court's Calendar Clerk will contact the parties to set a status conference that will focus on scheduling and discovery issues.

Dated: March 30, 2012

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge