

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Key Medical Supply, Inc.,
a Minnesota Corporation,

Civil No. 12-752 (DWF/JJG)

Plaintiff,

v.

ORDER AND MEMORANDUM

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.

This matter is before the Court on Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction, or in the Alternative, Motion for Summary Judgment Based on the Administrative Record (Doc. No. 29) and Plaintiff's Second Motion for Temporary Restraining Order (Doc. No. 70). At the February 15, 2013, hearing on the motions, the Court offered to issue a short order, with a full memorandum and opinion to follow.

Based upon the presentations and submissions of the parties, the Court having carefully reviewed the file and the entire record in this matter, and the Court being otherwise duly advised in the premises, the Court hereby enters the following:

ORDER

1. Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction (Doc. No. [29]) is **GRANTED**.
2. Defendants' Motion for Summary Judgment Based on the Administrative Record (Doc. No. [29]) is **DENIED AS MOOT**.
3. Plaintiff's Second Motion for Temporary Restraining Order (Doc. No. [70]) is **DENIED AS MOOT**.

Dated: February 26, 2013

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

MEMORANDUM

While the decision on the motions is supported by law, the Court is deeply concerned about the unjust consequences of its order. As such, the Court feels compelled to issue a short memorandum herewith, prior to issuing its full memorandum and opinion.

It is true, as zealously observed by counsel for Defendants, that, at Congress's direction, Defendants have, for almost a decade, implemented a competitive bidding program, the primary purpose and design of which was to reduce waste, fraud, and abuse relating to Medicare payments for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS"). 42 U.S.C. § 1395w-3(a)(1)(A). Admittedly, in furtherance of this objective, Congress barred judicial review of the key aspects of establishing and implementing the program. The Medicare Prescription Drug, Improvement, and

Modernization Act of 2003 (“MMA”), Pub. L. No. 108-173, 117 Stat. 2066 (2003), states in pertinent part:

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of—

- (A) the establishment of payment amounts under paragraph (5);
- (B) the awarding of contracts under this section;
- (C) the designation of competitive acquisition areas under subsection (a)(1)(A) of this section;
- (D) the phased-in implementation under subsection (a)(1)(B) of this section;
- (E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section; [or]
- (F) the bidding structure and number of contractors selected under this section

Id. at § 1395w-3(b)(11).

While the Court will discuss its analysis in more detail in a memorandum and opinion to follow, the Court observes that, not only did Congress apparently intend to preclude any administrative or judicial review of the items articulated above, but once such “no review” provisions are triggered, the Court may not inquire as to whether a challenged agency decision is arbitrary, capricious, or procedurally defective. Rather, the Court must determine whether the challenged agency action falls into any of the categories shielded from review. *Tex. Alliance for Home Care Srvcs. v. Sebilus*, 681 F.3d 402, 409 (D.C. Cir. 2012); *Amgen v. Smith*, 357 F.3d 103, 360 (2004).

Notably, if the Court did have jurisdiction over this case, it would likely conclude that Defendants' decision here was arbitrary and capricious. While the 1,300 page administrative record makes references to low profile enteral feeding tubes with respect to children and individuals with dementia, Defendants appear indifferent to, if not ignore entirely, the large number of individuals in the United States of America that are developmentally disabled and have other disabilities, who have been prescribed and provided low profile enteral feeding tubes for a number of years. In fact, more than 80 percent of Plaintiff's approximately 5,000 clients are individuals with developmental and other disabilities. (Doc. No. 17 at 2 n.2; *see also* Compl. ¶ 15.)

At the first TRO hearing in this matter, counsel for Defendants represented that a "searching inquiry" would be made by his clients into the situation in Minnesota and other regions of the United States regarding the effect of the Medicare competitive bidding program on the coordination of benefits for persons with developmental or other disabilities who are dually eligible for Medicaid. In the Court's view, no such searching inquiry was made, despite counsel's contention that its perusal of Internet pricing amounted to a sufficient search.

The affidavits of Colleen Wieck, Executive Director of the Minnesota Governor's Council on Developmental Disabilities (a position which she has held for over 31 years), and Steve Larson, Senior Policy Director and Interim Executive Director of the Arc Minnesota, more than substantiate that Defendants are entirely unaware of the adverse effect of the competitive bidding process on a significant number of individuals with disabilities. It is difficult for the Court to believe defense counsel's assertion that

Congress intended such a result. The record before the Court indicates a seeming indifference on the part of Defendants to the fact that individuals with developmental and intellectual disabilities, as well as other disabilities, have a clear need for low profile products because conventional feeding tubes with their long, protruding, external tubing carry a greater risk of accidental removal or dislodgement. Such occurrences may be caused by behavioral issues, mobility issues, or coordination difficulties.

Each and every citizen is entitled to equal justice under law, which is not measured by incidence of death or hospital admissions, but rather by the right to receive medically necessary treatment and to live each day with dignity and respect. In this case, such medically necessary treatment includes low profile and enteral feeding tubes—prescribed by physicians—for individuals with developmental and other disabilities for the reasons stated above.

This is a sad day for those who believe that when a judge adheres, even-handedly, to his or her oath of office, justice will prevail and the public interest will be served. To the extent that a civilized and democratic society is measured by the manner in which it treats and protects its most vulnerable members, it has failed today.

D.W.F.