

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION**

Mary K. Woodfill,	:	Case No. 3:11 CV 2236
	:	
Plaintiff,	:	
	:	
v.	:	
	:	
Kathleen Sebelius, Secretary,	:	MEMORANDUM AND
Health and Human Services, et al.,	:	ORDER
Defendant,	:	

I. INTRODUCTION

Plaintiff Mary K. Woodfill (“Plaintiff”) seeks judicial review, pursuant to 42 U.S.C. § 405(g), of Defendant Secretary’s (“Federal Defendant” or “Secretary”) decision to deny her Medicare coverage for a Medtronic Synchronomed infusion pump (“Medtronic pump”) (Docket No. 1, p. 2 of 8). Pending is Federal Defendant’s Motion to Dismiss, filed June 26, 2012 (Docket No. 34), Defendant Humana Inc.’s Motion to Dismiss, filed June 26, 2012 (Docket No. 35), Federal Defendant’s Motion to Withdraw its Motion to Dismiss, filed September 28, 2012 (Docket No. 48) and Defendant Humana’s Supplement to its Motion to Dismiss, filed October 3, 2012 (Docket No. 49). For the reasons that follow, the Magistrate grants the motions.

II. PROCEDURAL BACKGROUND

Plaintiff seeks judicial review of the Secretary’s decision to deny her Medicare coverage for a Medtronic pump, which is an implantable device designed to administer morphine (Docket No. 1, p. 2

of 8). Plaintiff's physician requested prior authorization for Plaintiff's use of the Medtronic pump from Defendant Humana, the Medicare Advantage organization responsible for administering Plaintiff's Medicare benefits (Docket No. 1, pp. 3-4 of 8). Defendant Humana denied Medicare coverage for the device and, after an administrative hearing, an Administrative Law Judge ("ALJ") affirmed the denial (Docket No. 1, p. 4 of 8). The Medicare Appeals Council ("MAC") adopted the ALJ's decision and its decision became the final ruling of the Secretary (Docket No. 1, p. 6 of 8).

Both the ALJ and the MAC based their decisions on the terms of National Coverage Determination ("NCD") 280.14, which states that implantation of an infusion pump is contraindicated in patients with other programmable devices (Docket No. 1, pp. 4-5 of 8). Because Plaintiff already had an implanted spinal cord stimulator, she did not qualify for Medicare coverage of the Medtronic pump, pursuant to NCD 280.14 (Docket No. 1, p. 3 of 8).

On October 19, 2011, Plaintiff filed a complaint in this Court challenging the MAC decision (Docket No. 1). The complaint alleges that the Secretary erred in denying Plaintiff coverage for the Medtronic pump because, contrary to the terms of the NCD, there is no crosstalk between Plaintiff's existing implanted spinal cord stimulator and the Medtronic pump (Docket No. 1, pp. 3-4 of 8).

On May 9, 2012, Plaintiff filed a Statement of Intention Relative to Alternative Appeal Route (Docket No. 32). In that statement, Plaintiff indicated she intended to "file an alternate appeal under Chapter 42 of the Federal Code of the United States" for review of the *validity* of the NCD (Docket No. 32). On June 26, 2012, Federal Defendant filed a Motion to Dismiss the Complaint or Alternatively to Stay the Proceedings (Docket No. 34). On that same date, Defendant Humana filed its Motion to Dismiss (Docket No. 35). These Motions were filed based on representation by the Plaintiff that she wished to pursue an administrative challenge of NCD 280.14 (Docket Nos. 32, 34, and 35).

According to both Defendant's, since Plaintiff's Complaint appeared to challenge the validity of the NCD, this Court should refer the matter back to the agency, under the doctrine of primary jurisdiction, as an issue involving the agency's expertise (Docket No. 34, pp. 3-5 of 7; No. 35, p. 3 of 5). On July 10, 2012, Plaintiff filed a Notice of Decision Not to Pursue Alternate Appeal (Docket No. 37). On August 6, 2012, Plaintiff filed a Supplemental Response to Defendants' Motions to Dismiss and requested a briefing schedule and hearing on the pending Motion (Docket No. 42).

On September 26, 2012, this Court conducted a hearing on the Motions to Dismiss. At that hearing, Plaintiff, through counsel, represented to the Court that she did not wish to challenge the validity of the NCD or pursue the administrative review process. On the contrary, Plaintiff alleged that her Complaint challenged only the *application* of the NCD, not its validity. In response to this argument, Federal Defendant filed a Motion to Withdraw its Motion to Dismiss on September 28, 2012 (Docket No. 48). On October 3, 2012, Defendant Humana filed a Supplement to its Motion to Dismiss citing new federal case law¹ which holds that the Secretary is the only proper defendant to an action of this nature (Docket No. 49).

¹ In *Logan v. Sebelius* (2012 U.S. Dist. LEXIS 136031 (Aug. 6, 2012)), plaintiff Logan was diagnosed with severe mandibular atrophy with pre-existing partial destruction of the bone. 2012 U.S. Dist. LEXIS 136031, *2. He was insured through a Medicare Advantage policy administered by MidRogue Independent Physician Association ("MidRogue"). *Id.* MidRogue initially informed Logan that her advantage plan would cover her surgery and hospitalization; however, MidRogue later denied coverage. *Id.* Following an administrative hearing, the ALJ ruled MidRogue was required to pay for the plaintiff's procedure. *Id.* The MAC later reversed the ALJ's decision. *Id.* On judicial review, the Court held that, pursuant to the plain language of 42 C.F.R. § 405.1136(d)(1), only the Secretary, in his or her official capacity, is the proper defendant in any action seeking judicial review of the MAC's decision. *Id.* at *8.

In *Madsen v. Kaiser Foundation Health Plan, Inc.* (2009 U.S. Dist. LEXIS 46122 (June 2, 2009)), plaintiff Madsen requested Defendant Kaiser's authorization and coverage for vascular surgery and a left total hip arthroplasty at the Mayo Clinic. 2009 U.S. Dist. LEXIS 46122 at *1-2. Kaiser denied coverage of both procedures. *Id.* at *2. This denial was upheld by an ALJ and the MAC. *Id.* Kaiser filed a motion to dismiss on the grounds that it was not a proper defendant to the action. *Id.* at *6. Upon judicial review, the Court held that since plaintiff Madsen was seeking review of the decision of the MAC, Kaiser was in fact not a proper defendant. *Id.* at *9. Kaiser's motion was therefore granted. *Id.*

In light of Plaintiff's clarification that she is challenging the *application* rather than the validity of NCD 280.14, this Court agrees with Federal Defendant that there is no longer a need to refer this matter to the agency under the doctrine of primary jurisdiction, as argued in Federal Defendant's Motion to Dismiss. Furthermore, in light of recent case law and pursuant to the plain language of 42 C.F.R. § 405.1136(d)(1),² this Court agrees with Defendant Humana that it is not a proper or necessary party to this case and should be permitted to withdraw.

III. CONCLUSION

For the foregoing reasons, Federal Defendant's Motion to Withdraw its Motion to Dismiss is granted. Likewise, Defendant Humana's Motion to Dismiss and request to be removed from the case are granted. Federal Defendant shall have thirty (30) days from receipt of this Order to file its Answer and the Administrative Record of the ALJ's decision in the underlying Medicare appeal.

Additionally, in the interest of the orderly and efficient disposition of this action and to afford the parties an opportunity to affirmatively present their factual and legal arguments, the following schedule shall prevail:

1. Plaintiff's **BRIEF** shall be filed within **forty-five (45)** days after the date of this order. Such brief shall be captioned "Plaintiff's Brief on the Merits," and at the conclusion thereof shall state the relief requested, e.g. reversal of the Commissioner's final determination and entry of final judgment in Plaintiff's favor. Plaintiff's brief shall also include a separate list of "Legal Issues" and a list of "Facts in Dispute" with appropriate citations to the transcript by page number.
2. Defendant's **BRIEF** shall be filed within **forty-five (45)** days after service of Plaintiff's brief. Such brief shall be captioned "Defendant's Brief on the Merits" and shall address the specific legal issues and facts in dispute cited by Plaintiff. Defendant's brief shall contain appropriate citations to the transcript by page number for all factual averments.

² Under 42 C.F.R. § 405.1136(d)(1), "in any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant."

3. If Plaintiff chooses to file a **REPLY**, such reply brief shall be filed within **fourteen (14)** days after service of Defendant's brief.
4. All briefs shall cite concisely the relevant statutory and case law supportive of the party's position and shall comply with Local Rule 7.1(g).
5. **REQUEST FOR EXTENSION OF FILING DEADLINES WILL BE GRANTED ONLY UPON A SHOWING OF IMPERATIVE CAUSE.**

SO ORDERED.

/s/Vernelis K. Armstrong
United States Magistrate Judge

Date: October 12, 2012