#### **Department of Health and Human Services**

## DEPARTMENTAL APPEALS BOARD

#### **Civil Remedies Division**

Erin Wells, IBCLC,

#### Petitioner

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-761

Decision No. CR4734

Date: November 10, 2016

## DECISION

For the reasons set forth below, I grant the Centers for Medicare & Medicaid Services' (CMS's) motion for summary judgment. Noridian Healthcare Solutions (Noridian), a Medicare administrative contractor, had a legitimate basis to determine that Erin Wells, IBCLC (Petitioner), did not meet the requirements to enroll in the Medicare program as a non-physician practitioner lactation consultant. I therefore affirm the contractor's determination to deny Petitioner's application.

#### I. Background

Petitioner has submitted documentation that she is certified by the International Board of Lactation Consultant Examiners as an "International Board Certified Lactation Consultant® IBCLC." CMS Exhibit (Ex.) 3 at 6. Petitioner seeks to enroll in the Medicare program as a non-physician practitioner, specifically as a lactation consultant.

Petitioner filed an enrollment application in February 2016. CMS Ex. 1. Noridian denied her enrollment application on March 1, 2016, because "[t]here is no statutory or regulatory basis which permits an International Board Certified Lactation Consultant to enroll into [the] Medicare Program for ordering and referring services." CMS Ex. 2 at 1.

Petitioner submitted a letter on April 4, 2016, that was construed as a request for reconsideration of the March 2016 decision. CMS Exs. 3, 4. On June 9, 2016, Noridian issued a letter denying Petitioner's request for reconsideration. CMS Ex. 4. Noridian explained, in pertinent part:

## Revocation, Denial, or Effective date reason: 42 CFR §424.530(a)(1) Not in Compliance with Medicare Requirements There is no statutory or regulatory basis which permits an International Board Certified Lactation Consultant to enroll into the Medicare Program for ordering and referring services.

CMS Ex. 4 at 1. Noridian further explained that "Medicare does not enroll International Board Certified Lactation Consultants for payment or ordering and referring." CMS Ex. 4 at 1.

Petitioner timely filed a request for an administrative law judge (ALJ) hearing that was dated July 22, 2016 and filed on July 26, 2016. I issued an Acknowledgment and Pre-Hearing Order (Order) on July 29, 2016, at which time I instructed that an "in-person hearing to cross-examine witnesses will be necessary only if a party files admissible, written direct testimony, and the opposing party asks to cross-examine." Order, § 10 (emphasis omitted). While Petitioner stated, in her brief, that "I request a formal hearing before this Tribunal where each side may present arguments to this matter," she has not submitted any written direct testimony such that a live hearing is necessary for the purpose of cross-examination. Petitioner's brief (P. Br.) at 7.

I informed each party that it could file a brief, motion to dismiss, or motion for summary judgment with its pre-hearing exchange. Order, § 4. CMS filed a pre-hearing brief, motion to dismiss, or motion for summary judgment (CMS Br.) on September 2, 2016, along with five exhibits. CMS Exs. 1-5. On September 29, 2016, Petitioner filed a brief in response, along with two exhibits.<sup>1</sup> P. Exs. 1-2. In the absence of objections, I admit CMS Exs. 1-5 and P. Exs. 1-2 into the record. I granted CMS's motion for leave to file a reply brief, and CMS filed its reply on October 13, 2016.

#### II. Issue

The issue in this case is whether CMS was authorized to deny Petitioner's application for enrollment as a supplier in the Medicare program.

<sup>&</sup>lt;sup>1</sup> In my Order, I instructed the parties to identify exhibits by whole numbers. Order, § 5(c). Because Petitioner identified her two exhibits as "Exhibit A" and "Exhibit B," I have re-identified those exhibits respectively as P. Ex. 1 and P. Ex. 2.

#### **III.** Jurisdiction

I have jurisdiction to decide this case. 42 C.F.R. §§ 498.3(b)(15), 498.5(*l*)(2)

## **IV.** Findings of Fact, Conclusions of Law, and Analysis<sup>2</sup>

#### 1. Summary judgment is appropriate.

Summary judgment is appropriate if there is "no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law." Mission Hosp. Reg'l Med. Ctr., DAB No. 2459, at 5 (2012) (citations omitted). In order to prevail on a motion for summary judgment, the moving party must show that there is no genuine dispute of material fact requiring an evidentiary hearing and that it is entitled to judgment as a matter of law. *Id.* If the moving party meets this initial burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial .... ."" Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). "To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact — a fact that, if proven, would affect the outcome of the case under governing law." Senior Rehab. & Skilled Nursing Ctr., DAB No. 2300 at 3 (2010). In moving for summary judgment, CMS must present evidence sufficient to show, if uncontradicted, that it is entitled to judgment as a matter of law and that there are no genuine issues of material fact in dispute. St. Catherine's Care Ctr. of Findlay, Inc., DAB No. 1964 at 6-7 (2005). In evaluating a petitioner's response to a motion for summary judgment, the ALJ is to view the evidence in the light most favorable to the facility and is to draw all reasonable inferences therefrom in the facility's favor. Id.

The role of the ALJ in deciding a motion for summary judgment differs from the role of an ALJ in resolving a case after a hearing: "[A]t the summary judgment stage the judge's function is not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Here, there is no genuine dispute of material fact. In fact, both CMS and Petitioner are in agreement regarding the undisputed material facts. CMS Br. at 2-3; P. Br. at 2-3 (agreeing on the following facts: Noridian received Petitioner's enrollment application on February 23, 2016 and denied that application on March 1, 2016; Petitioner's request for reconsideration was received by Noridian on April 8, 2016; Noridian issued an unfavorable reconsidered determination on June 9, 2016; and, Petitioner submitted a request for hearing dated July 22, 2016).

 $<sup>^{2}</sup>$  My findings of fact and conclusions of law are set forth in italics and bold font.

# 2. CMS, through its administrative contractor, correctly denied Petitioner's application for enrollment because she is not eligible to enroll as a supplier in the Medicare program.

Petitioner appeals Noridian's denial of her Medicare enrollment application to be a supplier of lactation consulting services. Noridian denied her application because there is "no statutory or regulatory basis which permits [lactation consultants] to enroll into the Medicare program for ordering and referring services." CMS Ex. 4 at 1.

Part B of the Medicare program is a voluntary supplemental insurance program covering outpatient services. Social Security Act (Act) §§ 1831-1848, 42 U.S.C. §§ 1395j – 1395w-4. The program provides reimbursement for physician services and certain "medical and other health services" provided by non-physician practitioners, including practitioners such as physician assistants, nurse practitioners, certified registered nurse anesthetists, physical therapists, occupational therapists, clinical nurse specialists, certified nurse-midwives, clinical social workers, clinical psychologists, registered dietitians or nutrition professionals, anesthesiology assistants, and speech language pathologists and audiologists. *See* Act § 1861(s), 42 U.S.C. § 1395x(s); Act § 1842(b)(18)(C), 42 U.S.C. § 1395u(b)(18)(C); Act § 1861(bb), 42 U.S.C. § 1395x(bb); Act § 1861(ll), 42 U.S.C. § 1395x(ll); 42 C.F.R. § 405.400. The entities or individuals furnishing such health care services are known as "suppliers." 42 C.F.R. § 400.202.

The Act requires the Secretary to issue regulations establishing a process for the enrollment of suppliers. Act § 1866(j). To receive payment, a supplier must be enrolled in the Medicare program. 42 C.F.R. § 424.505. The purpose of the Medicare Part B enrollment process is to determine a supplier's eligibility to bill and receive Medicare payment for health care services. 42 C.F.R. § 424.502 (defining the term "enrollment" to mean the process for establishing eligibility to submit payment claims to Medicare). CMS may deny a prospective supplier enrollment if Medicare Part B does not authorize payment for its services. *See* 42 C.F.R. § 424.505; *see Peter McCambridge, C.F.A.*, DAB CR1961 (2009), *aff'd*, DAB No. 2290 (2009). It is appropriate to deny an enrollment application if a prospective supplier is found not to be in compliance with the enrollment requirements. 42 C.F.R. § 424.530(a)(1).

The Medicare Program Integrity Manual (MPIM), CMS's guidance for affiliated contractors, lists the types of non-physician practitioners that may be enrolled in the Medicare program as suppliers, referencing the statutory and regulatory bases for Medicare payment to these suppliers. Pursuant to federal regulations, a lactation consultant is not included among the types of non-physician practitioners authorized to receive payment for services as a supplier under the Medicare program. MPIM, Ch. 15, Sections 4.4-4.4.15 (Rev. 519, iss'd May 30, 2014, effective July 31, 2014); *see* 42 C.F.R. § 405.400; *see also* 42 C.F.R. §§ 424.5, 410.1 – 410.175.

CMS does not dispute that Petitioner holds a certification from an accrediting body, the International Board of Lactation Consultant Examiners (IBLCE). CMS Br.; *see* CMS Ex. 3 at 6. Neither CMS's reconsidered determination, nor my decision, questions that Petitioner has received a certification from the IBLCE. My decision does not hinge on Petitioner's individual qualifications, but rather, is based on the fact that I have no authority to grant Petitioner the relief she seeks, namely enrollment in the Medicare program. Similarly, CMS lacked the authority to grant Petitioner's enrollment application.

The purpose of the Medicare Part B enrollment process is to determine a supplier's eligibility to bill and receive Medicare payment for health care services. 42 C.F.R. § 424.502; *see McCambridge*, DAB No. 2290 at 4. Neither CMS nor I can ignore binding statutory and regulatory authority, and Petitioner's appeal of her rejected enrollment application is not an appropriate means to challenge or change existing law. *See* 42 C.F.R. § 424.502 (explaining that the enrollment process is for establishing eligibility to submit payment claims to Medicare). Simply stated, I am bound by the law, and I cannot create a new policy that is inconsistent with the law. *1866ICPayday.com*, *L.L.C.*, DAB No. 2289, at 14 (2009) ("An ALJ is bound by applicable laws and regulations and may not invalidate either a law or regulation on any ground."). I must apply the Medicare laws as they currently exist, and there is no lawful provision that currently authorizes Medicare to enroll a lactation consultant as a practitioner and supplier of services. *See McCambridge*, DAB No. 2290 at 7-8.

Petitioner's arguments are largely premised on a document entitled, "United States Department of Labor, Employee Benefits Security Administration, FAQs about Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation" (FAQs) that was jointly prepared by the Departments of Labor, Health and Human Services, and Treasury. CMS Exs. 3 at 7-8; 5; see P. Br. at 1; http://www.dol.gov/ebsa/faqs/faq-aca29.html, last visited November 1, 2016. While Petitioner contends that this document supports her position, she is mistaken in her reliance on this document. First, Petitioner does not identify any statutory or regulatory authority supporting her interpretation that the FAQs support that lactation consultants such as Petitioner can be enrolled as suppliers in the Medicare program. See Act § 1861(s), 42 U.S.C. § 1395x(s); Act § 1842(b)(18)(C), 42 U.S.C. § 1395u(b)(18)(C); Act § 1861(bb), 42 U.S.C. § 1395x(bb); Act § 1861(ll), 42 U.S.C. § 1395x(ll). Petitioner's citation to the FAQs is not authoritative, in that the information posted on the Department of Labor website does not have the effect of law. More importantly, nothing in the FAQs cited by Petitioner indicates that *Medicare*, as opposed to the "nongrandfathered" group health plans and health insurance issuers referenced under the Patient Protection and Affordable Care Act (PPACA) that are the subject of the FAQs, must provide access to "lactation consultants." The FAQs cited by Petitioner are

pertinent *only* to "group health plans," as discussed by the PPACA<sup>3</sup>, and Medicare is not a group health plan; Medicare is a federal health insurance program for people who are age 65 or older or for younger people who are disabled. Furthermore, the FAQs relied upon by Petitioner only state, for non-grandfathered group health plans, that depending on the circumstances, plans must cover *lactation counseling* without cost sharing, and that this obligation does not necessarily obligate an insurer to retain a *lactation consultant's* services for providing covered lactation counseling services. Rather, and depending on the circumstances, a group health plan could satisfy the requirement to provide lactation counseling services through utilizing other professionals, such as a licensed health care professional (e.g., a registered nurse) other than a lactation consultant. CMS Ex. 5 at 3; *see* § 2713(a)(4) of the Public Health Service (PHS) Act; 42 U.S.C. § 300gg-13(a)(4); 29 C.F.R. § 2590.715-2713.

The Act is clear; only specified and eligible non-physician practitioners may enroll in the Medicare program so that they can individually bill for services. See 42 U.S.C. § 1395u(b)(18)(C). These practitioners include specified health care suppliers, such as physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives, clinical social workers, clinical psychologists, registered dietitian or nutrition professionals; and speech-language pathologists (to include qualified audiologists). Id: see Act § 1861(11), 42 U.S.C. § 1395x(ll). CMS's regulations contain essentially identical guidance, and once again, do not list lactation consultants among the non-physician practitioners who are entitled to payment for services from the Medicare program. 42 C.F.R. § 405.400 (defining "practitioner" to include physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, clinic social worker, registered dietitian or nutrition professional, who is currently legally authorized to practice in that capacity by each state in which he or she provides services). Finally, CMS policy guidance contained in the MPIM directs that the following "individual practitioners" may enroll in Medicare: anesthesiology assistants, audiologists, certified nurse-midwives, certified registered nurse anesthetists, clinical nurse specialists, clinical psychologists, clinic social workers, nurse practitioners, occupational therapists in private practice, physical therapists in private practice, physicians, physician assistants, psychologists practicing independently, registered dieticians, and speech language pathologists in private practice. MPIM, § 15.4.4-4.4.15. Neither statutes, regulations, nor Health and Human Services

<sup>&</sup>lt;sup>3</sup> CMS has explained that the PPACA, among other things, "reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets." 79 Fed.Reg. 51092 (August 27, 2014).

Department-level policy guidance provide for lactation consultants to independently enroll in the Medicare program, and Petitioner cannot cite to any legal authority mandating the enrollment of lactation consultants because no such authority currently exists.<sup>4</sup>

I must apply the law as it currently exists. The applicable law does not authorize CMS to enroll Petitioner in the Medicare program as a lactation consultant. Petitioner points to no source of authority for me to grant an exemption on policy or equitable grounds. Moreover, I have no authority to declare the statute or the regulations invalid or ultra vires. *See 1866ICPayday.com, supra*.

## 3. Petitioner's argument that "Medicare is currently set up to recognize Lactation Consultants as suppliers" based on the existence of a taxonomy code for lactation consultants is without merit.

Petitioner argues that the "Federal Government provides a specific Taxonomy Number for Lactation Consultant non-RN (174N0000X) to be recognized as a health professional" and this supports that Medicare should enroll lactation consultants. P. Br. at 9. I note that taxonomy codes are developed by the National Uniform Claim Committee, which is "a diverse group of health care industry stakeholders representing providers, payers, designated standards maintenance organizations, public health organizations, and vendors." *See <u>http://www.nucc.org/index.php</u>*, last visited November 1, 2016; *see also <u>https://www.cms.gov/medicare/provider-enrollment-and-</u> <i>certification/medicareprovidersupenroll/taxonomy.html*, last visited November 1, 2016 (explaining that the taxonomy code set is maintained by the National Uniform Claim Committee, which is not an entity of the federal government). I recognize that group health plans may choose to enroll lactation consultants who are not registered nurses, and

<sup>&</sup>lt;sup>4</sup> Section 2713 of the Public Health Service Act directs that non-grandfathered group health plans provide lactation counseling and breastfeeding equipment. PHS Act § 2713(a)(4); 42 U.S.C. § 300gg-13(a)(4). No provision of the PHS Act or the PPACA directs that covered lactation counseling services must be provided by lactation consultants. Rather, group health plans determine who will provide covered lactation counseling services, and are not obligated to reimburse unlicensed or uncertified practitioners. CMS Ex. 5 at 3. Petitioner has submitted evidence that she holds a certification, but has not submitted evidence that she is licensed. Thus, under some group health plans, Petitioner may not qualify as a provider of services.

the existence of a taxonomy code for lactation consultants is therefore appropriate and necessary. However, the existence of a taxonomy code for lactation consultants does not demonstrate that the federal government has determined it will enroll lactation consultants as Medicare suppliers.<sup>5</sup>

## 4. I have no jurisdiction over Petitioner's other requests for relief.

As I previously stated, my jurisdiction is derived from 42 C.F.R. §§ 498.3(b)(15), 498.5(l)(2). The only matter properly before me is the denial of Petitioner's Medicare enrollment by Noridian in its June 2016 reconsidered determination; any denial of any request of Petitioner to be an "in-network" or "Medi-Cal" practitioner (P. Br. at 6) is not the subject of an initial or reconsidered determination that is the subject of the instant request for hearing and is a matter entirely separate from the denial of her Medicare enrollment application. I therefore lack jurisdiction over these requests for relief.

## V. Conclusion

Petitioner does not qualify as a non-physician practitioner supplier under the regulations. I affirm the denial of Petitioner's Medicare enrollment application.

/s/ Leslie C. Rogall Administrative Law Judge

<sup>&</sup>lt;sup>5</sup> I recognize CMS's objection to Petitioner's argument on the grounds that she previously did not raise this argument.