Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Marcia M. Snodgrass, APRN
Docket No. A-15-35
Decision No. 2646
June 30, 2015

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Marcia M. Snodgrass (Petitioner) appeals the November 5, 2014 decision of an Administrative Law Judge (ALJ). *Marcia M. Snodgrass, APRN*, DAB CR3442 (2014) (ALJ Decision). The ALJ upheld a determination by the Centers for Medicare & Medicaid Services (CMS) to deny Petitioner's December 2013 application for enrollment as a nurse practitioner (NP) in Part B of the Medicare program. The ALJ granted summary judgment for CMS on the ground that the undisputed facts demonstrated that Petitioner's enrollment application was properly denied pursuant to 42 C.F.R. § 424.530(a)(1) because Petitioner did not meet the qualifications for a NP in 42 C.F.R. § 410.75(b) when she filed her application in December 2013.

For the reasons stated below, we conclude that the ALJ properly granted summary judgment for CMS and uphold the ALJ Decision.

Legal Background

Medicare is administered by CMS, which in turn delegates certain program functions to private contractors. *See* Social Security Act (Act) §§ 1816, 1842, 1874A[1]; 42 C.F.R. § 421.5(b).

The regulations in 42 C.F.R. Part 424, subpart P set out the requirements for establishing and maintaining Medicare billing privileges. In order to receive payment for services furnished to Medicare beneficiaries, a provider or supplier – "supplier" includes a NP –

[1] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp. Table.

must be "enrolled" in Medicare and maintain active enrollment status.[2] 42 C.F.R. §§ 424.500, 424.505, 424.510, 424.516. "Enrollment" is the process that Medicare uses to establish a provider's or supplier's eligibility to submit claims for Medicare-covered services and supplies, including validation of the provider's or supplier's eligibility to provide items or services to Medicare beneficiaries. *Id.* § 424.502.

CMS may deny a provider's or supplier's enrollment in the Medicare program for the reasons set out in 42 C.F.R. § 424.530(a), one of which is when a "provider or supplier at any time is found not to be in compliance with the Medicare enrollment requirements described in [section 424.530] or on the applicable enrollment application to the type of provider or supplier enrolling, and has not submitted a plan of corrective action as outlined in part 488 of this chapter." 42 C.F.R. § 424.530(a)(1). The regulations in 42 C.F.R. Part 488 do not specifically define what an "acceptable plan for correction" means and what it must entail, but section 488.28(a) provides that a provider or supplier found deficient with respect to one or more standards in the conditions of participation or conditions for coverage must submit "an acceptable plan for correction for achieving compliance within a reasonable period of time acceptable to the Secretary."

A provider or supplier that was denied enrollment but did not appeal the denial may reapply after its appeal rights have lapsed. *Id.* § 424.530(b)(1). A provider or supplier that appealed the denial of enrollment may reapply after the provider or supplier has received notification that the determination was upheld. *Id.* § 424.530(b)(2). The denial becomes effective within thirty (30) days of the initial denial notification. *Id.* § 424.530(e).

The regulations in 42 C.F.R. § 410.75(b) set out certain qualifications for NPs who seek Medicare coverage for their services. Section 410.75(b) provides –

> (b) *Qualifications*. For Medicare Part B coverage of his or her services, a nurse practitioner must be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law, and must meet one of the following:

[2] "Suppliers" also include physicians and other non-physician health care practitioners. 42 C.F.R. § 400.202 (stating that, unless the context indicates otherwise, "[s]upplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare"). "Providers" include, *inter alia*, hospitals, nursing facilities, and comprehensive outpatient rehabilitation facilities. *Id.*

(1) Obtained Medicare billing privileges as a nurse practitioner for the first time on or after January 1, 2003, and meets the following requirements:

(i) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

(ii) Possess a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

(2) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2003, and meets the standards in paragraph (b)(1)(i) of this section.

(3) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2001.

Case Background[3]

Petitioner is licensed as a "(APRN/NP) Nurse Practitioner" in Kansas.[4] Petitioner Exhibit (P. Ex.) 4 (Kansas State Board of Nursing's website printouts, obtained February 19, 2013 and on October 6, 2014, indicating original licensing date of October 24, 2002 and expiration date of February 28, 2015). She holds a Bachelor of Science degree in Nursing, awarded in 2002, and was awarded also in 2002 a certificate from the Women's Health Care Nurse Practitioner Program at Harbor-UCLA Medical Center. P. Ex. 1.[5] She originally enrolled in Medicare as a NP effective October 1, 2002. CMS Exhibit (CMS Ex.) 1 (CMS's December 16, 2002 letter informing Petitioner of her "participation status effective October 1, 2002").

[3] The factual information in this section, unless otherwise indicated, in drawn from the undisputed findings of fact in the ALJ Decision and undisputed facts in the record and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact.

[4] As the ALJ noted, Petitioner designated herself as an "advance practice registered nurse" (APRN), which, in Kansas, is the functional equivalent of a NP, as the Kansas licensing authority does not distinguish between a NP and a APRN. ALJ Decision at 1, n.1.

[5] Petitioner's Exhibit 1 is comprised of multiple documents, which are not marked with the exhibit number or exhibit page numbers. They include Petitioner's October 2, 2014 sworn affidavit in which she provided information about her educational, licensing and certification history, as well as copies of her Bachelor of Science degree diploma and the certificate from the Harbor-UCLA program.

In September 2010, Petitioner filed an enrollment application. She states that she received a letter of denial from CMS (or the Medicare contractor) in November 2010. Request for hearing (RFH) (not paginated) at 1.[6] Petitioner filed a new enrollment application on December 30, 2013. By determination dated February 28, 2014, the contractor informed Petitioner that her December 2013 application was denied because she was not certified as a NP by a national certifying body that has established standards for NPs. CMS Ex. 2 (citing 42 C.F.R. §§ 410.75(b)(1)(i), 424.530(a)(1)). Petitioner appealed. By reconsidered determination dated June 9, 2014, the contractor upheld the denial, citing the same reasons for denial. CMS Ex. 3.[7] The contractor informed Petitioner that a "certificate from Women's Health Care Nurse Practitioner Program [at Harbor-UCLA] is not recognized as a [certificate from a] national certifying body that has established standards for nurse practitioners." *Id.* at 1.

Petitioner appealed the reconsidered determination to the ALJ, chiefly asserting that contractor errors and omissions during the revalidation process beginning in 2010 caused her enrollment status, which had been in good standing for eight years since 2002 without the national certification, not to be simply "carr[ied] forth" to reflect continued enrollment in good standing. RFH at 1. The ALJ granted CMS's motion for summary judgment on the ground that there is no dispute on the central fact material to this case – that Petitioner was not certified as a NP by a recognized national certifying body that has established standards for NPs at the time of her December 2013 enrollment application. The ALJ concluded that Petitioner therefore was not qualified as a NP under the regulations and that CMS had authority to deny Petitioner's December 2013 enrollment application. ALJ Decision at 5-6.

The ALJ treated the September 2010 application as an application for revalidation, given undisputed evidence that Petitioner was initially enrolled on October 1, 2002, and found that that application was denied. *Id.* at 1-2, citing 42 C.F.R. § 424.515 (requiring

[6] The record does not include the September 2010 application, the November 2010 denial, or the December 2013 application. Petitioner herself referred to these materials and the date(s) of filing or receipt in her request for hearing, but did not offer them to the ALJ for inclusion into the record. The Board decides supplier enrollment appeals like this case based on the evidentiary record on which the ALJ based his or her decision. 42 C.F.R. § 498.86(a); *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program* (*Guidelines*). The *Guidelines* are available at http://www.hhs.gov/dab/divisons/appellate/guidelines/prosupenrolmen.html. The parties do not dispute that an application was filed in September 2010, which was denied, and that Petitioner then filed a new application in December 2013, which also was denied. Petitioner did not appeal the denial of the September 2010 application to an ALJ; she appealed only the denial of the December 2013 application, which resulted in the ALJ Decision now under Board review.

[7] The reconsidered determination, however, cited 42 C.F.R. § 410.75(d)(1)(i). CMS Ex. 3, at 1. Both parties have treated this as a clerical error and addressed the substantive requirements of section 410.75(b)(1)(i). We conclude that the contractor's citation was a typographical error for section 410.75(b)(1)(i).

submission of an enrollment application as part of the revalidation process). The ALJ further found that Petitioner filed a new enrollment application in December 2013, which also was denied, by letter dated February 28, 2014. That denial was appealed to the ALJ. *Id.* at 2. The ALJ stated:

> At the time of her 2010 enrollment application, only the qualification stated in subsection 410.75(b)(1)(i) applied to her because she first obtained her Medicare billing privileges as a nurse practitioner on October 1, 2002, prior to the deadline established in section 410.75(b)(2). However, neither party addressed in their briefs the legal quandary of whether section 410.75(b)(2) still applied to Petitioner after the contractor denied her 2010 enrollment application and Petitioner did not further challenge that denial. I need not resolve that issue because, regardless of whether section 410.75(b)(2) applied to Petitioner's December 2013 enrollment application, which is the only application subject to review in this proceeding, Petitioner needed to comply with at least the certification requirement listed in section 410.75(b)(1)(i), which she clearly did not.

Id. at 4.

The ALJ also determined that, while section 410.75(b) addresses the requirements for payment for NP services and does not state that its requirements are enrollment requirements, "any alternative interpretation" of section 410.75(b) to mean that it does not set out enrollment requirements would be unreasonable because a NP who cannot receive Medicare payment because he or she does not meet the eligibility requirements for NPs in section 410.75(b) would have "no purpose being enrolled as a supplier in the Medicare program." *Id.* The ALJ wrote, "[W]hile section 410.75(b) addresses the requirements for payment for services that a nurse practitioner provides, the qualifications of a nurse practitioner in that section must be construed as an enrollment requirement referred to in section 424.530(a)(1)." *Id.* (also citing section 424.502, which defines "[e]nrollment" as a process for establishing eligibility to submit Medicare claims for payment, and section 424.505, which requires that a supplier be enrolled before submitting claims for payment).[8]

The ALJ also determined that Petitioner failed to file a plan of corrective action (or a corrective action plan (CAP) as it is more commonly referred to) despite notice and an opportunity to do so. *Id.* at 2 ("The contractor provided Petitioner an opportunity to submit a [CAP] within 30 days of the notice of denial. CMS Ex. 2. There is no record of

[8] Petitioner expressly states that she does not dispute the ALJ's conclusion that she had to meet the section 410.75(b) NP qualification requirements in order to be enrolled in Medicare. Request for review (RR) at 3, n.5.

Petitioner having submitted a CAP.") and 5 ("The contractor complied with regulatory procedures for denying an enrollment application by providing Petitioner an opportunity to submit a CAP within 30 days of the denial notice letter, but she did not do so.").

Finally, the ALJ determined that Petitioner's "additional arguments," including those concerning alleged contractor errors in handling her enrollment and that she should not be held to the section 410.75(b) qualification requirements given the circumstances of her case, amounted to a request for equitable relief he could not grant. *Id.* at 5-6. The ALJ wrote:

> I am without authority to carve out equitable exceptions to the regulatory requirements. Petitioner's assertion that the regulation is inconsistent with the [Social Security] Act means that for me to take any action in Petitioner's favor, I must declare the regulation *ultra vires* the Act. I do not have the authority to do so.

Id. at 5. Moreover, the ALJ determined, to the extent Petitioner's complaints could be construed as a claim for equitable estoppel, the claim fails because Petitioner has not shown affirmative misconduct by CMS. *Id.* at 5-6.

Petitioner requests review of the ALJ Decision by the Board.

Standard of Review

Whether summary judgment is appropriate is a legal issue that we address *de novo*. *1866ICPayday.com*, DAB No. 2289, at 2 (2009), citing *Lebanon Nursing & Rehab. Ctr.*, DAB No. 1918 (2004). Summary judgment is appropriate when the record shows that there is no genuine dispute of fact material to the result. *See 1866ICPayday.com* at 2, citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986).

The Board's standard of review on a disputed conclusion of law is whether the ALJ Decision is erroneous. *See Guidelines*.

Analysis

Petitioner does not assert that the ALJ erred in determining the central factual question material to this case to be whether Petitioner is certified as a NP by a national certifying body that has established standards for NPs. She did not dispute, and still does not dispute, that she does not have national certification. RFH at 1. Rather, this appeal centers on allegations of legal error below, primarily that the ALJ failed to consider the "intent and meaning" of section 410.75(b)(1)(i). RR at 5. According to Petitioner, the

regulation, "properly construed and applied to [her] case," would warrant a conclusion that summary judgment for CMS was "not appropriate." *Id.* We find that none of the allegations, which we will address in more detail below, have merit. We uphold the ALJ Decision because the ALJ correctly determined the dispositive issue – that CMS reasonably determined that Petitioner lacked the required certification from a recognized national certifying body for NPs and therefore CMS had authority to deny her enrollment.

1. *The ALJ did not err in concluding that it is undisputed that Petitioner was not qualified as a NP at the time of her December 2013 enrollment application based on the applicable requirements of section 410.75(b).*

Petitioner asserts that the ALJ erred as a matter of law in "simplistically" declaring that, in order to take any action in her favor, he must declare the regulation *ultra vires* the Act, which he was without authority to do. What the ALJ failed to do, Petitioner argues, is to consider the "intent and meaning" of section 410.75(b)(1)(i), as applied to her case. RR at 5-6.

Petitioner traces the rulemaking history of section 410.75(b)'s NP qualification requirements since 1998, pointing out the gradual development of the NP qualification requirements, which presently require NPs enrolling in Medicare for the first time after January 1, 2003 to hold master's degrees and national certification by recognized certifying bodies. *Id.* at 8-12. According to Petitioner, at the earliest stage of rulemaking in 1998, CMS required NPs to have master's degrees, but later "retreated" from that requirement "without implementing it," and then took a "phase-in approach" that culminated in the promulgation of section 410.75(b) presently in effect. Under the regulation, a NP like Petitioner who first enrolled in Medicare after January 1, 2001 and before January 1, 2003 is held to an "interim standard," i.e., the NP must be certified as a NP by a recognized national certifying body that has established standards for NPs, but is *not* expressly required to have a master's degree. In contrast, a NP who first enrolled on or after January 1, 2003 *is* required to have either a master's degree in nursing or a Doctor of Nursing Practice degree, as well as national certification. *Id.* at 10-11. Petitioner points out that she was allowed to enroll in October 2002 with a Kansas state license and the Harbor-UCLA program certificate without requiring her to have a master's degree. *Id.* at 12.

Petitioner asserts that later CMS wrongly held her to more stringent requirements – effectively both the master's degree and national certification requirements – that were intended to be imposed on only those NPs initially enrolling in Medicare after January 1, 2003. What enabled CMS to do this was its publication in 2007, after she was first

enrolled but before she filed her 2013 application, in the Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, Ch. 15, § 200, of an exclusive list of national certifying bodies that certify NPs that CMS determined would be acceptable.[9] All of the certifying bodies in the MBPM list require candidates for certification to hold master's degrees, at least for those seeking certification more than five years after graduation. RR at 6-7, 13-16; RFH at 1. CMS denied Petitioner's December 2013 enrollment application because she held no certification from a recognized national certifying body; yet, she cannot now obtain national certification without a master's degree, which she does not have and was not required to have in 2002 when she first enrolled. RFH at 1-2.

Petitioner argues that CMS's denial of her December 2013 application was unlawful because it was based on the failure to meet a national certification requirement in the MBPM that was implemented informally, without following the notice and comment procedures of the Administrative Procedure Act (APA), 5 U.S.C. § 553. She states that, in combination, CMS's actions "irrevocably and substantively linked" the requirement of a master's degree to the requirement of national certification, thereby changing the legal meaning of section 410.75(b)'s NP qualification requirements as applied to her. RR at 6, 13-16; Petitioner's Reply (P. Reply) at 1-5. CMS, Petitioner asserts, attempts to apply an "'interpretive' gloss" over what was an "under the table selection of only certain organizations that certify nurse practitioners in a manner that effectively imposed master degree requirements as a condition of NP qualification without regard to state credentialing requirements that Congress had directed CMS to honor in its rulemaking and administration of the program." P. Reply at 3. She asserts that she should not have been held to the requirements that were promulgated in contravention of the APA and instead should have been permitted to continue to remain enrolled (or re-enroll) based on the determination in 2002 that she was qualified to enroll with a Kansas state license and the Harbor-UCLA program certificate. RR at 6-8, 12-13.

Petitioner's fundamental quarrel with CMS's interpretation of section 410.75(b) is that the list is too exclusive, because none of those bodies certify experienced NPs who do not have master's degrees. RR at 12. Petitioner's position, in essence, is that the impact of CMS's action on her is that she is, in effect, being treated as a new enrollee who is held

[9] MBPM, Ch. 15, § 200.A lists seven organizations that are recognized as national certifying bodies for NPs: American Academy of Nurse Practitioners; American Nurses Credentialing Center; National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties; Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses); Oncology Nurses Certification Corporation; AACN Certification Corporation; and National Board on Certification of Hospice and Palliative Nurses. Medicare Program Integrity Manual (PIM), CMS Pub. 100-08, Ch. 15, § 15.4.4.8 includes the same list.

The MBPM and PIM are available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html.

to the regulation now in effect, which flies in the face of the regulatory history of section 410.75(b). Her position is that CMS should be bound by its decision to specifically exempt NPs who, like her, initially enrolled before 2003 from the rule requiring NPs to have master's degrees.[10]

Our review of the rulemaking history of the section 410.75(b) NP qualification requirements shows that both the master's degree and the national certification requirements initially were initially adopted effective on January 1, 1999. 63 Fed. Reg. 58,814 (Nov. 2, 1998).[11] In relevant part, the regulation read as follows:

> (b) *Qualifications*. For Medicare Part B coverage of his or her services, a nurse practitioner must –
>
> (1) Possess a master's degree in nursing;
>
> (2) Be a registered professional nurse who is authorized by the State in which the services are furnished, to practice as a nurse practitioner in accordance with State law; and,
>
> (3) Be certified as a nurse practitioner by the American Nurses Credentialing Center or other recognized national certifying bodies that have established standards for nurse practitioners as defined in paragraphs (b)(1) and (2) of this section.

63 Fed. Reg. at 58,908; *see also* 64 Fed. Reg. 25,456, 25,457 (May 12, 1999) (adding language retroactive to January 1, 1999 to make regulation effective only after December 31, 1999). Thus, after December 31, 1999, NPs would be required to hold a master's degree in nursing, a state license, and national certification.

[10] We note that whether the regulation is *ultra vires* the Act is not the relevant inquiry. The issue here is not whether the regulatory language itself is inconsistent with the Act, but whether CMS's interpretation of the regulatory language in section 410.75(b) was reasonable or amounted to adding a binding legal requirement without notice and comment rulemaking. We are not bound by CMS's manual provision and do not accord it the force of a legal requirement. In general, however, where a regulation is susceptible to more than one interpretation, the Board will defer to CMS's interpretation so long as it is a reasonable reading and not inconsistent with the regulatory language or the statute and the party affected had notice. *See, e.g., Ark. Dep't of Health & Human Res.*, DAB No. 2201, at 12 (2008); *Missouri Dep't of Soc. Servs.*, DAB No. 2184 (2008). Petitioner here must be held to have had notice of CMS's interpretation since she was a Medicare-enrolled supplier at the time it was published in the manual and was obligated to maintain awareness of Medicare requirements. *Cf.* 42 C.F.R. § 411.406(e). As discussed later, we conclude that CMS's interpretation was not a substantive rule as to which notice and comment rulemaking was required.

[11] We note that the issuance of this regulation, and later revisions as final rules with comment period, complied with the APA's notice and comment rulemaking requirements.

However, section 410.75(b) was then revised effective January 1, 2000, to read as follows:

> (b) *Qualifications*. For Medicare Part B coverage of his or her services, a nurse practitioner must-
>
> (1)(i) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; *and*
>
> (ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*
>
> (2) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; or
>
> (3) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section; or
>
> (4) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nursing practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.

64 Fed. Reg. at 59,380, 59,440 (Nov. 2, 1999) (italics in original). In effect, under this version of the regulation, a NP who has a state license but not a master's degree or national certification (like Petitioner) would qualify for enrollment if he or she obtained a Medicare billing number as a NP **on or before December 31, 2000**. Otherwise, the NP must meet additional requirements as stated in the regulation.

With subsequent revision, section 410.75(b), as quoted above under the section headed "Legal Background," went into effect on January 1, 2009 and remains effective today. 73 Fed. Reg. 69,726, 69,933-34 (Nov. 19, 2008). Under the current regulation, NPs who initially obtained Medicare billing privileges before January 1, 2001 need only a state license (as was the case under section 410.75(b)(2) (2000)). NPs initially enrolled on or after January 1, 2003 must have a state license, national certification, **and** either a master's degree or DNP degree. NPs initially enrolled between January 1, 2001 and January 1, 2003 must have a state license and certification by a recognized national certifying body.

In sum, the rulemaking history of section 410.75(b) shows that national certification has been consistently required for NP who initially enrolled when Petitioner did. Petitioner has had a state license throughout but holds a certificate only from the Harbor-UCLA

program. The core question, therefore, is whether CMS is obliged to continue to accept this certificate as demonstrating certification by a recognized national certifying body.[12] Petitioner does not explicitly claim that CMS is permanently bound to accept her as certified by a recognized national certifying body merely because the contractor accepted her initial enrollment in 2002 without challenging whether the Harbor-UCLA program certificate was from a recognized national certifying body. We would, in any case, find no support for holding that CMS was somehow precluded by an initial enrollment decision from reviewing the basis for Petitioner's qualifications on a subsequent revalidation application or new application. Petitioner does not assert, and there is no evidence, that the Harbor-UCLA program certificate should have been deemed to have met the national certification requirements under earlier versions of section 410.75(b) requirements. *See* P. Reply at 6 (characterizing that the certificate as not from "a CMS favorite organization"). Indeed, her description of the certificate is that she received it after attending a program in 2001-02, which suggests it was awarded by an educational program for completing training rather than by a national standards-setting body. P. Ex. 1 (Petitioner's affidavit at 2, ¶ 10). While Petitioner states that the Harbor-UCLA program certificate was issued by a "credible" organization (P. Reply at 6), Petitioner gives no reason why CMS could not reasonably determine that that organization did not meet the characteristics of an acceptable certifying organization when CMS developed and announced the list in the MBPM. Petitioner has not shown that she has a right to expect or is entitled to a guarantee that the Harbor-UCLA program certificate (or the bachelor's degree), apparently accepted for the purposes enrollment in 2002, would continue to be accepted going forward for the revalidation or re-enrollment purposes despite changes in the regulation that were promulgated consistent with the APA.[13]

In any case, Petitioner's central contention is that the list of bodies in CMS's manual serves to extend the master's degree requirement sub rosa by excluding other bodies. Thus, Petitioner argues that the rulemaking history indicated that CMS was taking a gradual approach to implementing uniform (but more stringent) NP qualification requirements in furtherance of "accommodat[ing] differences in state law regarding NP eligibility to practice." P. Reply at 2-3. She contends that, rather than merely interpreting or clarifying the regulation, CMS's compilation in 2007 of a specific list of acceptable national certifying bodies amounted to a new substantive rule on NP qualification requirements. According to Petitioner, she was enrolled in the midst of the transitional process and "[h]er continued enrollment depends on [section 410.75(b)(1)(i)],

[12] The record does not address why Petitioner was permitted to enroll effective October 1, 2002, and apparently was permitted to remain enrolled until 2010, even though she did not meet the NP qualification requirements during that period. As we have noted, the only issue before us is whether she was entitled to enroll in 2013.

[13] Before the ALJ, Petitioner complained that the regulation that went into effect on January 1, 1999 had no provision for "grandparenting" the "licensed, certificate-prepared NPs without master's degrees." Petitioner's brief in opposition to CMS's motion for summary judgment at 7.

which requires national certification." *Id.* at 2. CMS, Petitioner asserts, attempts to apply an "'interpretive' gloss" over what was an "under the table selection of only certain organizations that certify nurse practitioners in a manner that effectively imposed master degree requirements as a condition of NP qualification without regard to state credentialing requirements that Congress had directed CMS to honor in its rulemaking and administration of the program." *Id.* at 3. Petitioner further asserts that CMS "covertly disregard[ed]" Congress's directive to take into consideration variances in state licensing laws. *Id.*

Congress, in section 1861(aa)(5)(A) of the Act, defined a "nurse practitioner" to mean a "nurse practitioner who performs such services as the individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law . . . *and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations*." (Italics added.) Thus, the statute did not direct the Secretary (or her delegate, CMS) to simply defer to state law requirements but clearly anticipated that CMS would articulate additional baseline standards by regulation. CMS did so by, among other things, adopting the regulatory requirement of certification by "a recognized national certifying body that has established standards[.]" 42 C.F.R. § 410.75(b)(1)(i). Therefore, the issue is simply what constitutes such a body.

We also reject Petitioner's argument that the APA's formal rulemaking requirements were violated for the reasons we set out below. Under section 553(c) of the APA, when a federal agency adopts, amends, or repeals a rule, the agency must publish notice of the proposed change in the Federal Register and give interested persons an opportunity to participate in the rulemaking through the submission of written data, views, or arguments. Section 553(b) of the APA excepts from its notice and comment rulemaking requirement interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice. Therefore, substantive or legislative rules must be promulgated through notice and comment procedures; interpretive rules need not undergo notice and comment procedures. The courts have consistently held that agency rules that are substantive or legislative are invalid if an agency fails to comply with the APA requirements. *See, e.g.*, *Buschmann v. Schweiker*, 676 F.2d 352, 358 (9th Cir. 1982) (holding that regulation was invalid until publication of final rule); *cf. Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979) ("[c]ertainly regulations subject to the APA [notice and comment requirements] cannot be afforded the 'force and effect of law' if not promulgated pursuant to the statutory procedure minimum found in that Act").

The Board discussed the general framework for analyzing whether an agency action is subject to notice-and-comment rulemaking in *Maryland Dept. of Human Resources*, DAB No. 1667, at 8-11 (1998):

While there is considerable diversity in the standards courts have used to distinguish between legislative and interpretative rules, it is generally agreed that when an agency is exercising its rule-making power in order to interpret or clarify an existing statute or regulation, the agency is considered to be engaged in interpretative rulemaking. "An interpretative rule simply states what the administrative agency thinks the statute means. . . ." *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc), *cert. denied*, 471 U.S. 1074 (1985); *see also Alcaraz v. Block*, 746 F.2d 593, 613 (9th Cir. 1984) (interpretative rule "simply explained something the statute already required").

In contrast, courts also agree that when an agency acts to create new law, rights, or duties in what amounts to a legislative act, it is engaged in legislative rulemaking. *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993); *Metr. School Dist. of Wayne Township v. Davila*, 969 F.2d 485, 489-490 (7th Cir. 1992), *cert. denied*, 113 S.Ct. 1360 (1993*); United Technologies Corp. v. EPA*, 821 F.2d 714, 718 (D.C.Cir. 1987). *See also Alcaraz*, 746 F.2d at 613 (legislative rules impose general, extra-statutory obligations pursuant to authority properly delegated by the legislature); *Cabais v. Egger*, 690 F.2d 234, 238 & n.9 (D.C.Cir. 1982) (legislative rules have effects completely independent of the statute).

In addition to the necessity for notice and comment, Kenneth Culp Davis, in *Administrative Law Treatise*, identifies three principal differences between legislative and interpretative rules. These distinctions are as follows.

- First, "a legislative rule has the same binding effect as a statute. It binds members of the public, the agency, and even the courts, in the sense that courts must affirm a legislative rule as long as it represents a valid exercise of agency authority." 1 Kenneth Culp Davis et al., *Administrative Law Treatise*. 6.3 (3rd ed. 1994). In contrast, "[a] court may choose to give binding effect to an interpretative rule . . . but it is the court that provides the binding effect of law through its process of statutory interpretation." *Id.*
- Second, "an agency has the power to issue binding legislative rules only and to the extent Congress has authorized it to do so . . . . By contrast, any agency has the inherent power to issue interpretative rules." *Id.*

- Third, "a legislative rule can impose distinct obligations on members of the public in addition to those imposed by statute, as long as the rule is within the scope of rulemaking authority conferred on the agency by statute. By contrast, an interpretative rule cannot impose obligations on citizens that exceed those fairly attributable to Congress through the process of statutory interpretation." *Id.*

Furthermore, an agency action that "merely explains how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion or permitting discretion under some extant statute or rule—is a general statement of policy." *National Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014).

Having considered Petitioner's argument within the context of the above principles and distinctions, we conclude that Petitioner's position that the MBPM list of certifying bodies is a substantive or legislative rule has no merit. We note that, other than generalized references to preambles in the Federal Register rulemakings on section 410.75(b), *see, e.g.*, RR at 10, Petitioner does not point to a specific source or authority in support of her apparent position that CMS somehow exceeded or deviated from statutory authority or Congress's directive to "accommodate differences in state law regarding NP eligibility to practice." P. Reply at 3. Petitioner herself acknowledged that section 1861(aa)(5)(A) permitted CMS to define the qualification requirements for NPs (RR at 7, n.15) and does not clearly show that CMS's use of a list to clarify and apply the regulatory requirements was somehow unreasonable.

Nor do we agree that using a gradual, "phase-in" process for elevating NP qualifications over time implies some guarantee that national certification standards would never become stricter to the disadvantage of earlier enrollees. The regulatory phase-in simply determined that, rather than a blanket master's degree requirement applied to all NPs (as was initially adopted), that requirement would only apply prospectively. There is no dispute, however, that the certification requirement in the regulation does apply to Petitioner. While Petitioner argues that the phase-in provision was intended to benefit NPs like her who "may never need a master's degree" (P. Reply at 2), we do not find any support for a claim that the phasing-in of a universal master's degree requirement amounted to a guarantee that those who were not subject to that requirement because of their earlier enrollment status would also continue to meet all other requirements. Here, Petitioner is not being held to the universal master's degree requirement, but rather has failed to show that she possesses a certification from any recognized national certifying body.

Further, the MBPM list of acceptable certifying bodies is just that – a list. Unlike a substantive or legislative rule, which "creates rights, assigns duties, or imposes obligations, the basic tenor of which is not already outlined in the law itself," *Warder v. Shalala*, 149 F.3d 73, 80 (1st Cir. 1998) (emphasis omitted) (quoting *La Casa Del Convaleciente v. Sullivan*, 965 F.2d 1175, 1178 (1st Cir. 1992)), the MBPM list itself does not effect a substantive change in the regulations in section 410.75(b). It does not create a right or obligation. It does not set out a requirement different from the NP qualification requirements in section 410.75(b). The publication of the list in the MBPM in 2007 did not change the meaning or impact of section 410.75(b) then in effect, or even the regulation as revised since then. The MBPM list does not, standing alone, have binding force of law. The MBPM list does not "effect[] a substantive change in the regulations" and thus, is akin to an interpretive rule that is not subject to notice and comment rulemaking. *See Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995). The regulations in section 410.75(b) themselves, as promulgated through formal rulemaking, require certification of NPs by recognized national bodies. The MBPM merely clarifies and explains what CMS would recognize as acceptable certifying bodies for the purposes of national certification of NPs required under the regulation.

If anything, the list might be viewed as expanding on the single acceptable certifying body expressly identified in the 1998 rulemaking, the American Nurses Credentialing Center, by identifying other recognized national certifying bodies that have established standards for NPs as of 2007. *See* 63 Fed. Reg. at 58,908 (section 410.75(b)(3) ("Be certified as a nurse practitioner by the American Nurses Credentialing Center or other recognized national certifying bodies . . . ."). Petitioner has provided no evidence that Harbor-UCLA Medical Center is a national certifying body that CMS should have recognized or why CMS was arbitrary or capricious in not accepting a certificate from that program as equivalent to certification by one of the NP national certifying bodies which CMS did recognize. Petitioner has not shown that the adoption of a requirement for a master's degree to qualify for certification as a NP results from CMS somehow adopting an artificially narrow list of bodies to recognize as national certifying bodies, rather than from changes within the profession and industry itself over time that caused that requirement to be adopted by all of the bodies themselves. Thus, it appears that any adverse impact on Petitioner may be as much the result of development of changes in the general standards for NP qualification requirements as of CMS's development of a list to identify national certifying bodies.

Finally, we note that Petitioner refers to variations in state licensing requirements for NPs, but also variations in state licensing requirements for advance practice clinical nurse specialists generally, as well as distinctions between the qualifications for NPs versus clinical nurse specialists. She points out that section 1861 of the Act does not require NPs to have a master's degree, but it does require clinical nurse specialists to hold a master's degree in their area of specialty. *See, e.g.*, RR at 10, n.25. But she does not clearly explain how those variations and distinctions, and in particular the distinction

between the qualifications for NPs and clinical nurse specialists, are material to the specific issues under review here. We disagree with the implication that she draws that the statutory requirement that a NP meet state requirements meant that CMS could not impose any standards for Medicare enrollment that exceeded the least stringent state requirement. To the contrary, as noted earlier, section 1861(aa)(5)(A) of the Act provides that an NP must **both** comply with state law requirements **and** meet any additional requirements imposed by CMS. Whatever differences there were among state credentialing requirements, CMS took appropriate action within its authority to standardize Medicare rules on the qualification of NPs.

Thus, based on the record before us, we conclude that, even in the absence of the MBPM list, CMS would not be obliged to accept a certificate from the Harbor-UCLA program as sufficient to meet the regulatory requirements for NP enrollment because the program has not been shown to constitute a recognized national certifying body. Furthermore, listing the recognized national certifying bodies in the MBPM represents a reasonable exercise of CMS's authority to explain its interpretation of and plans for enforcing the regulatory provision.

Since the ALJ did not err in concluding that Petitioner failed to meet the regulatory requirement to hold a certificate from a recognized national certifying body and hence that CMS had the authority to deny her enrollment, the Board upholds the ALJ Decision.

2. Petitioner's assertion of error concerning the proposed CAP has no merit.

Petitioner represents that her request for reconsidered determination (which is not of record) set out a CAP. RR at 3, 16-17. In her request for hearing, she wrote:

> I am willing to work toward my national certification. Additional education will be required for national certification consisting of 2 years part time, so that I can work and attend classes. If we could reinstate my number for the 2 years while I complete my master for national certification would be a working situation.

RFH at 2; RR at 17, n.50 (quoting the same statement from the request for hearing). Petitioner asserts that the contractor and the ALJ erred "under 42 C.F.R. § 424.530" in not recognizing her expression of willingness to pursue a master's degree and achieve national certification as a proposed CAP. RR at 17; *see also* P. Reply at 5.

As noted earlier, the ALJ stated that "there is no record of Petitioner having submitted a CAP." ALJ Decision at 2. Petitioner evidently sent what she characterizes as her request for reconsidered determination not directly to the contractor but to her U.S. Senator's office, which then routed it to the contractor, and objects that contractor did not expressly

address the sufficiency of this proposed CAP. *See* CMS Response at 9-10; CMS Ex. 3, at 1 (reconsidered determination, referring to a timely appeal sent to the U.S. Senator). The reconsidered determination did not specifically refer to a CAP. Instead, the contractor simply acknowledged the submittal of a "Reconsideration appeal request" and a "certificate from Women's Health Care Nurse Practitioner Program" and stated that Petitioner "has not provided evidence to show [that she has] fully complied with the standards for which [she was] denied [enrollment]." CMS Ex. 3, at 1. The request for reconsidered determination is not in our record but, even if it were, even if it contained the offer to return to school, and even if we viewed that as a CAP, we would conclude that the contractor here effectively rejected Petitioner's proposal as unacceptable.

The contractor's February 28, 2014 determination informed Petitioner that "[t]he CAP should provide evidence that you are in compliance with Medicare requirements"; be "signed by the authorized or delegated official within the entity"; and be submitted within 30 days "after the postmark date of this letter." CMS Ex. 2, at 1. In doing so, the contractor succinctly communicated to Petitioner that, for the purposes of this case, an acceptable CAP would be evidence of compliance with the requirement that was cited as a basis for denial, i.e., evidence of national certification.[14] The contractor clearly determined in the reconsidered determination that Petitioner still did not have the national certification that was a prerequisite for enrollment as a NP.[15] Therefore, we are not able to conclude that any omission by the contractor to specifically acknowledge receipt of the purported CAP in its reconsidered determination amounts to denial of an opportunity to submit a CAP.

To the extent that Petitioner asserts the ALJ also erred in not recognizing her expression of willingness to come into compliance, as stated in the request for hearing, as a CAP, Petitioner misses the point. RR at 3 ("Recognizing that the Contractor had given Petitioner an opportunity to file a [CAP], the ALJ *did not* recognize in his opinion that

[14] The contractor's explanation of what an acceptable CAP should include and when it is due is consistent with CMS's sub-regulatory guidance on point here. CMS has stated that a CAP submitted by a supplier whose Medicare enrollment is denied or whose Medicare billing privileges are revoked "must . . . [c]ontain, at a minimum, verifiable evidence that the supplier is in compliance with Medicare requirements." PIM, Ch. 15 (Medicare Enrollment), § 15.25.1.1.A. CMS also has established 30 days after the date of the denial or revocation notice as a reasonable period of time within which the provider or supplier must submit the CAP. *See id.*

[15] Indeed, Petitioner herself seems to recognize that, as a practical matter, she could not have submitted an acceptable CAP within the required 30-day period. RR at 18 ("The problem with [my] CAP is that it must establish that [I] would be in compliance with all requirements within 30 days from the notice denying [my] billing privileges. Obviously, although a CAP is offered, it is not helpful if the time to accomplish would take too long.") and RR at 20 (stating that all of the recognized national certification organizations would require a master's degree for the purposes of certification as NP and acknowledging that she did not have such a "credential" and, therefore, she "was not able to sit for a certification exam within the typical time CMS allows for a CAP to be implemented").

Petitioner had indeed included a CAP . . . in her brief to the ALJ." Emphasis in original.) and 18 ("Petitioner's CAP was simple and of Record in this case since July 2014 . . . ."). (We note that the request for hearing was filed in July 2014.) Only the contractor, and not the ALJ, may decide the sufficiency of a CAP.

We understand the ALJ's reference to the absence of a CAP to mean only that he found the record did not include evidence of a CAP submitted to the contractor. We do not read the ALJ Decision to mean that the ALJ determined the sufficiency of any CAP was an issue properly before him, and we agree that it was not. In *DMS Imaging, Inc.*, DAB No. 2313 (2010), the Board stated:

> After the initial notice of revocation, the supplier has two tracks to seek to avoid revocation and may elect to pursue either or both concurrently. The supplier, within 60 days, may request "reconsideration" of whether the basis for revocation is erroneous or, within 30 days, it may submit a CAP to demonstrate that it has corrected that basis. If the contractor accepts the CAP, it notifies the supplier, and any reconsideration request is withdrawn. If the contractor denies the CAP, the reconsideration process may proceed to a hearing before a hearing officer, who reviews "the Medicare contractor's reason for imposing a . . . revocation at the time it issued the action . . . ." An unfavorable hearing officer decision is appealable to an ALJ, who reviews the basis for the revocation. No provision is made for an appeal of the contractor's decision not to reinstate based on the CAP. The hearing officer conducting the reconsideration (and the ALJ on appeal of the hearing officer decision) are limited to reviewing the basis for revocation set out in the initial notice, not the merits of any contractor decision that corrective action under a CAP was unacceptable.

DMS Imaging, Inc., at 7-8 (internal citations and footnote omitted). *See also id.* at 5 ("Neither the Social Security Act nor the implementing regulations provide for administrative review of a contractor's refusal to reinstate a supplier's billing privileges on the basis of a CAP."); PIM, Ch. 15, § 15.25.1.1 (discussing the required contents of CAPs and process for contractor review of CAPs).

Thus, whether or not to accept a CAP is a matter for the contractor, not the ALJ, to determine. The supplier may appeal the contractor's reconsidered determination, the issuance of which would likely be an indication that a CAP, if one was submitted, was rejected. Under the regulations, the reconsidered determination to deny enrollment of a supplier under 42 C.F.R. § 424.530, as was the case here, made by CMS or its contractor, is an "initial determination" that may be appealed through the administrative process, to the ALJ and then to the Board. 42 C.F.R. § 498.3(b)(17). There is no right to appeal a contractor's determination on the sufficiency or rejection of a proposed CAP to the ALJ or the Board. *See* Act § 1866(j)(8) (providing that a "provider or supplier whose

application to enroll (or, if applicable, to renew enrollment) . . . is denied may have a hearing and judicial review of such denial . . . ."); *see also* 42 C.F.R. § 498.3(d) (non-exclusive list of examples of actions that are not initial determinations subject to appeal); *A TO Z DME, LLC*, DAB. No. 2303, at 8-10 (2010) (explaining why the ALJ's determination not to review CMS's rejection of A TO Z's plan of corrective action was not erroneous).

There is no dispute that Petitioner had not achieved compliance, i.e., at the time she requested reconsideration, she did not have the national certification.

3. Petitioner is not entitled to the relief she requests – reinstatement of her billing privileges prior to achieving compliance.

Petitioner does not dispute the ALJ's determination that he does not have the authority to grant equitable relief but denies that what she asks amounts to equitable relief. RR at 18. Petitioner states that CMS recognized that it would consider mitigating factors when determining whether to deny or revoke billing privileges and that the circumstances of this case present mitigating factors. *Id.* at 19-20 & 19 n.56 (citing 71 Fed. Reg. 20,754, 20,761 (April 21, 2006)). Petitioner identifies the need for NP services in a rural, underserved area of Kansas in particular as a mitigating factor in her case. She asks for relief in the form of reinstatement of her billing privileges until such time she achieves compliance by obtaining a master's degree and national certification. RR at 18-20; P. Reply at 5-6.

As CMS argues, the factors to which Petitioner alludes are mentioned only in relation to the revocation of enrollment of existing suppliers whereas Petitioner's application for revalidation was denied. 71 Fed. Reg. at 20,761; *see also* CMS Response at 11 (citing CMS Ex. 2). The discussion of denial of enrollment contains no similar provision. Petitioner's reply brief does not rebut CMS's argument that the Federal Register language on which she relies is inapplicable to enrollment denials and cites no other authority for the proposition that she is entitled to reinstatement. We therefore need not address whether the ALJ or the Board would have had any authority to review CMS's decision to exercise discretion to deny enrollment based on such factors as are set out in relation to revocations. *See generally Brian K. Ellefsen, DO*, DAB No. 2626 (2015) (where CMS has legal authority to deny enrollment application, neither the ALJ nor the Board may substitute discretion as to whether denial was appropriate, but may review whether CMS did exercise that discretion) and cases cited therein.

Accordingly, to the extent that the ALJ determined that Petitioner's statements amounted to a request for impermissible equitable relief, we agree.

Conclusion

Based on the foregoing reasons, we uphold the ALJ Decision.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Susan S. Yim
Presiding Board Member