

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Community Home Health Care of Western Michigan, Inc.
Docket No. A-18-7
Decision No. 2867
April 26, 2018

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Community Home Health Care of Western Michigan, Inc. (Community), a home health agency (HHA) in Michigan, requests review of the decision of an Administrative Law Judge (ALJ) upholding the Centers for Medicare & Medicaid Services' (CMS) denial of Community's application for enrollment of a new practice location in the Medicare program. *Cnty. Home Health Care of W. Mich., Inc.*, DAB CR4921 (Aug. 15, 2017) (ALJ Decision). The ALJ granted summary judgment for CMS on the ground that the undisputed facts demonstrated that Community's application was properly denied pursuant to 42 C.F.R. § 424.530(a)(10) because Community was subject to a temporary moratorium on the enrollment of HHAs imposed pursuant to 42 C.F.R. § 424.570(a)-(c). For the reasons stated below, we conclude that the ALJ properly granted summary judgment for CMS.

Legal Background

To participate in the Medicare program, an HHA, like other entities defined as a "provider of services" in section 1861(u) of the Social Security Act (Act), must be enrolled in the program. Enrollment confers on a provider the right to bill Medicare for health care services provided to Medicare beneficiaries. Act § 1866(a); 42 C.F.R. Part 424, subpart P. The process for the enrollment of an HHA begins with the submission of a completed enrollment application to the designated CMS contractor, which reviews the application to verify the prospective HHA's eligibility to participate in the program. 42 C.F.R. § 424.510. CMS reserves the right to perform an on-site review of the HHA in order to verify the accuracy of the enrollment information the HHA submitted to CMS or the contractor and to determine compliance with Medicare enrollment requirements. *Id.* §§ 424.510(d)(8), 424.517(a). CMS, through its contractor, may reject an enrollment application or deny enrollment. *Id.* §§ 424.517(a), 424.525, 424.530. Enrollment applications must be screened consistent with the level of risk CMS has assigned to the provider and supplier categories. *Id.* § 424.518; Act § 1866(j)(1), (2).

Section 6401(a) of the Patient Protection and Affordable Care Act (ACA), Pub. L. 111-148, amended section 1866(j) of the Act by adding a new section 1866(j)(7). This section authorizes the Secretary of Health and Human Services to impose temporary moratoria on the enrollment of new Medicare (title XVIII), Medicaid (title XIX), or Children's Health Insurance Program (CHIP, title XXI) providers and suppliers, including categories of providers and suppliers, if the Secretary determines that moratoria are necessary to prevent or combat fraud, waste or abuse under the programs. Act § 1866(j)(7)(A). Section 1866(j)(7)(B) of the Act provides that there "shall be no judicial review" of the imposition of a temporary moratorium imposed under section 1866(j)(7)(A) of the Act.

The Secretary published proposed regulations to implement the ACA amendments, including those concerning temporary moratoria on new enrollments of Medicare providers and suppliers. 75 Fed. Reg. 58,204, 58,242-43 (Sept. 23, 2010). Under the final regulations, which took effect March 25, 2011, *see* 76 Fed. Reg. 5862 (Feb. 2, 2011), CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. 42 C.F.R. § 424.570(a)(1)(i). CMS will announce the temporary enrollment moratorium in a Federal Register document that includes the rationale for imposition of the moratorium. *Id.* § 424.570(a)(1)(ii). "The temporary enrollment moratorium does not apply to any enrollment application that has been approved by the enrollment contractor but not yet entered into PECOS [the internet-based Provider Enrollment, Chain, and Ownership System] at the time the moratorium is imposed." *Id.* § 424.570(a)(1)(iv).

CMS may impose a temporary moratorium if, among other reasons, CMS determines that there is significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both, or CMS, in consultation with the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) or the U.S. Department of Justice or both and with the approval of the CMS Administrator, identifies either a particular provider or supplier type or a particular geographic area, or both, as having a significant potential for fraud, waste or abuse in the Medicare program. 42 C.F.R. §§ 424.570(a)(2)(i)-(iv). CMS may deny a provider's or supplier's enrollment if the provider or supplier "submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium." *Id.* § 424.530(a)(10). A moratorium on enrollment may be imposed for a six-month period and, if CMS deems necessary, may be extended in six-month increments. *Id.* § 424.570(b). "A Medicare contractor denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium as specified in [section 424.570(a)]." *Id.* § 424.570(c).

A prospective provider or supplier denied billing privileges based on the imposition of a temporary moratorium may appeal the denial in accordance with the appeal procedures in 42 C.F.R. Part 498, subpart A. *Id.* § 424.545(a). The scope of review in any such appeal “is limited to determining whether the temporary moratorium applies to the provider or supplier appealing the denial. The agency’s basis for imposing a moratorium is not subject to review.” *Id.* § 498.5(l)(4).

Background and Procedural History¹

Community’s Application and CMS’s Denial

Community submitted to Medicare contractor National Government Services (NGS) an application (form CMS-855A), dated February 1, 2016, changing its Medicare information to reflect the addition of a new practice location at 102 S. Whittacker Street, New Buffalo, Michigan, effective February 15, 2016. ALJ Decision at 6, citing CMS Ex. 2, at 13, 27;² and Pet.’s April 18, 2017 Pre-hearing Br. at 1. In a letter dated February 9, 2016, NGS confirmed receipt of Community’s application and requested corrections to it. *Id.*, citing CMS Ex. 3, at 2-5. Community submitted the corrections on March 2, 2016. *Id.*, citing CMS Ex. 3, at 1.

In a letter dated March 8, 2016, NGS provided the following information to Community: NGS had assessed Community’s application and forwarded it to the Michigan Department of Licensing and Regulatory Affairs for review; NGS had sent a copy of the application to the CMS Regional Office for review; the next step in the application process would be a site visit or survey by the State survey agency or CMS-approved accrediting organization to ensure Community complied with the conditions of participation; NGS would send Community its decision; and Medicare billing privileges would not commence before the survey and certification process was completed and a determination made that Community met all requirements. ALJ Decision at 6, citing CMS Ex. 4.

On August 3, 2016, CMS announced that effective July 29, 2016, it had extended to all counties in Michigan a temporary moratorium that it had previously imposed on HHAs in some counties of Michigan. 81 Fed. Reg. 51,120, 51,123 (Aug. 3, 2016). This Federal Register announcement stated, in part, that “beginning on the effective date of this document, no new HHAs will be enrolled in Medicare . . . with a practice location in . . . Michigan . . . unless their enrollment application has already been approved but not yet

¹ The facts stated here are taken from the ALJ Decision and the record and are not disputed in any material respect.

² The information that Community was applying to add a new practice location is actually on page 14 of CMS Exhibit 2, not page 13.

entered into PECOS . . . as of the effective date of this document.” ALJ Decision at 6-7, quoting 81 Fed. Reg. 51,123.

On August 4, 2016, NGS sent Community a letter stating that it had approved Community’s change of information application seeking to add a practice location effective February 15, 2016. *Id.* at 7, citing CMS Ex. 1 at 37. However, the same letter then informed Community that “CMS/State final approval and tie-in” was required and that for certain states, including Michigan, the change requested in the application (adding a practice location) would not occur until approved by CMS. *Id.*

On August 29, 2016, NGS notified Community that due to the temporary moratorium that began on July 29, 2016, its application to add a new practice location at 102 S. Whittacker Street, New Buffalo, Michigan, was denied pursuant to 42 C.F.R. § 424.530(a)(10). *Id.*, citing CMS Ex. 1, at 51. On reconsideration, a CMS hearing officer upheld the denial, concluding that the moratorium applied to the addition of a new practice location and that Community’s request to add a new practice location had not been approved before the moratorium took effect. *Id.*; CMS Ex. 1, at 1-6.

The ALJ Proceeding

Community timely requested an ALJ hearing. ALJ Decision at 2. CMS moved for summary judgment, and Community filed a cross-motion for summary judgment. *Id.* CMS filed four exhibits, all admitted without objection.³ *Id.* The ALJ granted summary judgment for CMS after finding no genuine dispute of material fact. *Id.* at 10. The ALJ concluded that CMS had a basis to reject Community’s application under section 424.530(a)(10) because the moratorium applied to Community’s application, and the application had not been approved at the time the moratorium took effect. *Id.* at 9, 10. The ALJ rejected Community’s argument that the documents of record showed that its application had been approved by NGS in March 2016 and held that he had no authority to consider Community’s argument that applying the moratorium to a branch location was ultra vires the statute authorizing CMS to impose moratoria.⁴ *Id.* at 8, 9-10.

³ Neither the record nor the ALJ Decision indicates that Community filed exhibits.

⁴ We note the ALJ generally used the terms “new branch” and “new branch location” to describe Community’s request to add a new practice location. *See, e.g.*, ALJ Decision at 9, 10. Community uses the term “branch office.” RR at 1, 4. We generally use the terminology “new practice location” in our decision, mirroring the language in 42 C.F.R. § 424.570(a)(1)(i), but the terms used by the ALJ, Community, and us are substantively interchangeable for purposes of applying this regulation.

Standard of Review

The ALJ's grant of summary judgment is a legal issue that we address de novo. *Patrick Brueggeman, D.P.M.*, DAB No. 2725, at 6 (2016). Summary judgment is appropriate if there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. *Id.* "The applicable substantive law will identify which facts are material, and only disputes over facts that might affect the outcome of the case under the governing law will properly preclude the entry of summary judgment." *Southpark Meadows Nursing & Rehab. Ctr.*, DAB No. 2703, at 5 (2016) (internal quotation marks and brackets omitted). In addition, with respect to an allegation of ALJ procedural error, the Board reviews the allegation to determine "whether the ALJ committed an error of procedure that resulted in prejudice (including an abuse of discretion under the law or applicable regulations)." *Precision Prosthetic, Inc.*, DAB No. 2597, at 10 (2014) (internal quotation marks omitted).

Discussion

- A. *The ALJ properly concluded on summary judgment that CMS was authorized to deny Community's enrollment application since the temporary moratorium applied to that application and took effect before CMS approved the application.*

Community argued before the ALJ that NGS approved its application to enroll a new practice location on March 8, 2016, citing a letter of that date sent to Community by the contractor. The ALJ found that the March 8 letter did not approve the application but, on the contrary, "clearly advised Petitioner . . . that the steps to enroll Petitioner's new branch at 102 S. Whittacker Street, New Buffalo, Michigan were not complete as of the date of that letter." ALJ Decision at 9. The ALJ cited the letter's having informed Community that a site visit or survey would be the next step in the application process and that billing privileges would not begin before the survey and certification process was complete and all federal requirements were met. *Id.*, citing CMS Ex. 4.

On appeal, Community reiterates its argument that NGS approved its application in March 2016, but then concedes that NGS's March 8, 2016 letter "did not state expressly that the application had been approved." Request for Review (RR) at 2 and n.2.⁵ Community relies, instead, on the letter issued by NGS on August 4, 2016, which Community characterizes as a "revised notice." RR at 2 n.1. The August 4, 2016 letter stated, "We have approved your information change request . . . [e]ffective 02/15/2016." CMS Ex. 1, at 37. However, immediately following this statement, the August 4, 2016

⁵ Community cites "Pet. Ex. 3, CMS Ex. 3" after this concession. However, the record contains no exhibits submitted by Community, and the March 8, 2016 letter is in CMS Exhibit 4, not CMS Exhibit 3.

letter added the information “(*requires CMS/State final approval and tie-in).” *Id.* The ALJ concluded from this additional information that the statement, “We have approved . . .,” did not mean that Community’s application had been finally approved but, rather, that NGS’s approval was “subject to ‘CMS/State final approval and tie-in.’” ALJ Decision at 9, quoting CMS Ex. 1, at 37. As further support for this conclusion, the ALJ cited the letter’s warning “that for certain states, including Michigan, the change would not occur until approved by CMS.” *Id.* at 7. The warning cited by the ALJ specifically provided as follows:

Please be advised, if you are a provider in the following states[,] your address change request requires CMS approval before it can be updated in the Fiscal Intermediary Shared System (FISS). These states are: Alaska, American Samoa, Arizona, California, Connecticut, Guam, Hawaii, Idaho, Michigan, Nevada, New York, Northern Mariana Island, Oregon, Washington and Wisconsin. In these cases the change will not be immediate, but will be done as soon as approval is received from CMS. All correspondence will be sent to the former address until the update is made.

CMS Ex. 1, at 37 (emphasis in original).

Community does not specifically challenge the ALJ’s finding that neither NGS’s March 8, 2016 letter nor NGS’s August 4, 2016 letter notified Community that its application to add the new practice location had been finally approved. Nor does Community dispute that on August 29, 2016, NGS issued a letter denying Community’s application because the moratorium on new HHAs and new practice locations of existing HHAs (the latter being what Community’s CMS-855A sought to add) had taken effect on July 29, 2016. Instead, Community attacks the legal validity of the contractor’s and CMS’s applying screening and approval criteria beyond the contractor’s initial approval.⁶ RR at 2-3. Petitioner cites the language of section 424.570(a)(1)(iv) which excepts from the moratoria CMS is authorized to impose under section 424.570(a) “any enrollment application that has been approved by the enrollment contractor but not yet entered into PECOS at the time the moratorium is imposed.” Relying on the language “approved by the enrollment contractor,” Community argues that it was “arbitrary and capricious” for the ALJ to conclude that the “have approved” statement in NGS’s August 2016 letter was not legally sufficient to invoke the regulatory exception. RR at 2-3.

⁶ Since Community raises only legal challenges, deciding the case on summary judgment was and is appropriate. We also note that Community does not contend otherwise on appeal.

We reject this argument. At the outset, we note that Community does not dispute the ALJ's finding that NGS qualified its statement of "approval" in the August 4, 2016 letter and advised of necessary additional screening procedures. Thus, even under Community's interpretation of the regulation, the August 4, 2016 letter, on its face, was not an "enrollment application that has been approved by the enrollment contractor" within the meaning of section 424.570(a). Moreover, the Board rejected Community's interpretation of section 424.570(a)(1)(iv) in *UpturnCare Co.*, DAB No. 2632 (2015). In that decision, the Board stated as follows:

Section 424.570(a)(1)(iv) does state that "the enrollment contractor" approves the enrollment application. But the enrollment contractor . . . acts with authority delegated by CMS. That an enrollment contractor *recommended* approval does not mean that CMS has endorsed that approval as a final determination on approval status. It is CMS, not Palmetto or any other CMS contractor, which ultimately decides whether a prospective provider or supplier meets the requirements for participation in Medicare and may be enrolled in Medicare. *See* 42 C.F.R. § 424.516(a); *see also id.* § 424.510(a) ("CMS enrolls the provider or supplier into the Medicare program.").

DAB No. 2632, at 12 (*italics in original*). The Board also cited CMS's "right, when deemed necessary, to perform onsite review of a provider or supplier . . . to determine compliance with Medicare enrollment requirements." *Id.*, quoting 42 C.F.R. § 424.517(a) (*internal quotations marks omitted*).

Here, as in *UpturnCare*, we reject a construction of section 424.570(a)(1)(iv) that ignores CMS's authority, plainly stated in the regulations, to make the ultimate decision whether to enroll a Medicare provider. We note that one of the regulations cited by the Board in *UpturnCare* specifically provides not only that "CMS enrolls" a provider or supplier but, also, that it does so after "CMS verifies that the [provider or supplier] meets, and continues to meet, all of the following [additional provider and supplier] requirements[.]" 42 C.F.R. § 424.516(a) (*emphasis added*).

Vesting the ultimate authority for enrollment decisions in CMS, rather than the contractor, has particular resonance in the case of certain providers and suppliers, including HHAs, that are subject to CMS's authority to impose temporary moratoria since a purpose of CMS's moratoria authority, as recognized by Congress, is to protect the Medicare program and beneficiaries from risks associated with such providers and suppliers. Act § 1866(j)(7)(A); *see also* 42 C.F.R. § 424.518. Section 424.518 specifically requires a "Medicare contractor . . . to screen all initial applications, including applications for a new practice location, . . . based on a CMS assessment of risk and assignment to a level of 'limited,' 'moderate,' or 'high.'" (*emphasis added*). CMS, as the ALJ noted, has implemented this regulation through program issuances and

procedural instructions that are available to the public, including the Medicare Program Integrity Manual (MPIM). *See* MPIM, CMS Pub. 100-08, § 15.19.2.1 (effective Dec. 29, 2014).⁷ The “Background” to section 15.19.2.1 provides as follows:

Consistent with 42 C.F.R. § 424.518, newly-enrolling and existing providers and suppliers will, beginning on March 25, 2011, be placed into one of three levels of categorical screening: limited, moderate, or high. The risk levels denote the level of the contractor’s screening of the provider when it initially enrolls in Medicare, adds a new practice location, or revalidates its enrollment information.

(emphasis added). This MPIM section then goes on to state that CMS has assigned to a new home health agency branch a “moderate” level of risk that specifically requires approval by the CMS regional office followed by a site visit:

The addition of a new HHA branch falls within the “moderate” level of categorical screening. The contractor shall order a site visit of the location through PECOS after the contractor receives notice of approval from the RO [regional office] but before the contractor switches the provider’s enrollment record to “Approved.” This is to ensure that the provider is in compliance with CMS’s enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not switch the provider’s enrollment record to “Approved” prior to the completion of the NSVC’s site visit and the contractor’s review of the results.

MPIM § 15.19.2.1 (Note).⁸ The MPIM requirement for an on-site visit prior to approval of a new branch location implements the specific requirement of an on-site visit in section 424.518(b)(2)(ii).

⁷ We cite to the MPIM in effect at the time of the reconsideration determination.

⁸ The ALJ stated that CMS designated HHAs “high risk.” ALJ Decision at 8. That is correct for newly enrolling HHAs; however, as noted above, adding a new branch of an enrolled HHA has been designated as posing “moderate risk.” The distinction is not material to the ALJ’s decision or ours because the screening procedures for both levels of risk required CMS regional office approval followed by an on-site review before an application could be approved. MPIM § 15.19.2.1(B) and (C).

In its Request for Review, Community does not deny that section 424.518 requires enhanced (moderate level of risk) screening for new HHA practice locations applying to enroll in Medicare and that this enhanced screening had not been completed at the time the moratorium took effect on July 29, 2016. Community also does not deny that CMS had not yet approved its application and that the required post-CMS approval site visit had not been conducted at the time the moratorium took effect. Nor does Community mention the Board's rejection in *UpturnCare* of the very same argument Community makes with respect to section 424.570(a)(1)(iv). Instead, Community argues that the ALJ reached his decision by improperly applying a CMS survey and certification (S&C) letter that Community contends "does not carry the weight of law and therein is not entitled to deference as a proper interpretation of the applicable regulation or statute." RR at 3. As we discuss below, there is no merit to this argument.

In the first place, the ALJ did not even cite, much less rely on, the Survey and Certification (S&C) letter that Community says has no legal authority. *See* RR at 2-3 (citing S&C: 13-53-HHA); *compare* ALJ Decision at 8 (containing no citation to S&C: 13-53-HHA). The ALJ did cite two survey and certification letters that Community does not discuss, as well as certain provisions of the MPIM that Community also does not discuss. *See* ALJ Decision at 8, 9. However, the ALJ properly cited these pronouncements as CMS guidance to contractors related to section 424.518, the regulatory authority which the ALJ properly concluded made Community's application to add a branch location "subject to a rigorous multi-tiered screening process[.]" *Id.* at 8. The ALJ properly relied on section 424.518 itself and on section 424.530(a)(10) in reaching the following conclusion: "Petitioner's application to add a new branch location of its HHA . . . was not processed through all required steps for approval prior to the moratorium going into effect Accordingly, Petitioner's new branch was subject to the moratorium and the application to enroll that branch was properly denied pursuant to 42 C.F.R. § 424.530(a)(10)." *Id.* at 10. We agree with the ALJ's conclusions.

- B. *The ALJ properly concluded that he had no authority to address Community's argument that in applying the moratorium to new branch locations of existing HHAs participating in the Medicare program, CMS's implementing regulations exceeded their statutory authority.*

As stated, the regulations authorize CMS to impose a moratorium on the Medicare enrollment of new practice locations for existing providers and suppliers as well as on newly enrolling Medicare providers and suppliers. 42 C.F.R. § 424.570(a)(1)(i). The statutory authority for this regulation is section 1866(j)(7) of the Act which provides, *inter alia*, that "[t]he Secretary may impose a temporary moratorium on the enrollment [in Medicare, Medicaid and the Children's Health Insurance Program] of new providers of services and suppliers, including categories of providers of services and suppliers" Community argued before the ALJ that section 424.570(a)(1)(i) impermissibly extended

the reach of the statute by including new practice locations of an existing HHA within CMS's moratorium authority. More specifically, Community argued, as quoted by the ALJ, that "the extension . . . to include branch applications is not in accordance with the authorizing statute [sic] and is otherwise arbitrary and capricious because HHA branches are not 'new providers' otherwise subject to the moratorium." ALJ Decision at 9-10, quoting Pet.'s April 18, 2017 Pre-hearing Br. at 4-5 (internal quotation marks omitted). The ALJ declined to address this argument on the ground that he was "bound to follow the Act and regulations and ha[d] no authority to declare statutes or regulations invalid." *Id.*, citing *1866ICPayday.com, L.L.C.*, DAB No 2289, at 14 (2009) (hereafter *1866ICPayDay*).

Community agrees that the ALJ correctly stated the Board's holding in *1866ICPayDay*. RR at 4. However, Community argues that the statement applies only to arguments asking an ALJ to invalidate a regulation on Constitutional grounds. *Id.* Petitioner states,

The decision in *19866ICPayDay* [sic] does include that statement, but without citation or support. A full review of the issue of ALJ authority revealed the apparent source of that statement, *Sentinel Medical Laboratories, Inc. v. Health Care Financing Administration*, DAB1762 (2001). However, in that instance, the issue was the *constitutionality* of the CLIA statute and regulations which in multiple instances courts have ruled to be outside the jurisdiction of administrative agency ALJ's [sic]. . . .

Id. (italics in original).⁹ Community provides no explanation for its conclusion that "the apparent source of" the Board's statement in *1866ICPayDay* was the Board's decision in *Sentinel Medical Laboratories*; Community also mistakenly limits the scope of the Board's decision in the *Sentinel* case regarding the limits of ALJ and Board authority with regard to following the applicable regulations. It is true that the precise question presented in *Sentinel* was whether an ALJ or the Board could ignore an unambiguous regulation based on Constitutional grounds. However, the case citations and parentheticals the Board presented in support of its holding that ALJs and the Board could not ignore an unambiguous statute or regulation do not support Community's limited reading of that holding as encompassing only constitutional challenges. See *Sentinel*, DAB No. 1762, at 9, citing, *inter alia*, *United States v. Nixon*, 418 U.S. 683 (1974) as holding "that the executive branch was bound by the terms of a regulation it had issued, even though it was within its power to change that regulation," and *Howard v. FAA*, 17 F.3d 1213, 1218 (9th Cir. 1994) as holding, *inter alia*, "that generally, an ALJ is bound by the regulations promulgated by his administrative agency." Moreover, in *Central Kansas Cancer Institute*, DAB No. 2749, at 10 (2016), the Board specifically held that while a petitioner "is free to make his *ultra vires* argument to a court, [ALJs and

⁹ The correct citation for the Board decision in the *Sentinel* case is *Sentinel Medical Laboratories, Inc.*, DAB No. 1762 (2001), *aff'd*, *Teitelbaum v. Health Care Financing Admin.*, 32 F. Appx. 865 (9th Cir. 2002).

the Board] may not invalidate a regulation.”

Accordingly, the ALJ correctly declined to address Community’s ultra vires argument, and we likewise decline to do so.

Conclusion

For the reasons stated above, we affirm the ALJ decision.

/s/
Christopher S. Randolph

/s/
Constance B. Tobias

/s/
Sheila Ann Hegy
Presiding Board Member