

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

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In the Case of:)	DATE: September 28, 2009
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Waianae Coast Comprehensive Health Center,)	
)	
Petitioner,)	Civil Remedies CR1929
)	App. Div. Docket No. A-09-94
)	
- v. -)	Decision No. 2270
)	
Centers for Medicare & Medicaid Services.)	
)	

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

The Waianae Coast Comprehensive Health Center (Waianae or Petitioner), a Federally Qualified Health Center (FQHC), appealed the March 24, 2009 decision of Administrative Law Judge (ALJ) Keith W. Sickendick concerning the effective dates for Medicare FQHC participation of three permanent units.¹ Waianae Coast Comprehensive Health Center, DAB CR1929 (2008) (ALJ Decision).

As of the end of 1993, Waianae operated a Medicare-approved FQHC permanent unit in one location. In 1994, 1996, and 2000,

¹ Waianae states, and the Centers for Medicare & Medicaid Services (CMS) does not dispute, that the Waianae District Comprehensive Health and Hospital Board, Inc., is the real party in interest and operates the facilities at issue here. Request for review (RR) at 2.

Waianae opened permanent units in three additional locations and furnished Medicare FQHC services at those locations. Section 491.5(a) of 42 C.F.R., as in effect since 1992, requires permanent units at more than one location to be independently considered for approval as FQHCs. At issue here is the approval by CMS of these units and their effective dates for Medicare FQHC participation.²

In the ALJ Decision, the ALJ upheld CMS's determination adopting an effective date of May 2, 2007 for each of the units. Waianae argues that the ALJ should have adopted earlier effective dates based on the years in which Waianae opened the respective units.

As explained below, we uphold the ALJ's determination for the following reasons.

- The governing regulations provide that the effective date of approval for an FQHC is the date on which CMS accepts a signed agreement which assures that the FQHC meets all federal requirements.
- Prior to 2007, Waianae did not request CMS approval for these three permanent units as Medicare FQHC locations or provide to CMS the regulatory assurances of compliance with Medicare FQHC requirements.
- After receipt of these requests and assurances in 2007, CMS accepted a signed agreement with Waianae for the units, and the effective date of participation resulting from this approval process was May 2, 2007.

Further, we reject Waianae's challenges to the adequacy of the record before the ALJ. Finally, we do not consider Waianae's argument that section 491.5(a)(3)(iii) is invalid as contrary to the Social Security Act (the Act) because we lack authority to declare regulations ultra vires.

² CMS was previously named the Health Care Financing Administration (HCFA). See 66 Fed. Reg. 35,437 (July 5, 2001).

Standard of Review

This case was decided on summary judgment. Whether summary judgment is appropriate is a legal issue that we address de novo. Lebanon Nursing and Rehabilitation Center, DAB No. 1918 (2004). Summary judgment is appropriate if there are no genuine disputes of fact material to the result. Everett Rehabilitation and Medical Center, DAB No. 1628, at 3 (1997). In reviewing a disputed finding of fact, we view proffered evidence in the light most favorable to the non-moving party. See Crestview Parke Care Center, DAB No. 1836 (2002), rev'd on other grounds, Crestview Parke Care Center v. Thompson, 373 F.3d 743 (6th Cir. 2004). The standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous.

Background

Waianae is eligible to qualify as an FQHC under section 1861(aa)(4) of the Act because it receives a grant under section 330 of the Public Health Service (PHS) Act (42 U.S.C. § 254b); see also 42 C.F.R. § 405.2401(b) (definition of FQHC). Section 330 grants are administered by the Health Resources and Services Administration (HRSA), a component of the Department of Health and Human Services.

In order to be approved to participate in Medicare as an FQHC, an entity must enter into an agreement with CMS. 42 C.F.R. § 405.2430. On August 3, 1992, Waianae submitted an application to CMS to be approved as a Medicare FQHC. On September 4, 1992, CMS notified Waianae that it had approved Waianae's request effective October 1, 1991. P. Ex. 9, at 72. As of August 1992, when it applied, Waianae was operating two permanent units,³ one in Waianae and one in Nanakuli, Hawaii. Declaration of James Chen at ¶ 3 (Declaration).

Beginning in 1994, Waianae opened three additional permanent units and obtained changes in scope to its PHS grant from HRSA to add these units to the grant. HRSA approved the addition of the Waiola Clinic to the PHS grant effective February 1994, the Waipahu Family Health Center effective July 1996, and the

³ A "permanent unit" is defined at 42 C.F.R. § 491.5(a)(3)(i). The parties do not dispute that the facilities at issue were permanent units. Waianae closed the Nanakuli unit in 1993. Declaration at ¶ 3.

Kapolei Health Care Center effective September 2000. CMS Ex. 7. Thereafter, Waianae provided FQHC services at these units and "billed Medicare for services provided." ALJ Decision at 6; CMS Ex. 7.⁴

Subsequently, Waianae was advised by a consultant assisting with the preparation of its 2006 FQHC cost report about complying with CMS enrollment procedures recently promulgated in a new regulation.⁵ RR at 9. Waianae represents that it sought to comply with these new requirements by submitting Medicare enrollment applications (Form CMS-855A) for each of the three units on February 12, 2007. CMS Exs. 1-3; CMS Ex. 7. The last of the certification statements for the applications was received by CMS on April 26, 2007. CMS Ex. 1, at 28; CMS Ex. 2, at 28; CMS Ex. 3, at 25. CMS notified Waianae by letters dated July 12, 2007, that each of the three units was accepted for participation in Medicare as an FQHC effective May 2, 2007. CMS Exs. 4-6.

Waianae asked CMS to reconsider the effective date, arguing that the three units were not new, that the February 2007 enrollment applications were not for new enrollments, and that the effective date of participation for the units as FQHCs should be the dates in 1994, 1996 and 2000 that HRSA approved the changes in scope to its PHS grant. CMS Ex. 7. On January 25, 2008, CMS denied Waianae's request for reconsideration. P. Ex. 2.

Waianae requested ALJ review. CMS filed a motion for summary judgment and CMS Exhibits 1 through 7. Waianae filed its opposition to the CMS motion for summary judgment and a cross-motion for summary judgment with Petitioner Exhibits 2, 9, and 33 through 37. The ALJ entered summary judgment in favor of CMS, and this appeal ensued.

Analysis

⁴ FQHC Medicare reimbursement is paid on a per-visit basis by a Medicare fiscal intermediary. 42 C.F.R. § 405.2460 et seq. The fiscal intermediary calculates the per-visit reimbursement rate from costs reported by the FQHC on its annual cost report. 42 C.F.R. § 405.2462 et seq.

⁵ See 71 Fed. Reg. 20,754 (April 21, 2006) (final rule requiring "all providers and suppliers . . . complete an enrollment form and submit specific information to us.")

1. The record supports the entry of summary judgment.

Waianae attacks the adequacy of the record for summary judgment, making the following interrelated arguments:

The ALJ erred in deciding this matter on summary judgment because the record is inadequate to allow a determination whether the undisputed material facts could have supported an earlier effective date. (Conclusion of Law (COL) No. 2).

The ALJ erred in concluding that the effective date of FQHC participation . . . was May 2, 2007, because he improperly failed to consider whether the undisputed material facts could have supported an earlier effective date. (Conclusion of Law No. 4).

RR at 12.⁶

These arguments are without merit for the following reasons.

A. The undisputed material facts support CMS's determination that the effective date for Medicare FQHC participation of these locations is May 2, 2007.

Section 491.5(a)(3)(iii) of 42 C.F.R. requires:

Permanent unit in more than one location. If . . . center services are furnished at permanent units in more than one location, each unit is independently considered . . . for approval as an FQHC.

A requirement for independent consideration of permanent units was first published as a "final rule with comment period" effective June 12, 1992. 57 Fed. Reg. 24,961 (June 12, 1992). When promulgated, the requirement was in section 491.5(a)(2) and

⁶ Waianae does not except to the ALJ's conclusion that the three units at issue are "permanent units in different locations and must be separately approved as FQHCs pursuant to 42 C.F.R. § 491.5(a)(3)(iii)." RR at 12, citing ALJ Decision at 8 (COL 3). Waianae does, however, challenge the validity of that regulation on the ground that it is inconsistent with the Act.

stated that "each unit will be independently considered . . . for coverage as a Federally qualified health center." CMS modified the language and numbering in the FQHC final rules published in 1996, effective May 3, 1996. 61 Fed. Reg. 14,640, at 14,658 (April 3, 1996). The parties do not assert that the modification constituted a substantive change to the requirement.

Sections 405.2430 and 405.2434 set forth the FQHC approval requirements and CMS's process "in response to a request from an entity that wishes to participate in the Medicare program" (section 405.2430(a)(1)). For approval, an entity is required to "assure[] CMS that it meets the [FQHC] requirements specified in this subpart and part 491, as described in 405.2434(a)." 42 C.F.R. § 405.2430(a)(1)(ii). CMS treats a document titled "Attestation Statement for Federally Qualified Health Centers" (Attestation Statement) set out as Exhibit 177 of CMS's State Operations Manual (SOM) as the assurance and the agreement required by section 405.2430. SOM § 2826; see CMS Exs. 4-6 for the Attestation Statements filed by Waianae in 2007 for the three additional units; P. Ex. 9, at 80 for the Attestation Statement filed by Waianae in 1992.

When the section 405.2430(a)(1) requirements are met, including the assurance, "CMS sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to CMS." 42 C.F.R. § 405.2430(a)(3). "If CMS accepts the agreement filed by the [FQHC], CMS returns to the center one copy of the agreement with the notice of acceptance specifying the effective date (see § 489.11), as determined under § 405.2434." 42 C.F.R. § 405.2430(a)(4).

Section 405.2434(b) provides that the effective date of this agreement (with one irrelevant exception) is "the date CMS accepts the signed agreement, which assures that all Federal requirements are met." Similarly, section 489.13(a)(2)(i) provides that, for an agreement with an FQHC, the effective date "is the date CMS accepts the signed agreement which assures that the . . . FQHC meets all Federal requirements."

In February 2007, Waianae filed, with the CMS fiscal intermediary, Medicare Enrollment Applications (CMS-885As) for each of the three units at issue, identifying them as FQHC units, and also filed FQHC Attestation Statements for each unit. CMS Exs. 1-6. Waianae represents that it filed the 855As for

the three units in response to regulations that became effective in 2006 establishing general enrollment requirements for Medicare and Medicaid suppliers and providers. RR at 8-9, citing 68 Fed. Reg. 22,064 (April 25, 2003) and 71 Fed. Reg. 20,754, at 20,764-65 (April 21, 2006). Waianae also represents that, by filing the 855As, it sought "revalidation of its status as an entity recognized as an FQHC, which operated facilities in multiple locations. Only later did it learn that CMS deemed the satellite facilities as separate FQHCs and, therefore, considered their forms CMS-855 to be new applications." *Id.* at 10. As noted above, however, section 491.5(a)(3)(iii), which requires separate consideration of permanent units in other locations, has been in effect since 1992. 57 Fed. Reg. 24,961 (June 12, 1992). On July 12, 2007, CMS notified Waianae that it had accepted its FQHC agreements effective May 2, 2007 for each of the three units and attached the Attestation Statement for that unit signed by CMS. CMS Exs. 4-6.

Waianae has not shown any error in CMS's processing of its 2007 applications for approval but argues that the record is inadequate to allow a determination as to whether undisputed material facts could have supported an earlier effective date unrelated to the 2007 applications. We explain next why we reject that argument.

B. The undisputed material facts do not support any reasonable inference that could result in an earlier effective date finding for these units.

(i) Summary judgment is not contrary to the Board's prior holdings.

Waianae relies on Family Health of Darke County, Inc., DAB No. 2092 (2007) (referred to here after as Family Health I). In Family Health I, the Board remanded the case to the ALJ because the initial record before the ALJ was insufficient to support his summary judgment upholding CMS's FQHC effective date determination.

Family Health I is inapposite here. In Family Health I, Family Health pointed to actions that it and CMS had taken immediately upon and after the opening of the additional permanent units at issue there, including Family Health's obtaining changes in scope from HRSA for its PHS grant, Family Health's identifying the costs for the additional units on its FQHC cost reports, and

CMS's paying FQHC reimbursement for these costs over the subsequent years. Waianae cites some similar factual circumstances here. RR at 13. However, in Family Health I there were additional undisputed material facts before the ALJ including: Family Health timely consulted a CMS contractor about approval for the new locations, Family Health filed CMS application forms with a CMS contractor for the new locations, and the applications forms included attestations about compliance with Medicare requirements. These facts raised the issue of whether Family Health had, upon opening the units, requested CMS approval for them as FQHCs and attested to CMS that they complied with Medicare FQHC requirements. Given these facts (which CMS did not contest or address either before the ALJ or on appeal to the Board) and the absence of the relevant documents from the record, including some of the purported applications, at the time of the initial appeal, the Board remanded the case for further record development.⁷

Here, Waianae has not shown (or even alleged) any facts that would raise a question as to whether it: (1) contemporaneously requested approval from CMS for these units, (2) provided CMS with assurances that they met Medicare FCHA requirements, or (3) tried to consult with CMS about what actions section 491.5(a)(3)(iii) required for new units.⁸ Therefore, the record here is materially different from that in Family Health I.

⁷ Moreover, the Board recently issued Family Health of Darke County, Inc., DAB No. 2269 (2009) (referred to as Family Health II). That decision reviewed the ALJ decision on remand (Family Health of Darke County, Inc., DAB CR1862 (2008)) in which the ALJ upheld CMS's effective date determinations. In Family Health II, the Board found that, after review of a more complete record, the facts previously alleged by Family Health did not support earlier effective dates. Specifically, the Board found that the CMS applications filed by Family Health were unrelated to the FQHC approval process, that they were filed with a contractor who had nothing to do with FQHC approval, that Family Health had not properly sought CMS advice as to approval of FQHC units, that the general attestations of compliance in the applications filed by Family Health were not sufficient to satisfy the assurance requirements for FQHCs, and that CMS's payment of FQHC costs for these locations did not constitute approval of the locations.

⁸ Waianae does make other factual allegations about pre-2007 events. We discuss below why these allegations do not

(ii) Waianae failed to show that it formulated any interpretation of section 491.5(a)(3)(iii) prior to 2007 or that it acted to its detriment in reliance on any such interpretation.

In the preamble to its 1996 regulations, CMS explained that it interpreted section 491.5(a)(3)(iii) to require independent attestation of compliance with Medicare FQHC requirements and the issuance of a unique provider number for each FQHC permanent unit. 61 Fed. Reg. at 14,641.⁹ On appeal before the Board, Waianae takes the position that section 491.5(a)(3)(iii) allows an FQHC opening a new permanent unit to rely on its original Attestation Statement and its original CMS-FQHC approval as covering the later unit, and therefore contends that such an FQHC need only obtain a change of scope from HRSA for its PHS grant. RR at 18, 36.

Waianae misstates the holding in Family Health I by stating that the Board "rejected the position that 42 C.F.R.

§ 491.5(a)(3)(iii) requires an FQHC to obtain a separate certification for each permanent unit." RR at 13 (emphasis in original). In Family Health I, the Board held that the ALJ incorrectly concluded that this regulation required "separate CMS approval to participate in the Medicare program" for each unit. Id. at 11. The Board rejected only the ALJ's statement that section 491.5(a)(3)(iii) "clearly" required separate certification of all permanent units and then explained why the wording of the regulation could be subject to interpretations other than that "separate certifications" were required. Family Health I, DAB No. 2092, at 11, n.9. For the following reasons, Waianae has not shown that it actually relied on any reasonable alternative interpretation here.

First, before the ALJ, Waianae did not allege or show that its administrators formulated, prior to 2007, any interpretation of section 491.5(a)(3)(iii) that would have justified its failure to request CMS's approval for these units or file separate

(Continued. . .)

support its assertions of error.

⁹ As explained above, these regulations, among other things, renumbered the permanent unit requirements first promulgated in 1992.

attestations for them. Indeed, before the ALJ, Waianae argued only that the regulation was contrary to the Act and that CMS's position violated the notice and comment requirement of the Administrative Procedure Act, 5 U.S.C. §§ 551 et seq. See P. Memorandum in Opposition to CMS's Motion for Summary Judgment (CMS MSJ); P. Memorandum in Support of Cross-Motion. Therefore, nothing in the record below supports even an inference that Waianae was relying on any interpretation of section 491.5(a)(3)(iii) at the time it opened the additional units.

Second, at least by 1996 (prior to the opening of two of the units), CMS gave explicit public notice of its interpretation of section 491.5(a)(3)(iii) in the preamble to the 1996 final rule. In rejecting a commenter's objection to the "site-specific approval" requirement for permanent units, CMS stated:

[W]e independently approve each site for Medicare participation and assign it a unique provider number [E]ach site must independently attest to meeting the conditions of part 491 subpart A.

61 Fed. Reg. at 14,461. CMS went on to explain how this requirement simultaneously protected beneficiaries and served the interests of FQHCs in the event that one permanent unit failed to meet requirements. Id. Therefore, as to the later two units, Waianae could not reasonably have misunderstood the need to affirmatively seek consideration by CMS of new permanent units under section 491.5(a)(3)(iii).

Third, while Waianae is correct that section 491.5(a)(3)(iii) is not explicit as to how independent approval of permanent units is obtained, the regulation provides clear notice that some sort of independent and site-specific approval by CMS is required. As discussed below, Waianae's construction of section 491.5(a)(3)(iii) here is simply not reasonable, particularly in light of the absence of any allegation that it consulted CMS as to what was required under the section.

(iii) None of the other considerations alleged by Waianae provide a basis for concluding that summary judgment was inappropriate or the record was inadequate.

Waianae makes several additional arguments and allegations in support of its position that the record is inadequate to support summary judgment.

Waianae's principal argument is based on its assertion that, between 1992 and 2000, no regulations or CMS written instructions set forth a specific approval process for complying with section 491.5(a)(3)(iii) and thus that CMS "fail[ed] to have in place any procedure for the approval process at the relevant time." RR at 19, see also 6, 7-8, 15, 18. Waianae then relies on facts which it asserts, in the absence of such guidance, gave it "no reason to believe that more was required" for these units than obtaining changes in scope from HRSA for its PHS grant and relying on the Attestation Statement that it gave in 1992 for its original location(s). Id. Waianae concludes that CMS's failure before the ALJ to "identify any 'process' that was in place prior to the implementation of CMS Form 855A" makes the record inadequate to support summary judgment. Below we discuss why this argument is without merit.

First, section 405.2430 does (and did during the relevant time period) set forth an FQHC approval process, and CMS used this process in approving these units in 2007. While Waianae points out reasons why an FQHC could have had questions about whether section 405.2430 applied to approvals of separate permanent units pursuant to section 491.5(a)(3)(iii), section 491.5(a)(3)(iii) is sufficient to notify an FQHC that some site-specific CMS approval is required for compliance.¹⁰ If Waianae was actually unsure that the section 405.2430 process did not apply, it should have consulted CMS about the relevant approval process. Waianae proffers no claim or evidence that it did so.

Second, Waianae also fails to allege or proffer evidence that the absence of explicit guidance as to the process for approval of additional permanent units confused Waianae or resulted in its adopting a reasonable alternative interpretation about how

¹⁰ For example, Waianae points out that section 491.5(a)(3)(iii) does not state from whom approval should be sought. RR at 17.

to proceed when it established new permanent units. Indeed, before the ALJ, Waianae did not raise the alleged lack of written guidance as relevant to this dispute.

Third, while Waianae is correct that CMS submitted no evidence about its pre-2000 policies before the ALJ, this absence does not make the record inadequate. CMS had no reason to submit such evidence since Waianae never alleged before the ALJ that it relied on or was confused by the absence of policies. Nor did Waianae (unlike the petitioner in Family Health I) argue before the ALJ that the actions it did take between 1994 and 2002 for these units were requests for their approval as FQHCs under Medicare or that CMS's actions somehow constituted such approval. Therefore, CMS may not be faulted on appeal for having failed to deny or submit proof to rebut allegations that were not made.

Fourth, even assuming for the sake of argument that Waianae relied on some interpretation of section 491.5(a)(3)(iii) when it opened these units, its additional assertions (discussed below) fail to show that any such interpretation by Waianae was reasonable or that the record below was somehow inadequate.

Waianae objects that CMS's position that the effective date is dependent on Waianae's having filed a "CMS-855A" is "totally irrational in light of the facts that, when the [units] commenced operation, the document that would, eventually, evolve into Form CMS-855A" was not yet in use or had not been implemented. RR at 20, see also RR at 11, 18; P. Ex. 2 (CMS reconsideration letter). We agree that CMS may not reasonably insist on the retroactive use of a specific form for a period of a time in which that form did not exist. However, the ALJ did not adopt CMS's reasoning, nor do we. This case turns on Waianae's failure to request CMS approval or give the required compliance assurances by any means for these units prior to 2007, not its failure to use a particular CMS form.

Waianae cites CMS's 1992 approval letter in which CMS instructed Waianae that it "must notify [CMS] immediately if your facility changes owners." P. Ex. 9, at 72. Waianae states that the letter did not give it notice that section 491.5(a)(3)(iii) required it to take any particular action if it added additional permanent units in the future. RR at 7. This fact is not material here. CMS is not required to include, in correspondence, every possible reason a provider generally, or

an FQHC particularly, might be required to give notice of an operating change in the future.

Waianae points out that section 405.2430(a)(1)(iii) requires (with specific exceptions) non-provider-based FQHCs to "terminate[] other provider agreements" in order to qualify as an FQHC. It notes that the regulations do not inform FQHCs that the "operation of satellite facilities constituted an exception to the requirement that non-provider based FQHCs would be permitted to enter into no more than one provider agreement with [CMS] simultaneously." RR at 6. Waianae's complaint reflects a misunderstanding of the "other provider agreement" restriction. The preambles to both the 1992 and 1996 FQHC rules demonstrate that this requirement concerned non-FQHC provider agreements. 57 Fed. Reg. at 24,961, at 24,964 (June 12, 1992);¹¹ 61 Fed. Reg. at 14,644.¹²

For FQHC reimbursement, CMS allows FQHCs "the option to file a single consolidated cost report for the entire entity or individual costs reports for each site within the entity." 61 Fed. Reg. at 14,641. Before the Board, Waianae alleges that "CMS never denied . . . that the operations of the three new satellites at issue in this appeal were reported in its cost reports from the time they commenced operation in a manner that specifically identified costs attributable to each facility." RR at 8 (emphasis added); see also, id. at 18 ("CMS does not contend that it was unaware of the operation of the satellites" (emphasis in original)). Waianae argues that payment based on these cost reports amounted to acceptance of the units as FQHCs (RR at 18) and cites Petitioner Exhibits

¹¹ "The agreement [between CMS and the FQHC], among other provisions, will assure that the FQHC is paid only as an FQHC for services covered under the FQHC benefit. If an entity that is not provider-based has other agreements under Medicare, they must be terminated before the FQHC agreement is effective." 56 Fed. Reg. 24,964.

¹² In response to a commenter's objection to the termination requirements, CMS wrote:

The intent of this provision is to prohibit an entity from using the same space, staff, and resources simultaneously as two distinct provider types.

12, 17, 19, 21, 23, 25, 27, and 29 (RR at 8) in support of its allegations.¹³ Since Waianae did not make these allegations in the proceedings before the ALJ, CMS had no reason to deny them. In any event, in Family Health II, DAB No. 2269, at 17, the Board held that CMS's payment of costs under a cost report does not, in itself, establish that CMS has approved the additional FQHC permanent unit or accepted an attestation that federal requirements are and will be met for the unit to provide FQHC services.

Waianae asserts that the regulations "did not indicate that qualification . . . of such satellite facilities were not among the activities delegated by CMS to HRSA." RR at 6. Waianae points to the preamble for the 1992 regulations in which, at the inception of the Medicare FQHC program in 1992, entities wanting to become FQHCs were instructed to "apply for FQHC qualification through HRSA Regional Offices. HRSA will notify the [CMS] of entities that it recommends for qualification as FQHCs because they meet the PHS requirements, either as [PHS] grant recipients or as look-alikes." RR at 4, citing 57 Fed. Reg. at 24,963. This preamble language does not show that CMS delegated to HRSA the "qualification" of Medicare-approved FQHCs or that HRSA would undertake notification about any later-added permanent units. As the language indicates, HRSA was simply responsible for informing CMS whether a facility was a PHS grant recipient or look-alike, which was necessary information in order to satisfy one of the Medicare FQHC conditions (section 405.2430(a)(1)(i)). That information did not constitute compliance with all the requirements for an FQHC to receive Medicare reimbursement for FQHC services. Sections 405.2430 and 405.2434 of the regulations promulgated in conjunction with that preamble set forth the Medicare approval process, which is administered by CMS. Thus, in 1992 when Waianae first sought to qualify as a Medicare FQHC, it requested approval from CMS. P. Ex. 9, at 73 (Waianae's "Medicare FQHC Application" dated August 3, 1992 addressed to CMS, stating "Enclosed is the required application form for our health center to become an eligible

¹³ These exhibits are not in the record. Under the ALJ's prehearing order, the parties engaged in a prehearing exchange of proposed exhibits with one another and submitted an index of the proposed exhibits to the ALJ. Order dated April 22, 2008, at 2-3. In conjunction with the summary judgment process, both parties submitted to the ALJ some, but not all, of the proposed exhibits listed in their indexes.

Medicare FQHC retroactive to October 1, 1991."). The approval of this request was issued by CMS. Id. at 72.

In its reply brief before the Board, Waianae also makes the following allegations:

CMS does not dispute that HRSA notified [CMS] of the addition of the [permanent units] to [Waianae's] PHS grant.

CMS does not dispute that upon receipt of HRSA's notification of the addition of the clinics to [Waianae's] PHS grant - in keeping with its practice during the relevant time period - it did not notify [Waianae] that the clinics were separately eligible for FQHC status or forward additional copies of the Attestation Statement to be executed for each of the separate sites as provided for by the process in the Federal Regulations.

P. Reply Br. at 4. Even assuming the regulation contemplated HRSA notification of every change in scope to add new permanent units to FQHC grants, and that HRSA in fact notified CMS about the 1994, 1996 and 2000 changes in scope to Waianae's PHS grants (assumptions for which Waianae offered no basis), we could not accept Waianae's bald claim that CMS had some established "practice" to notify FQHCs that the new "clinics were separately eligible for FQHC status" after such notification. As we have discussed elsewhere, there is no basis to believe that either HRSA or CMS considered the units as "separately eligible for FQHC status," but rather that CMS regulations required that the units be separately considered for approval to bill for FQHC services based on independent applications and attestations. Moreover, the "process in the Federal Regulations" to which Waianae refers here calls for CMS to act "in response to a request from an entity that wishes to participate in the Medicare program," not in response to any notification from HRSA. 42 C.F.R. § 405.2430. Finally, since Waianae did not allege any of these facts before the ALJ (or even in its Request for Review on appeal), CMS could not be expected to have denied them.

- 2. The fact that Waianae was operating two units at the time CMS first approved it as an FQHC does not constitute grounds for reversing the summary judgment.**

Waianae submitted proof before the ALJ (and CMS did not dispute) that, when CMS first approved it as an FQHC in 1992 under one application, Attestation Statement, and Medicare number, it was operating two units (one in Waianae and one in Nanakuli).¹⁴ Declaration at ¶ 3; P. Ex. 1, at 72-82; P. Exs. 33-37; P. Memorandum in Opposition to CMS MSJ at 2. Based on this evidence and the fact that CMS reimbursed Waianae for the costs of the units, Waianae asserts that CMS had a practice of approving multiple FQHC permanent units under a single application, attestation and provider number that continued through 2000 despite the publication of section 491.5(a)(3)(iii). RR at 16-18. Waianae argues: "The ALJ erred in finding that, during the relevant time period, CMS did not have a practice to ignore the regulatory requirement for separate approval of permanent units of an FQHC that were located in separate locations." RR at 2-3 (emphasis in original). Waianae argues further that this practice supports earlier effective dates for these units. Id. at 18.

Waianae's arguments are without merit.

First, the record does not support any of Waianae's allegations about a CMS practice between 1992 and 2000. Even viewed in the light most favorable to Waianae, nothing in the record indicates that, in issuing the 1992 approval and provider number, CMS actually knew that Waianae was operating two units. See P. Ex. 9, at 72-82.¹⁵ Before the ALJ, Waianae did not allege that, in

¹⁴ For purposes of summary judgment, the ALJ accepted Waianae's assertion that "from September 1991 to September 1993, it operated two facilities under a single participation agreement and a single Medicare number." ALJ Decision at 9. The Nankuli unit closed in September 1993.

¹⁵ The record contains the following documents from Waianae's original 1992 FQHC application. The cover letter identifies the applicant as "the Waianae Coast Comprehensive Health Center" and lists one address at 86-260 Farrington Highway, the address of that Center. P. Ex. 9, at 73; see also id. at 70. The "Disclosure of Ownership and Control Interest Statement" identifies the "Name of Entity" as "Waianae District Comprehensive Health and Hospital Board," which was identified as "D/B/A" [doing business as] "Waianae Comprehensive Health Center" and one address at "86-260 Farrington Highway." Id. at 75. The Attestation Statement for Federally Qualified Health

applying to become a Medicare FQHC, it informed CMS about the second unit; that CMS knew about the second unit; or that CMS had a practice of approving multiple units under one application between 1992 and 2000. See P. Memorandum in Opposition to CMS MSJ at 2-3; P. Cross-Motion for Summary Judgment; P. Memorandum in Support of Cross Motion at 6-7, 18. The absence of such allegations is consistent with the fact that, before the ALJ, Waianae cited the 1992 approval as the only support of both (1) its argument that there was a dispute of material fact as to whether it was operating two units in 1992 (P. Memorandum in Opposition at 6-7) and (2) its argument that CMS's actions in not treating the later units as already approved was a change in policy that violated the notice and comment provisions of the Administrative Procedure Act (P. Memorandum in Support of MSJ at 18), an argument that it has abandoned on appeal.

Second, these allegations do not show that the record was inadequate. Even if we assume for the sake of argument that CMS did knowingly approve two existing sites, such an approval would not support Waianae's position here that the 1992 Attestation Statement and approval should apply to three facilities that did not exist until 1994, 1996, and 2000. Section 491.5(a)(3)(iii) cannot be reasonably read to mean that approvals and attestations of compliance that predate a permanent unit's existence satisfy the section 491.5(a)(3)(iii) requirement of separate approval of each permanent unit. Family Health II, DAB No. 2269, at 17.

(Continued. . .)

Centers" listed the "name of the entity" as the "Waianae District Comprehensive Health & Board" and no address. The CMS approval letter was addressed to the "Waianae Coast Comprehensive Health Center" at 82-260 Farrington Highway and gave Waianae a "provider number" to "be entered on all forms and correspondence relating to the Medicare program." Id. at 72.

3. Waianae's argument that the regulation conflicts with the Act is unavailing.

Waianae argues that the ALJ erred in concluding that section 491.5(a)(3)(iii) was "not inconsistent with the language of Section 1861(aa)(4) of the Social Security Act." RR at 21. Section 1861(aa)(4) states that "[t]he term 'Federally qualified health center' means an entity which" meets the subsequently listed criteria. (Emphasis added.) Waianae argues that "[b]ecause of the statutory requirement that an FQHC be an 'entity' capable of contracting for grant funds on its own, an FQHC cannot be defined by regulation to include separate facilities that do not fit within the statutory definition." RR at 14. Waianae asserts that these units, which were "subparts of an entity" [i.e., the Waianae District Comprehensive Health and Hospital Board, Inc.] "lack an independent legal identity" and "cannot themselves be an 'entity.'" RR at 25. Waianae extensively discusses the Act's legislative history and other authorities which it argues support the position that section 491.5(a)(3)(iii) is invalid because it conflicts with the Act in treating units as independent entities. RR at 23-36.

The Board is bound by and has no authority to invalidate the Secretary's regulations as inconsistent with the Act. CarePlex of Silver Spring, DAB No. 1627, at 18 (1997). Moreover, even were we to accept Waianae's contention that the Act precludes treating permanent units as themselves FQHCs or "entities," that would not compel a different outcome here. As we have pointed out, it is not necessary to the enforcement of the regulation at issue that permanent units be viewed as independent FQHCs or entities for CMS to require separate requests for approval and contemporaneous attestations when a previously-approved FQHC opens a new permanent unit at a different location and seeks to qualify for Medicare reimbursement for FQHC services provided at that new location.

Conclusion

Based on the preceding analysis, we affirm the ALJ's upholding CMS's determination adopting an effective date of May 2, 2007 for each of the units.

_____/s/_____
Judith A. Ballard

_____/s/_____
Stephen M. Godek

_____/s/_____
Leslie A. Sussan
Presiding Board Member