Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: June 12, 2007
Family Health Services of Darke County Petitioner,	Civil Remedies CR1518 App. Div. Docket No. A-07-31
- v. -	Decision No. 2092
Centers for Medicare & Medicaid Services.	

REMAND OF
ADMINISTRATIVE LAW JUDGE DECISION

Family Health Services of Darke County (Family Health or Petitioner), a federally qualified health center (FQHC), appealed the October 12, 2006 decision of Administrative Law Judge (ALJ) Steven T. Kessel. Family Health, DAB CR1518 (2006) (ALJ Decision). The ALJ upheld a determination by the Centers for Medicare & Medicaid Services (CMS) adopting an effective date of September 8, 2005 for Medicare participation of two additional Family Health locations as FQHC sites.

In its Request for Review before the Board, Family Health argues that the ALJ erred in granting CMS's request for summary disposition by failing to consider certain undisputed material facts that could support earlier effective dates for these locations. These facts involve Family Health's actions taken pursuant to CMS's advice and CMS's response to those actions beginning in 2002 when Family Health first sought to provide FQHC services at additional locations. As described by Family Health, the actions and responses included: obtaining a change of scope for Family Health's Public Health Service (PHS) Act grant to include these locations; consulting with CMS and its intermediaries about how to qualify additional locations for

Medicare FQHC reimbursement; receiving CMS's advice to file and then filing CMS-855B applications ("Medicare Enrollment Application – Clinics/Group Practices and Certain Other Suppliers") and CMS-855Rs ("Medicare Federal Health Care Benefits Enrollment Application – Reassignment of Medicare Benefits") for the doctors practicing at the locations; and CMS's subsequent payment of reimbursement to Family Health for FQHC services at these locations. CMS has never denied instructing Family Health to proceed in this manner, nor has it explained why Family Health's filing of CMS-855Bs could not constitute requests by Family Health for these locations "to participate in the Medicare program" as FQHCs as well as "a signed agreement, which assures that all Federal requirements have been met" by Family Health for these locations. See 42 C.F.R. §§ 405.2430(a), 405.2434(b)(1). Moreover, CMS has never explained why its alleged response to the filing of the CMS-855Bs and CMS-855Rs at the time, i.e., payment for FQHC services at these locations, could not constitute "acceptance" by CMS of Family Health's agreements and assurances. See 42 C.F.R. § 405.2430(a)(4).

We conclude, as a consequence, that the ALJ erred because he failed to consider whether these undisputed material facts alleged by Family Health could support earlier effective dates and because he concluded that the regulations vest non-reviewable discretion in CMS to set effective dates for FQHC approval for Medicare. The current record, however, needs to be developed further before the ALJ (or we) would be able to evaluate whether Family Health complied with the applicable regulations and whether CMS had effectively approved earlier effective dates by its own actions. Among other things, the record does not contain copies of the CMS-855Bs submitted by Family Health.

Accordingly, we remand this appeal to the ALJ to develop the record as to this issue and to determine whether earlier effective dates are established based on Family Health's filing of CMS-855Bs and CMS-855Rs and CMS's subsequent actions. Alternatively under 42 C.F.R. § 498.78(b), the ALJ may consider remanding this case to CMS to determine whether, pursuant to the principles articulated in this decision, the actions of Family Health and CMS beginning in 2002 provide a basis for CMS's approving earlier effective dates for these locations.

Standard of Review

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.

Case Background[1]

Family Health qualifies as an FQHC under section 1905(l)(2)(B)(i) of the Social Security Act (42 U.S.C. § 1396d) because it receives a grant under section 330 of the PHS Act (42 U.S.C. § 254b).[2] See also 42 C.F.R. § 405.2401 (definition of FQHC at subparagraph (1)); P. Ex. 7 (Family Health's Notice of Grant Award). CMS originally approved Family Health as an FQHC in the Medicare program effective October 1991. CMS Br. before the ALJ (CMS Br.) at 2. At that time, Family Health's only location was 5735 Meeker Street, Greenville, Ohio.

Beginning in 2002, Family Health added two locations, first at Central Avenue, Greenville, Ohio, and then at North Main Street, Arcanum, Ohio. Family Health alleges (and CMS does not deny) that, in 2002 when it added the Central Avenue location, it consulted with both the Health Resources and Services Administration (HRSA) and CMS about how to add the location and, pursuant to this advice, sought a Change in Scope to its PHS Act grant and filed CMS forms CMS-855B and CMS-855R.[3] The actions resulted in a Change in Scope to Family Health's PHS Act grant to reflect the Central Avenue location (P. Ex. 7) and payment by CMS to Family Health for FQHC services provided at this location (P. Ex. 2, at 1). The record supports a reasonable inference that similar actions occurred for the North Main location. See Request for Hearing at 2-5; P. letter of September 22, 2005 attached to Request for Hearing.

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[1] The following background information is drawn from the ALJ Decision and undisputed allegations made by Family Health in its Request for Hearing filed October 26, 2005.

[2] Section 330 grants are administered by the Health Resources and Services Administration, a component of the Department of Health and Human Services.

[3] The record contains a copy of the CM-855Rs for Central Avenue (CMS Ex. 5, at 4-9) but not the CMS-855Bs for either location.

Two years later in a CMS audit of Family Health's 2003 cost report, an auditor questioned whether either of these locations had been properly approved to participate in Medicare. P. Ex. 2, at 1. Thereafter, in May 2005 and pursuant to different advice from CMS, Family Health filed CMS form CMS-855A (CMS Ex. 5, at 10-34) and an "Attestation Statement for Federally Qualified Health Centers" (Attestation Statement) (CMS Ex. 3).

On September 8, 2005, the Medicare intermediary for Ohio, United Government Services (Medicare intermediary or UGS), advised CMS that it had reviewed Family Health's CMS-855A and "found no evidence to indicate the application should be denied." CMS Ex. 5, at 1. On September 19, 2005, CMS notified Family Health that it had "accepted [Family Health's] request for approval as a [FQHC] in the Medicare program" for the Central Avenue and North Main locations. CMS Ex. 2, at 1 (Central Avenue); CMS letter dated September 19, 2005, attached to Family Health's Request for Hearing (North Main Street). CMS also informed Family Health that the "effective date of participation is September 8, 2005" and issued new Medicare provider numbers to Family Health for each of these two locations. Id.

Family Health requested a hearing before an ALJ, arguing essentially that the effective dates should be at least as early as the dates CMS began reimbursing it for FQHC services at these locations.[4]

CMS moved for summary disposition. Family Health opposed CMS's motion. The ALJ granted CMS's motion, upholding CMS's determination of September 8, 2005 as the effective date for Medicare participation for the two locations.

Analysis

[4] In its brief, Family Health asserted in the alternative that the effective dates should be October 1, 1991 for both locations (the date Family Health was first approved as an FQHC in the Medicare program) or November 11, 2002 for the Central Avenue location (the date HRSA approved a Change of Scope to Family Health's PHS Act grant adding the Central Avenue location.) P. Br. before ALJ at 2; see also Request for Review (RR) at 2. In its request for reconsideration to CMS, Family Health requested effective dates of December 19, 2002 and April 1, 2004 (with no explanation). P. Letter of September 22, 2005 at 1.

Summary disposition in the nature of summary judgment is appropriate when there is no genuine dispute as to any material fact, and the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Lebanon Nursing and Rehabilitation Center, DAB No. 1918 (2004). In deciding a summary disposition motion, a tribunal must view the entire record in the light most favorable to the non-moving party, drawing all reasonable inferences from the evidence in that party's favor. Madison Health Care, Inc., DAB No. 1927 (2004).

We conclude that the ALJ erred by summarily concluding that September 8, 2005 was the earliest possible effective date for Medicare participation for these locations and that CMS has "non-reviewable discretion" to decide the effective date of approval of an FQHC for participation in the Medicare program. In reaching his result, the ALJ failed to consider whether Family Health's and CMS's actions beginning in 2002 constituted CMS approval of these locations as FQHC sites. The ALJ's review in this case was materially hampered by the fact that CMS, in its initial filing and prior to moving for summary disposition, did not respond to the factual assertions and arguments made by Family Health in its Request for Hearing. After Family Health repeated these arguments in its brief in opposition to CMS's motion for summary disposition, the ALJ specifically requested CMS to file a reply brief to address "arguments raised by Petitioner which were not addressed by CMS in its initial brief" (letter transmitted August 17, 2006). CMS did not do so.[5]

Below, we discuss the applicable regulations and explain why, given the undisputed facts alleged by Family Health, the ALJ erred in concluding, on summary disposition, that September 8 was the earliest possible effective date. We remand the case to the ALJ because, while CMS did not deny that Family Health filed CMS-855Bs and CMS-855Rs for these locations, we cannot evaluate the legal effect of these forms – in particular, whether they provided assurances to CMS that these locations met applicable

[5] We note that CMS's failure appears to have been related to difficult circumstances in CMS counsel's life during this time. However, before us, CMS also did not file a brief. Therefore, CMS has never disputed the facts alleged by Family Health and has filed no response to Family Health's arguments concerning the actions Family Health and CMS took beginning 2002 and their legal effect. Nor has CMS ever referred to any applicable policies or the specific relevant forms in effect in 2002.

Medicare requirements -- without further record development including copies of the forms. Additionally, while CMS did not deny Family Health's assertions that CMS reimbursed Family Health for FQHC services at these locations, in the absence of further record development, we cannot evaluate the legal effect of the actions CMS took in response to Family Health's CMS-855Bs and, particularly, whether CMS paid FQHC reimbursement, as opposed to non-FQHC physician reimbursement, for services provided at these locations.

> 1. The ALJ erred because he failed to consider whether the undisputed facts alleged by Family Health could support earlier effective dates for Family Health's two additional locations as FQHCs in the Medicare program.

In Medicare, an FQHC is classified as a supplier. 42 C.F.R. § 498.2. In order to qualify for approval as a Medicare supplier, an FQHC must meet the applicable conditions of coverage found in 42 C.F.R. Part 491, Subpart A. 42 C.F.R. § 491.1. As to locations, one of these conditions provides –

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

42 C.F.R. § 491.5(a)(3)(iii).

There is no dispute that the locations at issue were permanent units.[6]

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[6] A "permanent unit" is defined as existing where --

> [t]he objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a permanent structure.

42 C.F.R. § 498.5(a)(3)(i).

The regulation distinguishes between a permanent unit and a "mobile unit," which does not require separate certification. A "mobile unit" is defined as existing where --

> [t]he objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a mobile structure which

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The ALJ concluded that section 491.5(a)(3)(iii) requires an FQHC "to obtain separate [Medicare] certification for each permanent unit that is part of the FQHC's overall operation." ALJ Decision at 4. In determining when such certification (or approval, as the regulation describes it) is effective, the ALJ correctly relied on sections 405.2434(b) and 489.13(a)(2)(i). Section 405.2434(b) provides that an FQHC's agreement with CMS to participate in Medicare is effective as of "the date CMS accepts the signed agreement, which assures that all Federal requirements are met." Section 489.13(a)(2)(i) provides:

> For an agreement with . . . a (FQHC), the effective date is the date on which CMS accepts a signed agreement which assures that the . . . FQHC meets all Federal requirements.

Based on Family Health's and CMS's actions in 2005, the ALJ concluded that --

> the *earliest* date that CMS could have accepted either of the two sites as a participating FQHC was the date when CMS accepted a signed agreement verifying that each of the sites met all federal requirements. The undisputed facts establish that this date was September 8, 2005, the date which CMS determined was the effective date of participation. It was on that date that the Intermediary for FQHCs in Ohio, UGS, certified to CMS that Petitioner's two sites met all federal requirements. The certification from UGS was the "agreement" that CMS had to receive in order to certify the sites. CMS could not certify the sites prior to that date because it did not have an agreement prior to September 8 that the sites met all federal requirements.

ALJ Decision at 5 (emphasis in original).

As to Family Health's argument that the events beginning in 2002 qualified these locations for an earlier effective dates, the ALJ wrote:

> The possibility that one of the two sites may have had a Public Health Service grant prior to September 8, 2005

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[6](...continued)
has fixed, scheduled location(s).

42 C.F.R. § 498.5(a)(3)(ii).

> does not alter my decision. CMS could not have certified the site at a date earlier than the date that UGS certified to CMS that the sites met all federal requirements even if, in fact, one of the sites may have actually met federal requirements at an earlier date. That is because CMS had to have an agreement from UGS certifying that the sites met federal requirements before it could certify them. That was not forthcoming until September 8, 2005.

ALJ Decision at 5-6.

We agree with the ALJ that, if the only facts at issue involved the 2005 events, an effective date of September 8, 2005 is consistent with (though not required by) the regulatory requirements.[7] As explained below, however, we conclude that the

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[7] We note that the ALJ seems to have articulated an unsupported and narrow reading of CMS's scope of discretion. He wrote that CMS could not have "accepted" this agreement any earlier than the date the fiscal intermediary "certified to CMS that Petitioner's two sites met all federal requirements." ALJ Decision at 5.

This reading of sections 405.2434(b) and 489.13(a)(2)(i) unnecessarily constrains CMS. CMS's present practice may be to rely on the date the intermediary completes its review of a CMS-855A, although it appears that, in an FQHC review, the intermediary does not review whether the FQHC meets FQHC conditions of coverage. See CMS Ex. 5, at 1 describing UGS's review. Since the FQHC approval process uses self-attestation by the FQHC (see 61 Fed. Reg. 14,640, at 14,641 (April 3, 1996)), we see nothing in the language of these regulations that would deprive CMS of the discretion to adopt a practice of accepting agreements as of the date of the FQHC's application or attestation, if it subsequently determined that the requirements had been met as of that date. Indeed, a prior version of the SOM provided that "the earliest effective date of a FQHC's approval will be the date the [Regional Office] receives the signed attestation statement and the FQHC attests in writing that it meets all the Federal requirements in the FQHC regulations." Harriet Cohn Center, DAB No. 1817, at 16-17 (2002) (citing State Operations Manual § 2826.H effective in 1998).

Similarly, we note that the reconsideration decision issued by the CMS Non-Long Term Care Branch of the Midwest Consortium also

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ALJ erred by not considering whether the undisputed facts alleged by Family Health support earlier effective dates on the grounds that CMS approved these two new locations beginning in 2002 by accepting Family Health's assurances and agreements, made in CMS-855Bs and 855Rs, for meeting Medicare FQHC requirements for these locations.

In its request for review before the Provider Reimbursement Review Board, Family Health made the following factual assertions about events prior to 2005.

> In 2002, two local physicians approached Family Health about joining our practice. The proposal was reviewed and we determined that incorporating these physicians into our practice would help us further our mission of "building healthy lives." We did not have space to incorporate their practice, so the decision was made to leave the physicians practice at the current facilities until Family Health would expand its building. We applied and received a Change of Scope [see P. Ex. 7] to add the facility to our Federal HRSA/BPHC grant effectively qualifying them as part of our FQGHC reimbursement services. We contacted Medicare and were told that we need to complete 855B's [a "Medicare Enrollment Application - Clinics/Group Practices and Certain Other Suppliers"] for the new physicians. The physicians received their Medicare numbers and we received FQHC reimbursement for the physicians from Medicare as agreed upon. Family Health did everything that we were told had to be done.
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> * * *
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> We completed the 855B, Change of Scope, and the Federal Grant listing the address. We filed claims that were paid for over a year. We called Medicare and asked what needed to be done and were not told of the 855A requirement.

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[7](...continued)
appears to restrict CMS's discretion in a manner not supported by the regulations. CMS Ex. 1. The letter refers to both CMS's practice (i.e., use of the Medicare intermediary's review date) and the terms of section 489.13(a)(2) as "guidelines" even though they have very different legal status and binding effect on the agency and on suppliers. CMS would not necessarily have to follow its current practice so long as the requirements of the applicable regulations are met.

P. Ex. 2, at 1-2.

In its Request for Hearing, Family Health made the following factual assertions in support of its position that it should receive earlier effective dates for these locations.

> Family Health submitted forms 855B (and, later, 855R) as instructed (and as specified in the Nationwide Medicare Provider Enrollment notice). Nobody at CMS informed Family Health that an 855A had to be completed until three years following the initial submission . . . .
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> Within a period of 18 months, Family Health was approached by four independent family practice physicians in our community that wanted to join our practice due to the high cost of malpractice insurance and the increasing legal and administrative burden being placed on physicians. Family Health, knowing that our community could not afford the possibility of losing four highly respected physicians, researched what was necessary to add these physicians to our practice and determined that it was feasible to add the physicians. However, due to space limitations at our home location, we decided it would be best to assume the existing leases for office space with the local hospital.
>
> Our research, including questions to CMS and Palmetto [a Medicare contractor], concluded we needed to get an approved Change of Scope from HRSA, our federal grant authority, to add the new locations and complete the Medicare 855R's ["Medicare Federal Health Care Benefits Enrollment Application – Reassignment of Medicare Benefits"]. We successfully completed both these processes before the physicians joined our practice. We thought all requirements were met and this was confirmed by the fact that we were getting reimbursement from CMS for the services rendered. Not until over two years later when CMS audited our cost report was it discovered that Family Health needed to complete an 855A in addition to the 855R. . . . Family Health did not know that the 855A had to be completed. The forms that CMS identified (855R) following our submission of the 855B were completed.

Request for Hearing at 3-4.[8]

As noted above, section 491.5(a)(3)(iii) provides that each FQHC permanent unit is "independently considered for approval as an . . . FQHC." The ALJ correctly concluded that this regulation required separate CMS approval to participate in the Medicare program for each unit or permanent location.[9] Before the ALJ,

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[8] Family Health included in the record the CMS notice ("Provider Enrollment News Flash") it allegedly relied on. See P. Ex. 8. The notice was issued in October 2001, refers to forms CMS-855I, 855B, and 855R, and indicates that CMS-855B should be "used to enroll or to make changes for groups." The notice no where refers to the CMS-855A, which is the form CMS used in approving these locations in 2005.

[9] We disagree with the ALJ that this regulation "clearly requires that an FQHC obtain separate certification [from CMS] for each permanent unit that is part of the FQHC's overall operation." ALJ Decision at 4 (emphasis added). The regulation requires "approval" but does not refer to any particular approval process. Nor is the term "certification" used in section 405.2430, which sets forth the process by which CMS initially qualifies an FQHC to participate in Medicare. Further, the regulation does not indicate from whom approval should be sought. Finally, the regulation could be confusing since, as Family Health points out, the locations at issue could not have been approved as FQHCs since they did not independently meet PHS Act grant requirements, which is a requirement for a PHS Act grant-qualified FQHC. Thus, while the ALJ is correct that CMS intended FQHCs to obtain separate provider numbers for each permanent location, this becomes apparent only if one consults the 1996 preamble to final adoption of the FQHC regulations and, in any event, Family Health did apparently obtain separate numbers for each location. 61 Fed. Reg. 14,640, 14,641-14,642 (April 3, 1996).

We note that the preamble confirms that the ALJ correctly rejected Family Health's argument that there were disputed material facts as to whether the new locations were "entities" as that term is used in the definition of an FQHC. P. Br. at 6; see 42 C.F.R. § 405.2401. This argument is based on a mistaken understanding of applicable regulations. Family Health erroneously assumes that each of the new locations must be "entities" that have an "independent legal status" (RR at 7) and "qualify independently to receive a grant under section . . . 330

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CMS cited section 405.2430 as the approval process for FQHC locations added as part of an existing FQHC. CMS Br. before ALJ (CMS Br.) at 4.[10] Under that process, CMS approves an FQHC's request for participation in Medicare by "accept[ing] [an] agreement filed by [Family Health]" (42 C.F.R. § 405.2430(a)(4))), "which assures that all Federal requirements are met" (42 C.F.R. § 405.2434(b)(1)). The process does not specify the use of any particular CMS form, nor does it expressly address how to add an additional location to an existing FQHC that has an agreement.

CMS appears to have generally followed this process in 2005 in approving the locations at issue as FQHCs in the Medicare program. After the audit in 2005, Family Health was instructed to file a CMS-855A for these locations.[11] P. Ex. 2. The CMS-

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[9](...continued)
of the Public Health Services Act" (RR at 9). As the preamble explains, however, a permanent location is not required to be a separate "entity" and "need not independently meet the PHS Act grant requirements. The fact that a site is within the scope of a grant . . . is sufficient." 61 Fed. Reg. at 14,641-14,642. Therefore, whether the two locations at issue are "entities" as that term is used in 42 C.F.R. § 405.2401 or independently meet all requirements for a PHS Act grant are not material facts.

[10] The process includes a request by the FQHC "to participate in the Medicare program"; a recommendation from the Public Health Service that the entity qualifies as an FQHC; an assurance by the FQHC to CMS that it meets the Medicare FQHC requirements in Part 405, subpart X and Part 491; termination by the FQHC of other provider agreements unless the FQHC assures CMS that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier; a signed agreement by the FQHC assuring CMS that those requirements are met; and an acceptance by CMS of that agreement. The effective date of such an agreement is "the date CMS accepts the signed agreement, which assures that all Federal requirements are met." 42 C.F.R. § 405.2434(b)(1).

[11] CMS did not state why Family Health was told in 2005 that it had to file a CMS-855A. We note that regulations proposed in 2003 and made final in 2006 specified that a provider or supplier must submit the appropriate CMS-855 enrollment application based on the type of provider or supplier enrolling. The revised CMS-855A is for providers billing fiscal

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855A (used at the time) was titled "Medicare Federal Health Care Provider/Supplier Enrollment Application – Application for Health Care Providers that will Bill Medicare Fiscal Intermediaries." See CMS Ex. 5, at 10. The CMS-855A for Central Avenue was received by CMS on May 6, 2005. Id. (CMS states it was then forwarded to the intermediary. CMS Br. at 2.) Family Health also executed an "Attestation Statement for Federally Qualified Health Centers" (Attestation Statement) on May 24, 2005 in which it made various assurances to CMS about its compliance with FQHC requirements.[12] CMS Ex. 3; CMS Ex. 5, at 1; CMS Ex. 2.

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[11](...continued)
intermediaries and the revised CMS-855B is for supplier organizations billing carriers. 77 Fed. Reg. 20,754, 20,756 (Apr. 21, 2006). The preambles to both the final rule and the proposed rule referred to the existing definitions of provider and supplier at 42 C.F.R. §§ 400.202 and 488.1, which include an FQHC in the definition of supplier. 77 Fed. Reg. at 20,756; 68 Fed. Reg. 22,064 (Apr. 25, 2003). At the time of the proposed rule, CMS published its revised forms for public comment. It is not clear from the preamble to the final rule exactly when CMS started using those revised forms, however.

[12] It is unclear whether CMS, in this case, regarded the Attestation Statement or the CMS-855A as the "agreement" referred to in section 405.2430. When CMS notified Family Health that it had "accepted your request for approval as a [FQHC] in the Medicare program" as of September 8, 2005, CMS stated that "the enclosed attestation statement will serve as your provider agreement and should be retained for your records." CMS Ex. 2, at 1. This statement, and the format of the Attestation Statement, would seem to indicate that it is the agreement CMS uses to implement section 405.2430. However, the CMS "acceptance" date recorded on the Attestation Statement is September 19, 2005, not September 8. CMS Ex. 3. Nor does the Attestation Statement in the record refer to any specific location. CMS Ex. 3. Further, in its denial of Family Health's request for reconsideration, CMS stated –

> the beginning date of Medicare participation is the date CMS accepts a signed agreement that assures the FQHC meets all Federal requirements. In the case of a FQHC, CMS applies the date of the letter from the fiscal intermediary recommending approval of an FQHC 855A application as the date Federal requirements are met.

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Family Health's undisputed allegations in its notice of appeal and brief, however, raise the question of whether actions by CMS and Family Health beginning in 2002 constituted compliance by Family Health with the regulatory requirements and acceptance by CMS of a "signed agreement [by Family Health], which assures that all Federal requirements are met" as provided by section 405.2434(b). As described by Family Health, those actions included: obtaining a change of scope for Family Health's PHS Act grant to include these locations; consulting with CMS and its intermediaries about how to qualify additional locations for Medicare FQHC reimbursement; pursuant to that consultation, filing of CMS-855B applications ("Medicare Enrollment Application – Clinics/Group Practices and Certain Other Suppliers") and CMS-855Rs ("Medicare Federal Health Care Benefits Enrollment Application – Reassignment of Medicare Benefits) for the doctors practicing at the location; and CMS's subsequent payment of reimbursement to Family Health for FQHC services at these locations.

In response to Family Heath's assertions, CMS has never denied instructing Family Health to proceed in this manner, nor has it explained why Family Health's filing of CMS-855Bs could not constitute requests by Family Health for these locations "to participate in the Medicare program" as FQHCs as well as "a signed agreement, which assures that all Federal requirements have been met" by Family Health for these locations, particularly

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[12](...continued)
CMS Ex. 1, at 1.

This statement raises the question of whether CMS regards the CMS-855A as the relevant signed agreement.

In either case, there appears to be no basis for the ALJ's apparent treatment of the Medicare intermediary's letter as the agreement. He wrote:

> It was on [September 8, 2007] the Intermediary for FQHCs in Ohio, UGS, certified to CMS that Petitioner's two sites met all federal requirements. The certification from UGS was the "agreement" that CMS had to receive in order to certify the sites. CMS could not certify the sites prior to that date because it did not have an agreement prior to September 8 that the sites met all federal requirements.

ALJ Decision at 5.

when considered with Family Health's previous FQHC agreement.[13] See 42 C.F.R. §§ 405.2430(a), 405.2434(b). Nor has CMS ever referred to any applicable policies or the specific relevant forms in effect in 2002. Moreover, CMS has never explained why its alleged response to these actions at the time, i.e., payment for FQHC services at these locations, would not constitute "acceptance" by CMS of Family Health's agreements and assurances. See 42 C.F.R. § 405.2430(a)(4).

Further, we note that these events could satisfy the concerns expressed by CMS in the preamble to the final rule on FQHCs. In response to public comments from the public, CMS reaffirmed its responsibility "to ensure the health and safety of beneficiaries" receiving services from FQHCs. 61 Fed. Reg. at 14,641. In furtherance of this responsibility, it rejected comments that Medicare conditions of coverage were unnecessary because FQHCs were subject to "stringent standards established by HRSA." Id. Rather, CMS stated that "[i]n the absence of [Medicare] health and safety standards, we would have no means to protect beneficiaries from potentially serious health and safety threats that have materialized with other types of providers and suppliers over time." Id. Similarly, CMS explained that it believed it was appropriate to "independently approve each site for Medicare participation and assign it a unique provider number." Id. CMS stated that such separate approval was needed to enable it to ensure that "each site is adequately meeting the required health and safety standards" and was appropriate because separate approval would "allow[] each site in an [FQHC] to continue to operate despite individual problems that may arise in other sites under the same [FQHC]. By requiring individual site approval, all of the sites of an entity are not jeopardized if one site does not meet health and safety requirements." Id. However, CMS considered the fact that PHS Act grantees were already monitored by HRSA when it structured the FQHC approval process. CMS stated that --

> we are implementing the requirements in a fashion that is as administratively simple as possible. That is, we are not surveying potential FQHCs prior to participation

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[13] CMS enrollment applications typically require the provider/supplier to certify that it will comply with Medicare requirements. For example, in the 2001 version of the CMS-855A, the applicant must "agree to adhere to the following requirement in this Certification Statement . . . I agree to abide by the Medicare laws, regulations, and program instructions that apply to this type of provider." CMS Ex. 5, at 27.

> or on a routine basis. Rather, centers merely attest to meeting the requirements. The standards thus establish a set of expectations for FQHCs to monitor themselves and provide an enforcement mechanism for those very few centers that do not take adequate health and safety precautions.

Id.

Thus, if Family Health's actions in executing CMS-855Bs and CMS-855Rs provided CMS with adequate assurances that these locations would meet FQHC Medicare requirements and CMS issued a unique supplier identification number to each of the locations that CMS could revoke, CMS would have had both the assurances it deemed necessary from an FQHC and an "enforcement mechanism" for these locations if Family Health did not meet those requirements.

Finally, we note that Family Health asserted that, if the September 8, 2005 effective date was upheld, the financial liability resulting from adjustments to four cost reports would "shut down Family Health which currently sees approximately half of the population of Darke County. Darke County, which is already [a] medical shortage area, will no longer have a safety net provider." Request for Hearing at 3. This consequence would not, as Family Health argues, provide a basis in equity for overturning an effective date mandated by regulatory requirements. See Request for Review to Board (RR) at 12-13. The consequence, however, may figure in CMS's evaluation of the scope of its discretion in adopting effective dates in this case, given our conclusion that the regulations do not mandate the date applied here.

> 2. The ALJ erred by concluding that 42 C.F.R. § 489.13(a)(2)(i) vests non-reviewable discretion in CMS to set effective dates for FQHC Medicare approval.

It was error for the ALJ to conclude that section 489.13(a)(2)(i) "vests non-reviewable discretion in CMS to decide when to certify an FQHC as meeting participation requirements." ALJ Decision at 5.[14] Section 498.3(b)(15) defines "the effective

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[14] The ALJ wrote:

> Moreover, 42 C.F.R. § 489.13(a)(2)(i) vests non-reviewable discretion in CMS to decide when to certify an FQHC as meeting participation requirements. The regulation very

(continued...)

date of a Medicare . . . supplier approval" as an "initial determination" that is subject to appeal under section 498.5(d). When it adopted this change to Part 498, CMS stated that the change "[m]akes existing Medicare appeals procedures available, and requires Medicaid agencies to make their existing appeals procedures available, for effective date determinations." 62 Fed. Reg. 43,931, at 43,934 (Aug. 18, 1997). Further, nothing in section 489.13(a)(2)(i) suggests an ALJ may not review CMS's determination of an effective date, if, as here, the FQHC alleges a basis for doing so. We note also that CMS counsel did not argue that CMS had non-reviewable discretion to set an effective date. Rather, CMS argued before the ALJ that the effective date set by CMS here was required by the regulations. Finally, we note that, when CMS rejected Family Health's reconsideration request for earlier effective dates, CMS informed Family Health that it could seek ALJ review of "this determination." CMS Ex. 1, at 2.

Conclusion

For the reasons stated above, we reverse and remand this appeal to the ALJ for further proceedings. The ALJ should develop the record as necessary in view of the legal conclusions reached herein. Relevant documents could include the CMS-855Bs that Family Health filed; possible assurances Family Health made by other means of compliance with Medicare requirements for these

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[14](...continued)
plainly states that the effective date of number is the date when CMS *accepts* an agreement that a supplier meets certification requirements. Nothing in the regulation suggests that I have the authority to look behind CMS's determination to accept an agreement effective a particular date and rule that CMS ought to have accepted the agreement at an earlier date.

ALJ Decision at 5.

He also wrote:

> Moreover, inasmuch as CMS's discretion to accept the agreement from UGS is non-reviewable, I have no authority in any event to conclude that CMS – or UGS – ought to have found one of the sites to have met federal requirements on a date earlier than September 8, 2005.

Id. at 6.

locations; documentation of CMS's actions in response to those applications; and reimbursement records that show whether CMS made payments for visits at these sites as FQHC services.

Alternatively under 42 C.F.R. § 498.78(b), the ALJ may consider remanding this case to CMS to determine whether, pursuant to the principles articulated in this decision, the actions of Family Health and CMS beginning in 2002 provide a basis for CMS's approving earlier effective dates for these locations. This alternative may be particularly appropriate since, in its reconsideration decision, CMS adopted an unnecessarily narrow view of its discretion for setting an FQHC effective date (see note 7), and CMS has not there or elsewhere addressed Family

Health's assertions as to the actions taken by Family Health and CMS as to the locations in question beginning in 2002.

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Donald F. Garrett
Presiding Board Member