PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2012-D4

PROVIDER –
Oakwood Annapolis Hospital
Wayne, Michigan

Provider No.: 23-0142

vs.

INTERMEDIARY -
BlueCross BlueShield Association/
National Government Services, Inc.

DATE OF HEARING -
September 15, 2010

Cost Reporting Periods Ended -
December 31, 2004; December 31, 2005
and December 31, 2006

CASE NOs.: 09-0894; 08-1351;
09-0892

INDEX

ISSUE:

Did the Oakwood Annapolis Family Practice Residency Program, which received "provisional accreditation" from the Accreditation Council for Graduate Medical Education (ACGME) meet the definition of a "new" program in 2004.[1]

MEDICARE STATUTORY AND REGULATORY BACKGROUND:

This is a dispute over the amount of Medicare reimbursement due a provider of medical services.

The Medicare program was established to provide health insurance to the aged and disabled. 42 U.S.C. §§ 1395 *et seq*. The Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), is the operating component of the Department of Health and Human Services (DHHS) charged with administering the Medicare program. CMS' payment and audit functions under the Medicare program are contracted to organizations known as fiscal intermediaries. Fiscal Intermediaries (FIs) and Medicare Administrative Contractors (MACs)[2] determine payment amounts due providers under Medicare law and interpretive guidelines published by CMS. *See* 42 U.S.C. § 1395h; 42 C.F.R. §§ 413.20 and 413.24.

At the close of its fiscal year, a provider must submit a cost report to the intermediary showing the costs it incurred during the fiscal year and the portion of those costs to be allocated to Medicare. 42 C.F.R. § 413.20. The intermediary reviews the cost report, determines the total amount of Medicare reimbursement due the provider and issues the provider a Notice of Program Reimbursement (NPR). 42 C.F.R. § 405.1803. A provider dissatisfied with the intermediary's final determination of total reimbursement may file an appeal with the Provider Reimbursement Review Board (Board) within 180 days of the receipt of the NPR. 42 U.S.C. § 1395oo(a); 42 C.F.R. § 405.1835.

Background on "New Programs" for Training Residents

Medicare payments for direct graduate medical education are made on a per-resident basis subject to a hospital-specific "cap" which is the number of residents in the 1996 base year. 42 C.F.R. § 413.79(c)(2). Hospitals that did not engage in residency training in 1996, the base year for setting the cap, have a cap of zero. Section 1886(h)(4)(H)(i) of the Social Security Act, however, requires the Secretary to "prescribe rules for the application of FTE resident cap for medical residency training programs established on or after January 1, 1995," and in August 1997, CMS issued rules for counting residents in "new" programs. 62 Fed. Reg. 45966, 46006 (Aug. 29, 1997)[3]

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[1] Transcript, pp. 5-6.

[2] FIs and MACs are hereinafter referred to as intermediaries.

[3] Exhibit P-21, pp. 1-2.

A hospital with a resident cap of zero can increase its cap if it participates in a "new medical residency training program," a term defined by Medicare regulations as "a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995." 42 C.F.R. at § 413.79(l).

The Federal Register preamble language which accompanied this regulatory definition of a "new" program explained that "initial accreditation" included "provisional accreditation." The Preamble states: "For purposes of this provision, a 'program' will be considered newly established if it is accredited for the first time, including provisional accreditation on or after January 1, 1995, by the accrediting body."[4] Both "initial accreditation" and "provisional accreditation" were terms used by the ACGME at the time the regulation was enacted in 1997.[5]

CMS published a further interpretation of this regulation in Program Memorandum No. A-99-51, Section VII (A) (Dec. 1999) (the "Program Memorandum").[6] This interpretation affirmed that the definition of a "new medical residency training program" was a program that received an "initial accreditation by the appropriate accrediting body" while elaborating on how a program could qualify as a new program under the second option provided for in the regulation, i.e., as a program that began training residents after 1994.

Background on "New Programs" for Training Residents

The ACGME designates a Residency Review Committee (RRC) to maintain and determine the accreditation status of each residency program in a particular specialty.[7] RRC members, among other requirements, "must be board-certified specialists in the field" and "must have demonstrated substantial experience in administration and/or teaching within the specialty."[8] There is a separate RRC for each specialty, such as family medicine, internal medicine, and obstetrics.[9] These committees make determinations on new program applications and/or reaccreditations of existing programs.[10] Decisions of each RRC are the decisions of the ACGME.[11]

The RRCs are authorized by the ACGME to grant provisional accreditation:

> For initial accreditation of a program, or for a previously accredited program which had its accreditation withdrawn and has subsequently applied for re-accreditation. Provisional accreditation may also be used in the unusual circumstance in which separately accredited general specialty programs merge into one or an accredited program has been

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[4] 62 Fed. Reg. at 46006 (Ex. P-21 at 2).
[5] Ex. P-8 at 22-23
[6] Ex.I-5.
[7] Trans. at 59-60.
[8] Ex. P-9 at 53.
[9] Supra, not 6.
[10] *Id.*
[11] *Id.*

> so altered that in the judgment of the RRC it is the equivalent of a new program.[12]

Provisional accreditation entails heightened oversight of the new program by the RRC and effectively constitutes a probationary period before full accreditation is granted and obligates the ACGME to perform an additional site visit to ensure compliance with all residency program requirements before full accreditation can be achieved.[13]

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

Oakwood Health Care Inc. is a metropolitan Detroit area not-for-profit healthcare system that includes four acute care hospitals, including Oakwood Hospital and Medical Center ("OHMC) and Oakwood Annapolis Hospital (OAH). OHMC is a teaching, tertiary care hospital with approximately 632 available beds that is located in Dearborn, Michigan. OHMC maintained several residency programs including a family practice residency program. Oakwood Annapolis Hospital (Provider) is a full service community hospital located in Wayne, Michigan. The Provider serves the city of Inkster, an area designated as a "medically underserved area (MUA)."[14] The Provider did not train any residents prior to the academic year beginning July 1, 2004. In late 2003, OHMC opted to close its family practice residency. OHMC submitted a letter to the ACGME announcing its intent to relinquish its authority and control as a sponsoring institution for its family practice residency program.[15] ACGME approved the withdrawal effective June 30, 2004.[16] Concurrent with the closing of the program at OHMC, the Provider was considering the possibility of opening a family practice residency program at its facility and, to that end, contacted Wisconsin Physicians Services (Intermediary) to determine what effect the closure at OHMC would have on its own FTE cap for a new program. The Intermediary advised the Provider that it would receive its own cap in the third full cost reporting period and that for the first three years, the hospital would be limited by the approved number of FTEs in the program.[17] Acting upon the Intermediary's advice, the Provider secured provisional accreditation for its program from the ACGME that included recognition as a new program.[18] The Provider opened its program on July 1, 2004 with 9 residents and it grew to 16 residents in 2005 and 21 in 2006. The Provider timely filed its cost reports for fiscal years 2004 and 2005, and received uncontested settlement of the cost claimed for its residency program. In 2008, the Intermediary issued a reopening notice that advised the Provider that CMS was imposing additional requirements on "new' programs. The Intermediary subsequently determined that the Provider did not meet the additional requirements, rescinded the programs "new status" designation and recouped all prior payments for the program. The Provider disputed the

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[12] "Manual of Policies and Procedures for ACGME Residency Review Committees," September 10, 2002, (Ex.P-9 at 59).
[13] *Id.*
[14] Ex. P-7.
[15] Ex. P-11
[16] Ex P-13.
[17] Ex. P-6.
[18] Ex. P-14.

application of the additional standards and appealed the Intermediary's disallowance to the Provider Reimbursement Review Board ("Board").

The Provider appeal was timely filed pursuant to 42 CFR §§ 405.1835-1841, and met the jurisdictional requirements of those regulations. The Provider was represented by Dennis M. Barry, Esq., and Daniel J. Hettich, Esq., of King & Spalding, LLP. The Intermediary was represented by Bernard M. Talbert, Esq., Senior Medicare Counsel, Blue Cross and Blue Shield Association.

INTERMEDIARY'S CONTENTIONS:

The Intermediary argues that the disallowance was the product of a reevaluation by the Intermediary of its own initiative, not a disallowance that was driven by CMS' retroactive analysis of what the Intermediary had accepted. The Intermediary further contends that it properly applied the instructions per Program Memorandum A-99-51. The instruction defines a "new Medical Residency program" as:

> ...A program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.

The definition was further clarified in 74 Federal Register at pages 24191 and 24192 which states in pertinent part:

> It has come to our attention that there has been some misinterpretation or misunderstanding of the regulations among hospitals and Medicare contractors despite previous discussions of the topic in the **Federal Register**. Specifically, some hospitals or contractors took the regulations to mean that, as long as the relevant accrediting body . . . grants an "initial" accreditation or reaccredits a program as "new" the hospital may receive an FTE cap adjustment for that program, regardless of whether that program may have been accredited previously at another hospital.

The section states further:

> [I]n the FY2000 IPPS final rule (64 FR 41519), we responded to a public comment suggesting that CMS include within the definition of "new residency program" a residency program that may have been in existence at other clinical sites in the past. We replied that "the language 'begins training residents on or after January 1, 1995' [m]eans that the program may have been accredited by the appropriate accrediting body prior to January 1, 1995, but did not begin training in the program until on or after January 1, 1995. The language does *not* mean that it is the first time a particular hospital began training residents in a program on or after January 1, 1995, *but that program was in existence at another hospital prior to January 1, 1995, . . .*"

The section concludes:

> [R]ather than relying solely on the accrediting body's characterization of whether a program is new, we continue to believe it is appropriate that CMS require a hospital to evaluate whether a particular program is a newly established one for Medicare GME purposes by considering whether a program was initially accredited "for the first time," and is not a program that existed previously at another hospital."

According to guidance in Federal Register, in evaluating whether or not a program is new, or has relocated to a new site, it is important to consider the supporting factors such as whether:

- the program directors the same as the previous program.
- the teaching staff is the same.
- the same residents are training in the program, only at a new site.
- there is common ownership.

The accreditation documents[19] indicate that the entire faculty and curriculum remained the same, the family practice centers did not change, and Oakwood Dearborn Hospital (OHMC) and Oakwood Annapolis Hospital were under the same ownership, i.e., Oakwood Healthcare, Inc. Further, the residents in the program at OHMC enrolled in the newly accredited program and the program Director remained unchanged. The Intermediary argues that all of these factors indicate that the Family Practice Residency Program merely transferred from Oakwood Hospital and Medical Center to Oakwood Annapolis Hospital.

The Intermediary also argues that the Provider sought and received guidance from CMS relative to the proper classification of the program. CMS responded in a letter dated January 15, 2009[20]:

> In the case of the family medicine program at Oakwood Annapolis Hospital, it appears that this program was initially accredited <u>for the first time</u> at Oakwood Dearborn Hospital and then was transferred; it received a <u>second</u> accreditation from the Accreditation Council on Graduate Medical Education (ACGME) at Oakwood Annapolis Hospital on July 1, 2004.

CMS states further:

> If we were to find that the family practice program at Oakwood Annapolis Hospital was a new program after its re-location from the Oakwood Dearborn Hospital, the result would be that FTE resident cap adjustments would be made with respect to the same program at two different hospitals. Such an increase in the aggregate number of FTE residents is

[19] Ex. I-4.
[20] Ex. I-7.

> not consistent with the intent of Congress as expressed in the BBA Conference Report's direction to prescribe rules for counting residents in new programs without allowing the aggregate number of residents to increase over current levels.

The Intermediary contends that CMS makes clear that this is a transfer of an existing program rather than a new program and accordingly believes that its adjustments are appropriate.

PROVIDER'S CONTENTIONS:

The Provider contends that the Intermediary's determination violates the plain language of the regulation which defines a new program to be "a medical residency that receives initial accreditation by the appropriate accrediting body . . . on or after January 1, 1995."[21] The Provider contends that the regulatory definition has been met because CMS specifically stated that "initial accreditation" includes "provisional accreditation,"[22] and the program at OAH received "provisional accreditation" from the ACGME in 2004.[23] The Provider also points to two letters from CMS, which it received in response to a request that it made under the Freedom of Information Act.[24] The request solicited examples of the manner in which CMS' applied the language of the regulation. The provider argues that the letter demonstrate that CMS interpreted the regulation to mean that a program must only receive ACGME "provisional accreditation" to be considered new. It is undisputed that OAH's program received "provisional accreditation" from ACGME in 2004, and the Provider, therefore, concludes that the Intermediary's determination must be overturned.

The Provider also contends that the Intermediary's determination is contrary to substantial evidence which shows that the OAH program is a new program under any standard. The Provider points to testimony at the hearing and to a 1999 report from OHMC's internal review committee to support its contention that the program at OAH was substantially altered to address numerous deficiencies present in the closed OHMC program. These deficiencies included: OHMC's family practice residents were competing with residents in other residency programs for crucial procedural training, were being trained primarily by internal medicine doctors instead of family medicine doctors, lacked continuity of care and were distant from the community medicine setting in which they were training to practice.[25] In addition, nearly all the affiliated faculty and rotations were different at OAH compared to OHMC and these elements play a particularly important role in the training of family practice residents.[26] The Provider

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[21] 42 C.F.R. § 413.79(l).
[22] 62 Fed. Reg. at 46006.
[23] Ex. P-14.
[24] Ex. P-24, P-25.
[25] Trans. at 62-71; *see also,* Ex. P-10.
[26] Trans.,at 109-110.

also points to the significant changes in the resident "match" results between the two programs to support its contention that the OAH program was a "new" program.[27]

The Provider argues that the Intermediary's determination is not based on standards that can be inferred from the regulation and is unduly vague. An agency cannot "leave the provider to guess as to what rule will be applied."[28] Although CMS argues that intermediaries should have been determining whether programs were "new" for Medicare purposes without further guidance, the Intermediary's inability to articulate a specific standard is evidenced by its testimony at the hearing that "you know [a new program] when you see it."[29] The Provider argues that absent defining criteria, the Intermediary's determination is based on unduly vague criteria that render effective compliance with or judicial review of that determination virtually impossible.

The Provider states that it did not have "fair notice" of CMS's policy. The courts have articulated the following test for the presence of "fair notice": "[i]f, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expects parties to conform, then the agency has fairly notified a petitioner of the agency's interpretation."[30] Even if an agency's interpretation of a regulation is reasonable, that interpretation cannot be applied to penalize a party unless the party had "fair notice" of the agency's interpretation: "The agency's interpretation is entitled to deference, but if it wishes to use that interpretation to cut off a party's right, it must give full notice of its interpretation." [31] The Provider argues that, prior to CMS' 2008 clarification, it could not, "by reviewing the regulations and other public statements issued by the agency . . . identify, with 'ascertainable certainty'" a requirement to show that a program was new through a myriad of factors that are beyond the regulatory requirement of receiving initial accreditation from ACGME. As discussed above, the regulation clearly states that receiving "initial accreditation from the appropriate accrediting body" qualifies a program as a new program. Nowhere is there any mention of other factors or that a new program must receive initial accreditation from the ACGME and also prove that it is a "new" for Medicare purposes."[32] The Provider concludes therefore, that "the agency has [not] fairly notified a petitioner of the agency's interpretation,"[33] and the new clarification cannot be used to penalize parties that have relied on a fair reading of the regulation. [34]

The Provider also argues that the policy employed by the Intermediary violates Congress' mandate that CMS publish in the Federal Register all "interpretative rules, statements of

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[27] Trans. at 73, 142-144; see also Ex. P-9 at 51.
[28] *Maximum Home Health Care, Inc. v. Shalala*, 272 F.3d 318, 321 (6th Cir. 2001)
[29] Trans. at 321.
[30] *General Elec. Co. v. U.S. E.P.A.*, 53 F.3d 1324, 1329 (D.C. Cir. 1995).
[31] *Satellite Broadcasting v. F.C.C.*, 824 F.2d1 at 8 (D.C. Cir. 1987); *see also General Elec. Co. v. U.S. E.P.A.*, 53 F.3d 1324, 1330 (D.C. Cir. 1995) ("as long ago as 1968, we recognized this 'fair notice' requirement in the civil administrative context.").
[32] 74 Fed. Reg. at 24192.
[33] *General Elec.*, 53 F.3d at 1329.
[34] *GranCare, Inc. v. Shalala*, 93 F. Supp. 2d 24, 32 (D.D.C. 2000).

policy, and guidelines of general applicability."[35] In addition to the general rule requiring all government agencies to provide the regulated party with "fair notice" of an agency interpretation before applying that interpretation to the detriment of the party, CMS in particular is obligated under statute to publish "interpretative rules, statements of policy, or guidelines of general applicability" in the Federal Register. Soc. Sec. Act § 1871(c)(1) (requiring that "[t]he Secretary . . . publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability.").

Finally, the Provider contends that the Intermediary's determination and CMS's 2009 clarification constitute prohibited retroactive rulemaking and otherwise violate the APA.[36] CMS established through its statements and practice that a new residency program is a program that receives initial accreditation from the ACGME or AOA. CMS must invoke the notice-and-comment rulemaking procedures mandated by the APA and Title XVIII before changing that position.[37] Aside from the 1999 Program Memorandum, CMS never amended, clarified, or explained the definition of "new program" published in 1997 until 2009, six years after this Provider committed itself to the Family Medicine training program at issue. CMS must comply with the APA's directive for notice and comment procedures: "Once an agency gives its regulation an interpretation, it can only change that interpretation as it would formally modify the regulation itself: through the process of notice and comment rulemaking."[38]

Furthermore, the Provider contends that while CMS has attempted to frame the additional guidelines in the Federal Register preamble as a "clarification," the additional requirements completely re-define what constitutes a new medical residency training program to the detriment of parties that have relied on the plain language of the regulation. CMS's "clarification" effectively instructs the Intermediary to ignore the regulation's requirement of whether a program received "initial accreditation" from an appropriate accrediting body and, "rather than relying solely on the accrediting body's characterization of whether a program is new," CMS requires a hospital to evaluate whether a particular program is newly established for Medicare GME purposes."[39] The proposed clarification clearly attempts to do just what is prohibited under the tenets of administrative law: make a substantial change to that policy and effect an amendment to this regulation without amending the regulation itself. Similarly, the Intermediary's determination violates the well-settled prohibition on retroactive rulemaking. The regulation at issue has been in effect since 1997. CMS cannot now apply its "clarification" to that entire period since "retroactive rulemaking lies beyond the

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[35] Soc. Sec. Act § 1871(c)(1); *see also, Chippewa Dialysis Servs. v. Leavitt*, 511 F.3d 172, 176-78 (D.C. Cir. 2007).

[36] *see* Administrative Procedure Act (APA), 5 U.S.C. § 706(a).

[37] *See, e.g., Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 813-14 (D.C. Cir. 2001); *Alaska Prof'l Hunters Ass'n, Inc. v. FAA*, 177 F.3d 1030, 1033-34 (D.C. Cir. 1999); *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997); *see also, Nat'l Family Planning*, 979 F.2d at 240-41.

[38] *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997); *Alaska Prof'l Hunters Assoc. Inc. v. FAA*, 177 F.3d 1030, 1034 (D.C. Cir. 1999).

[39] *See* 74 Fed. Reg. at 24192; *see also* 74 Fed. Reg. at 43912.

Secretary's power."[40] The prohibition on retroactivity applies based upon the rule's practical impact regardless of the rule's agency-given label as a legislative or interpretive rule. [41] Courts, therefore, afford no deference to interpretive rules that did not exist at the time of the prior regulation.[42]

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

After considering the Medicare law and program instructions, the evidence presented, the stipulations of the parties, and the parties' contentions, the Board finds and concludes that the Intermediary's decision to rescind "new" program status from OAH's family practice residency program, and thereby reduce its FTE cap to zero, was improper.

The central issue presented for the Board's review is whether the Provider's family practice residency program was properly classified as an existing program versus a new program. The issue required the Board to interpret the governing regulations and instructions that were in effect at the time the Provider received initial accreditation as a medical education program. It is undisputed that the ACGME is the relevant accrediting body or that the Provider opened its program on July 1, 2004, based upon provisional accreditation from the ACGME. The regulations in effect at that time define a new program to be "a medical residency that receives initial accreditation by the appropriate accrediting body . . . on or after January 1, 1995."[43] The Federal Register preamble language accompanying this regulatory definition of a "new" program explained that "initial accreditation" includes "provisional accreditation." The Preamble states: "For purposes of this provision, a 'program' will be considered newly established if it is accredited for the first time, including provisional accreditation on or after January 1, 1995, by the appropriate accrediting body."[44] The language of both the regulation and the Preamble make clear that the determination of a new program vests with the accrediting body. In this case, the Provider received initial accreditation from ACGME in 2004. The program therefore qualified as "new" under the regulation's plain language.

The Intermediary argues that CMS established the criteria under which a program was to be considered "new" in the Preamble language at 74 Fed. Reg. 43912 (August 27, 2009). The Intermediary contends that the definition of a new medical residency program as found in Federal Register is a clarification of existing evaluation standards. However, the Board's examination of the indicated section identified specific standards for the Intermediary's review of the residency program that were not previously included in the requirements for a new residency program nor communicated to the provider community. The Board does not consider the section a clarification but, rather, an articulation of a brand new standard under which medical residency programs are to be evaluated. The Board considers the application of that standard to the Provider's circumstances an

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[40] *Health Ins. Ass'n of America, Inc. v. Shalala*, 23 F.3d 412, 425, 428 (D.C. Cir. 1994) (citing *Bowen v. Georgetown University Hospital,* 488 U.S. 204 (1988)).
[41] *Health Ins. Ass'n of America, Inc.*, 23 F.3d at 425, 428
[42] *Id.*
[43] 42 C.F.R. § 413.79(l).
[44] 62 Fed. Reg. 45966, at 46006 (August 29, 1997).(Ex. P-21 at 1-2).

impermissible retroactive application of the new standard and, consequently, concludes that the Intermediary's adjustment was improper.

DECISION AND ORDER:

The Intermediary improperly disallowed the Provider's resident FTEs. The Board directs the Intermediary to set a resident cap treating Oakwood Annapolis Hospital's Family Practice residency training program as a "new" program.

BOARD MEMBERS PARTICIPATING:

Michael W. Harty
Yvette C. Hayes
Keith E. Braganza, C.P.A.
J. Gary Bowers, C.P.A.

FOR THE BOARD:

Michael W. Harty
Chairman

DATE: DEC 30 2011