PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2014-D22

PROVIDER –
Cleveland Clinic Florida Hospital
Weston, Florida

Provider No.: 10-0289

vs.

INTERMEDIARY –
Wisconsin Physicians Service

DATE OF HEARING -
April 24, 2012

Cost Reporting Periods Ended -
May 31, 2002; May 31, 2003; May 31, 2004;
May 31, 2005 and May 31, 2006

CASE NOs: 06-1304; 07-0199; 08-0025;
08-0231; 08-1852

INDEX

ISSUE:

Whether the Intermediary's removal of residents who participated in Colorectal Surgery (fiscal years ("FYs") 2002-2006), Internal Medicine (FYs 2004-2006), and Neurology (FYs 2004-2006) programs (collectively, "Programs") from the Provider's Graduate Medical Education ("GME") and Indirect Medical Education ("IME") full-time equivalent ("FTE") counts on the basis that these programs did not qualify as "new programs" under 42 C.F.R. § 413.79(l) was correct.[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 under Title XVIII of the Social Security Act, as amended ("Act"), to provide health insurance to eligible individuals. Title XVIII of the Act was codified at 42 U.S.C. Chapter 7, Subchapter XVIII. 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. [3]

Providers are required to submit cost reports annually, with reporting periods based on the provider's fiscal year. A cost report shows the costs incurred during the relevant fiscal year and the portion of those costs allocated to the Medicare program.[4] 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").[5]

A provider dissatisfied with the intermediary's final determination of total reimbursement (*i.e.*, the NPR) may file an appeal with the Provider Reimbursement Review Board ("Board") provided it meets the following conditions: (1) the provider must be dissatisfied with the final determination of the intermediary; (2) the amount in controversy is $10,000 or more for an individual appeal (or $50,000 for groups); and (3) the appeal must be filed with the Board within 180 days of the receipt of the NPR. [6]

A. BACKGROUND ON "NEW PROGRAMS" FOR TRAINING RESIDENTS

Since the inception of the Medicare program, Congress has authorized payment to hospitals for the direct cost of training of physicians. That Medicare program payment is known as the Direct Graduate Medical Education ("DGME") payment.

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[1] Transcript ("Tr.") at 6.
[2] FIs and MACs are hereinafter referred to as intermediaries.
[3] *See* 42 U.S.C. §§ 1395h, 1395kk-1; 42 C.F.R. §§ 413.20, 413.24.
[4] 42 C.F.R. § 413.20.
[5] 42 C.F.R. § 405.1803.
[6] 42 U.S.C. § 1395oo(a); 42 C.F.R. §§ 405.1835-405.1837.

DGME payments are made on a per-resident basis subject to a hospital-specific "cap" which is the number of residents in the 1996 base year.[7] Hospitals that did not engage in residency training in 1996, the base year for setting the cap, have a cap of zero. However, 42 U.S.C. § 1395ww(h)(4)(H)(i) requires the Secretary to "prescribe rules for the application of [the FTE resident cap for] medical residency training programs established on or after January 1, 1995."

In the final rule issued on August 29, 1997 ("August 1997 Final Rule"), CMS promulgated regulations to set forth the rules for counting residents in "new" programs.[8] Under these rules, a hospital with a resident cap of zero can increase its cap if it participates in a "new medical residency training program." Specifically, the Medicare regulations at 42 C.F.R. § 413.79(l) defined "new program" as "a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995."[9]

The preamble to the August 1997 Final Rule explained that "initial accreditation" included "provisional accreditation." Specifically, 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."[10] Both "initial accreditation" and "provisional accreditation" were terms used by the Accreditation Counsel for Graduate Medical Education ("ACGME") at the time the regulation was enacted in 1997.[11] In the preamble, CMS also provided the following discussion in reconciling this policy with the purpose of the FTE resident cap:

> Although the Secretary has broad authority to prescribe rules for counting residents in new programs, the Conference Report for Public Law 105-33 [*i.e.*, the Balanced Budget Act of 1997] indicates concern that aggregate number of FTE residents should not increase over current levels. Accordingly, we will continue to monitor growth in the aggregate number of residency positions and may consider changes to the policies described below if there continues to be growth in the number of residency positions.[12]

In the preamble to final rule issued on July 30, 1999 ("July 1999 Final Rule"), CMS included the following discussion to clarify how a GME program qualifies as "a new residency training program" under 42 C.F.R. § 412.79:

> *Comment:* Several commenters expressed concern about our definition of "new medical residency training program" for purposes of determining the FTE cap adjustment under

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[7] 42 C.F.R. § 413.79(c)(2) (2004) (previously located at 42. C.F.R. § 413.86(g)(4) prior to being redesignated pursuant to 69 Fed. Reg. 48916, 49236, 49254, 49259-49260 (Aug. 11, 2004)).
[8] 62 Fed. Reg. 45966, 46006 (Aug. 29, 1997) (excerpt at Intermediary Exhibit I-5).
[9] 42 C.F.R. § 413.79(l) (2004) (previously located at 42. C.F.R. § 413.86(g)(4) prior to being redesignated pursuant to 69 Fed. Reg. at 49238, 49254, 49264).
[10] 62 Fed. Reg. at 46006.
[11] Provider Exhibit P-11 at 22-23 (copy of ACGME Manual of Policies and Procedures for GME Review Committees (June 10, 1997)).
[12] 62 Fed. Reg. at 46006.

§ 413.86(g). One commenter raised questions regarding the situation where the original sponsor of a residency program has been notified that it has lost its accreditation and a new sponsor assumes the training of all or most of the residents of an existing program. The commenter believed that the program under the new sponsor should be treated as "new" as well. Another commenter suggested we have interpreted "new residency training program" to be simply a new site for a residency program that may have been in existence at other clinical sites in the past.

Response: Under the existing § 413.86(g)(7) (proposed to be redesignated as § 413.86(g)(9)), we define "new medical residency training program" to be a program "that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995." The language "begins training residents on or after January 1, 1995" means 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 the program was in existence at another hospital prior to January 1, 1995, as the commenter suggests.

We believe there may be some confusion on the part of the commenters as to how to determine when a hospital may receive an adjustment to its FTE cap for a new residency program. The definition can be more easily understood if we explain the application in two steps. First, determine if the hospital's residency program qualifies to be "new" under 413.86(g)(9). Second, once the residency training program is determined to meet the definition of "new," apply the criteria under §§ 413.86(g)(6)(i) and 413.86(g)(6)(ii) to determine whether a hospital's new program qualifies for an adjustment to its FTE cap. A hospital's sponsorship of the program plays no role in determining whether a hospital qualifies to receive an adjustment under either § 413.86(g)(6)(i) or § 413.86(g)(6)(ii).

If two hospitals "merge" separate residency program, the single residency program resulting from the merger would not be considered "new" for purposes of either hospital receiving an adjustment to its FTE cap. The programs have already been in existence and, presumably, the hospitals have been able to count the residents training in each individual program as part of the hospitals' respective FTE caps. If the hospital that is training the residents in the merged program would like to receive an

> adjustment to its FTE cap for the added residents it presumably now trains, that hospital may wish to affiliate for purposes of establishing an aggregate FTE cap.[13]

CMS published further guidance on this regulatory definition in Program Memorandum No. A-99-51 issued in December, 1999 (the "1999 Program Memorandum").[14] This guidance 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.[15]

Finally, in the preamble to the final rule published on August 27, 2009 ("August 2009 Final Rule"), CMS included a section entitled "Clarification of Definition of New Medical Residency Training Program." In particular, this section provided the following discussion of this "clarification":

> [I]t has come to our attention that there has been some misinterpretation or misunderstanding of these regulations among some 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 (either the Accreditation Council on Graduate Medical Education (ACGME) for allopathic programs or the American Osteopathic Association (AOA) for osteopathic programs) 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. In other words, some hospitals and contractors appear to have read our regulations to mean that the Secretary would defer, in all circumstances, to the relevant accrediting body's identification of a particular accreditation as a "new" or "initial" accreditation of a medical residency training program.
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> In the FY 1998 IPPS final rule that established § 413.79(l) of the regulations, we discussed both the meaning of this regulation and the rational for establishing it:
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> "For purposes of this provision, a 'program' will be considered newly established it it accredited for the first time, including provisional accreditation on or after January 1, 1995, by the accrediting body. Although the Secretary of the Department of

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[13] 64 Fed. Reg. 41490, 41519 (July 30, 1999) (excerpt included as Intermediary Exhibit I-11).
[14] Program Memorandum, HCFA Pub. No. 60A, Transmittal No. A-99-51 at Section VII(A) (Dec. 1, 1999). *See:* CCH Medicare & Medicaid Guide, ¶150,830
[15] *Id.*

Health and Human Services has broad authority to prescribe rules for counting resident in new programs, the Conference Report for Public Law 105- 33 [House Conference Report No. 105-217, pp. 821-822] indicates concern that the aggregate number of FTE residents should not increase over current levels." (62 FR 46006 [*i.e.*, the August 1997 Final Rule])

Similarly, in the FY 2000 IPPS final rule (64 FR 41519 [*i.e.*, the July 1999 Final Rule]), 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' [in the regulation at 413.79(l)] means 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, as the commenter suggests.*" (Emphasis added.)

Accordingly, as we have suggested in discussions in our previous rules, rather 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. In evaluating whether a program is truly new, as opposed to an existing program that is relocated to a new site, it is important to consider not only the characterization by the accrediting body, but also supporting factors such as (but not limited to) whether there are new program directors, new teaching staff, and whether there are only new residents training in the program(s) at the different site. In determining whether a particular program is a newly established one, it may also be necessary to consider factors such as the relationship between hospitals (for example, common ownership or a shared medical school or teaching relationship) and the degree to which the hospital with the original program continues to operate its own program in the same specialty. . . . In any case, we believe it is appropriate to be deliberate in the determination regarding FTE resident cap adjustments relating to residents in new programs. The statute clearly requires that our rules regarding adjustments to hospitals' FTE resident caps for newly established

> programs must adhere to the principles of the statutory provision limiting the count of FTE residents for direct GME and IME payments to the count for the most recent cost reporting period ending on or before December 31, 1996. In addition, as we indicated in our final rule establishing FTE cap adjustments for "new programs," the Conference Report for the BBA explicitly indicate that the aggregate number of FTE residents should be held to the "current" levels at the time the BBA was enacted (House Conference Report No. 105-217, pp. 821-822).
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> If we were to find that a program at one hospital is a newly established program merely because it was relocated from another hospital, the result would be that an FTE resident cap adjustment would be granted based on the same program at two different hospitals. Furthermore, if both hospitals continue to operate, the FTE resident cap slots that were vacated from the program at the first hospital could potentially be filled with residents from that hospital's other residency training programs. We do not believe such an increase in the aggregate number of FTE residents and the potential duplication of the FTE resident cap adjustment would be consistent with the statutory mandate to adhere to the principles of the base-year FTE resident caps when devising rules to account for newly established medical residency training programs. Therefore, in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24192), we proposed to clarify our policy that a new medical residency program is one that receives initial accreditation for the first time, as opposed to reaccreditation of a program that existed previously at the same or another hospital. Furthermore, we indicated that we believe it is appropriate and necessary that CMS expect a hospital that wishes to claim an adjustment to its direct GME and IME FTE caps based on residents training in a medical residency program to first evaluate whether the program is "new" for Medicare purposes, rather than to rely exclusively on the characterization of a particular program by the relevant accrediting body.[16]

B. BACKGROUND ON THE ACGME PROCESS TO ACCREDIT "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.[17] RRC members, among other requirements, "must be board-certified specialists in the field" and "must have

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[16] 74 Fed. Reg. 43754, 43909-43910 (Aug. 27, 2009) (excerpt included as Intermediary Exhibit I-12).

[17] *See* Provider Exhibit P-30 at 15 (copy of hearing transcript from PRRB Case Nos. 08-1351, 09-0892, and 09-0894 and refer to transcript pages 59-60 on page 15 of exhibit); Provider Exhibit P-11 at 13, 15 (copy of ACGME Manual of Policies and Procedures for GME Review Committees (June 10, 1997)).

demonstrated substantial experience in administration and/or teaching within the specialty."[18] There is a separate RRC for each specialty, such as family medicine, internal medicine, and obstetrics.[19] These committees make determinations on new program applications and/or reaccreditations of existing programs.[20] Decisions of each RRC are the decisions of the ACGME.[21]

The ACGME grants provisional accreditation as follows:

> Provisional accreditation is granted 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 so altered that in the judgment of the RRC it is the equivalent of a new program.[22]

Provisional accreditation entails heightened oversight of the new program by the RRC and effectively constitutes a probationary period before full accreditation is granted. Provisional accreditation also obligates the ACGME to perform an additional site visit to ensure compliance with all residency program requirements before full accreditation can be achieved.[23]

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

Cleveland Clinic Florida Hospital ("Provider") is a Medicare-participating hospital located in Weston, Florida. From its opening on July 2, 2001 until October 1, 2006, the Provider was owned and operated by a joint venture partnership named TCC Partners ("TCC"). The partners in TCC were Tenet Healthcare-Florida Inc. ("Tenet") and the Cleveland Clinic Foundation ("Foundation"), an Ohio non-profit corporation located in Cleveland Ohio.

The Foundation is the sole member of Cleveland Clinic Florida (A Nonprofit Corporation) ("CCF"), which operates a physician group practice located on the grounds of the Provider in Weston, Florida. The Foundation was also the sole member of Cleveland Clinic Florida Hospital (A Nonprofit Corporation), which operated a Medicare-participating hospital located in Ft. Lauderdale, Florida ("Ft. Lauderdale Hospital") until that hospital's closure in 2001.

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[18] *Oakwood Annapolis Hosp. v. Blue Cross Blue Shield Ass'n*, PRRB Dec. No. 2012-D04 at 3 (Dec. 30, 2011) (copy included as Provider Exhibit P-34), *declined review*, CMS Administrator (Feb. 3, 2012) included as Provider Exhibit P-41.

[19] Provider Exhibit P-30 at 15 (refer to transcript pages 59-60 on page 15 of exhibit).

[20] *Id.*

[21] *Id.*; Provider Exhibit P-11 at 15-16 (copy of ACGME Manual of Policies and Procedures for GME Review Committees (June 10, 1997)); Provider Exhibit P-13B at 3 (excerpt from the ACGME Graduate Medical Education Directory 2002-2003 (2002)).

[22] Provider Exhibit P-13A at 3 (excerpt from Manual of Policies and Procedures for ACGME Residency Review Committees (Sept. 10, 2002)).

[23] *Id.*

In 2006, Cleveland Clinic Florida Health System Non-Profit Corporation (the "System"), acquired through a series of transactions, Tenet's share of TCC. Accordingly, the System assumed 100 percent ownership of the Provider.

Prior to the opening of the Provider in July 2001, the Cleveland-based Foundation sponsored programs for Internal Medicine, Colorectal Surgery, and Neurology at the Ft. Lauderdale Hospital.[24] Each program was operated under the auspices of an Affiliation Agreement between the Foundation and the Ft. Lauderdale Hospital under which the Foundation served as each program's sponsor and the Ft. Lauderdale Hospital served as a "major participating institution."[25] The Affiliation Agreement provided that, in the event that one facility closed, the other facility would absorb the closed facility's FTE cap.[26] The Medicare regulations in effect prior to October 1, 2002 allowed for this type of contractual transfer of FTEs. [27] In 2001, the Ft. Lauderdale Hospital closed. As required by the Affiliation Agreement, the Ft. Lauderdale Hospital's FTE cap was transferred and added to the Foundation's Cleveland cap upon the closure of the Ft. Lauderdale Hospital.

On July 2, 2001, TCC opened the Provider. TCC wanted to establish new GME programs at the Provider. In particular, TCC wanted to establish GME programs "newly accredited" by the ACGME for Internal Medicine, Colorectal Surgery, and Neurology. The following chart shows when each of the three GME programs at issue were established and accredited by the ACGME:

GME Program	Month Established	Effective Date for ACGME Accreditation
Internal Medicine	July 2001	July 2, 2001
Colorectal Surgery	July 2003	July 1, 2003
Neurology	July 2003	July 1, 2003

These three residency programs will be referred to collectively as the "Programs." Counsel and executives for both the CCF and Tenet had multiple correspondences with individuals at CMS regarding Medicare's requirements for establishing the Programs.[28]

During the time at issue, the Provider's fiscal year ended on May 31st. The fiscal years ("FYs") at issue are 2002, 2003, 2004, 2005 and 2006. Wisconsin Physicians Service ("Intermediary") reviewed the cost reports for these FYs and initially treated the Programs as new in the original NPRs that it issued for these FYs.[29]

In 2009, however, the Intermediary reversed its position following the issuance of guidance from CMS in 2009. This 2009 guidance includes both a letter dated January 15, 2009 from the CMS

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[24] Tr. at 58.
[25] Provider Exhibit P-15.
[26] *Id.* at 3.
[27] 67 Fed. Reg. 49982, 50070, 50075-76 (Aug. 1, 2002).
[28] Provider Exhibits P-17 - P-21.
[29] Tr. at 92, 96.

Deputy Administrator[30] and the preamble to August 2009 Final Rule. Based on this guidance, the Intermediary changed its position and determined that the Programs were not new despite having received initial accreditation from the ACGME in 2001 and 2003.[31] Accordingly, the Intermediary issued revised NPRs for all the FYs under appeal reflecting that new position and recouped all prior payments for the Programs.[32] The Provider disputed the application of the additional standards regarding new programs found in CMS' 2009 policy statement and appealed the Intermediary's disallowance to the Board. The Provider's appeals were timely filed pursuant to 42 CFR §§ 405.1835 - 405.1841, 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 Stacey Hayes and Joseph O. Aydt.

PROVIDER'S CONTENTIONS:

The Provider contends that the Intermediary's determination violates the plain language of the regulatory definition for "new program" at 42. C.F.R. § 413.79(l). The Provider contends that the regulatory definition has been met because CMS specifically stated that "initial accreditation" includes "provisional accreditation,"[33] and the Programs received "provisional accreditation" from the ACGME after January 1, 1995.[34] The Provider also points to letters from CMS[35] which, it argues, demonstrate that CMS interpreted the regulation to mean that a program must only receive ACGME "provisional accreditation" after January 1, 1995 in order to be considered a "new program." As it is undisputed that the Programs received "provisional accreditation" from ACGME after January 1, 1995, the Provider concludes that the Intermediary's determination must be overturned.

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.[36] Although CMS argues that intermediaries should have been determining whether GME 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 there was virtually no scenario where it could simply define a GME program as new without seeking CMS guidance.[37] 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.

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[30] Intermediary Exhibit I-15.
[31] Tr. at 40-41.
[32] *See* Provider Exhibit P-25.
[33] 62 Fed. Reg. at 46006.
[34] Provider Exhibit P-6 (ACGME accreditation letters and printouts dated April 30, 2008 from ACGME website of information on the GME programs at issue and includes date of original accreditation, from ACGME website).
[35] *See* Provider Exhibits P-17, P-19, P-21, P-22, P-32 (responses from CMS to inquiries by the Provider in P-17, P-19, and P-22 and by an unrelated provider in P-32).
[36] *See Maximum Home Health Care, Inc. v. Shalala*, 272 F.3d 318, 321 (6th Cir. 2001).
[37] Tr. at 230-31.

The Provider states that it did not have "fair notice" of CMS' policy as described in the preamble to the August 2009 Final Rule. The courts have articulated the following test for the presence of "fair notice":

> If, *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.[38]

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.[39] The Provider argues that, prior to CMS' 2009 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 "new" for Medicare purposes."[40] In addition, despite requesting clarification from CMS on multiple occasions, the Provider was never informed that any other criteria applied besides receipt of initial ACGME accreditation. The Provider concludes therefore, that the agency has not fairly notified a petitioner of the agency's interpretation,[41] and the new clarification cannot be used to penalize parties that have relied on a fair reading of the regulation.[42]

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 policy, and guidelines of general applicability."[43] 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.[44]

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[38] *General Elec. Co. v. U.S. E.P.A.*, 53 F.3d 1324, 1329 (D.C. Cir. 1995) (citing to *Diamond Roofing Co. v. OSHRC*, 528 F.2d 645, 649 (5th Cir. 1976) (emphasis added).

[39] *See Satellite Broadcasting Co., Inc. v. F.C.C.*, 824 F.2d 1, 4 (D.C. Cir 1987) ("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."); *General Elec. Co.*, 53 F.3d at 1329 (stating "[a]s long ago as 1968, we recognized this 'fair notice' requirement in the civil administrative context").

[40] 74 Fed. Reg. 24080, 24192 (May 22, 2009).

[41] *See General Elec.Co.*, 53 F.3d at 1329.

[42] *See GranCare, Inc. v. Shalala*, 93 F. Supp. 2d 24, 32-33 (D.D.C. 2000).

[43] 42 U.S.C. § 1395hh(c)(1). *See also Chippewa Dialysis Servs. v. Leavitt*, 511 F.3d 172, 176-78 (D.C. Cir. 2007).

[44] 42 U.S.C. § 1395hh(c)(1) (stating that "[t]he Secretary shall 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 . . . .").

The Provider also contends that the Intermediary's determination and CMS' 2009 clarification constitute prohibited retroactive rulemaking and otherwise violate the Administrative Procedure Act ("APA").[45] 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.[46] Aside from the 1999 Program Memorandum, CMS never amended, clarified, or explained the definition of "new program" published in 1997 until 2009. 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 . . . ."[47]

Furthermore, the Provider contends that, while CMS has attempted to frame the additional guidelines in the preamble of the August 2009 Final Rule 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' "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] continue[s] 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...."[48] 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 Secretary's power.[49] 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.[50] Courts, therefore, afford no deference to interpretive rules that did not exist at the time of the prior regulation.[51]

Finally, the Provider contends that the Intermediary's determination is contrary to substantial evidence which shows that the Programs were new under any standard. In support of its

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[45] 5 U.S.C. Pt 1, Ch. 5.
[46] *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. F.A.A.*, 177 F.3d 1030, 1033-34 (D.C. Cir. 1999) quoting language in *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997), *cert. denied*, 523 U.S. 1003 (1998). *See also Nat'l Family Planning& Reproductive Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 240-41 (D.C. Cir. 1992).
[47] *Paralyzed Veterans of Am.*, 117 F.3d at 586; *Alaska Prof'l Hunters Ass'n, Inc.*, 177 F.3d at 1033-34 (quoting *Paralyzed Verteran of Am.*).
[48] 74 Fed. Reg. at 24192. *See also* 74 Fed. Reg. at 43912.
[49] *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 425, 428 (D.C. Cir. 1994) (citing in the concurring opinion to *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988)).
[50] *Id.* at 428.
[51] *Id.*

contention that the Programs are new, the Provider points to such factors as the change in program sponsor, patient acuity, facilities, the proximity of the outpatient clinic, and the ACGME's own determination that the Programs were new after a full consideration of the relevant documents.[52]

INTERMEDIARY'S CONTENTIONS:

The Intermediary contends that the disallowance is consistent with CMS' 2009 policy "clarification" as published in the preamble to the August 2009 Final Rule.[53] According to guidance in the August 2009 Final Rule, 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 are the same as in 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 Intermediary argues that a consideration of these factors indicates that the Programs merely transferred from the hospital that closed in Ft. Lauderdale and were not "new." The Intermediary cites to a letter from CMS dated January 15, 2009 in which the CMS Deputy Administrator argues that the Programs "do not meet the standard for new programs."[54] The Intermediary contends that CMS makes clear in that letter that this is a transfer of existing programs rather than new programs and accordingly believes that its adjustments are appropriate.

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 the Programs and, thereby, reduce the Provider's FTE cap was improper.

The central issue presented for the Board's review is whether the Programs were properly classified as existing programs versus new programs. The issue requires the Board to interpret the governing regulations and instructions that were in effect at the time the Programs received initial accreditation as GME programs for the Provider. It is undisputed that the ACGME is the relevant accrediting body and that the Provider opened the Programs after January 1, 1995 based upon provisional accreditation from the ACGME.[55]

The controlling regulations in effect at that time defined a new program to be "a medical residency that receives initial accreditation by the appropriate accrediting body . . . on or after

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[52] Provider Exhibit P-30 at 62-71.
[53] Intermediary's Post-Hearing Brief at 9, 15 and Tr. at 41-42.
[54] Intermediary Exhibit I-15.
[55] *See* Intermediary Exhibit I-7.

January 1, 1995."[56] The preamble to the August 1997 Final Rule that promulgated this regulatory definition explained that "initial accreditation" includes "provisional accreditation." Specifically, 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.*[57]

ACGME defined "provisional accreditation" as:

> Provisional accreditation is granted for initial accreditation of a program, or for a previously accredited program which had its accreditation withdrawn and has subsequently applied for reaccreditation. Provisional accreditation may be used in the unusual circumstance in which separately accredited specialty programs merge into one or an accredited program has been so altered that in the judgment of the RRC it is the equivalent of a new program.
>
> Provisional accreditation implies that a program is in a developmental stage. It remains to be demonstrated that the proposal for which accreditation was granted will be implemented as planned. Accordingly, a review committee will monitor the developmental progress of a program accredited on a provisional basis. . . . . In the course of monitoring a program's development, a review committee may continue provisional accreditation; however, the total period of provisional accreditation should not exceed five years for programs of four years duration or less, or the length of the program plus one year for programs of five years duration or more.[58]

Based on the above, the Board concludes that the language of both the regulation and the preamble makes clear that the determination of a "new" program vests with the accrediting body through initial accreditation or provisional accreditation. To this end, CMS stated its intention in the August 1997 Final Rule "to monitor growth in the *aggregate* number of residency positions and [that CMS] may consider changes to the policies described below if there continues to be growth in the number of residency positions."[59]

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[56] 42 C.F.R. § 413.79(l).
[57] 62 Fed. Reg. at 46006 (Aug. 29, 1997) (emphasis added).
[58] ACGME, Manual of Policies and Procedures for Graduate Medical Education Review Committees at 13-14 (June 10, 1997) (copy included as Provider Exhibit P-11 at 23-24); ACGEM, Manual of Policies and Procedures for Graduate Medical Education Review Committees at 51-52 (Sept. 10, 2002) (excerpt included as Provider Exhibit P-13A at 3-4)
[59] 62 Fed. Reg. at 46006 (emphasis added).

The Board recognizes that in the preamble to the July 1999 Final Rule, CMS provided some clarification on how the controlling regulations are to be applied. In particular, the preamble discussion both of the regulatory paths for a graduate medical education program to qualify as "new": (1) "a medical residency that receives initial accreditation by the appropriate accrediting body"; and (2) "a medical residency that . . . begins training residents on or after January 1, 1995." In support of its position, the Intermediary has cited that portion of the preamble discussion that only pertains to this second pathway (*i.e.*, a medical residency that . . . begins training residents on or after January 1, 1995").[60] However, this discussion is not applicable as the Provider is qualifying under the first pathway (*i.e.*, "a medical residency that receives initial accreditation by the appropriate accrediting body").

The Board also recognizes that CFF sought and received guidance from CMS on how a graduate medical education program could qualify as "new" prior to establishing the Programs at the Provider. In a letter dated January 18, 2000, the Director of the Division of Acute Care for the CMS Purchasing Policy Group stated the following in response to an inquiry by a consultant for CCF:

> In your letter you also mentioned that CCF's GME programs will be transferred to the Weston Hospital. However, because the Weston Hospital is a new provider, in order to receive an adjustment to its cap for a new GME program in accordance with § 413.86(g)(6)(i), the GME programs will need to be newly accredited by the Accreditation Council on Graduate Medical Education (ACGME). The FTE cap cannot be adjusted for CCF's programs by simply transferring to the Weston Hospital.[61]

Similarly, in a letter dated April 20, 2001, the Director of the Division of Acute Care for the CMS Purchasing Policy Group stated the following in response to an inquiry by counsel for CCF:

> Because the Weston hospital is considered "new" under the regulations at 413.86(g)(6)(i), the Weston hospital may receive an adjustment to its FTE cap for residents training in programs newly accredited by the American Council for Graduate Medical Education (ACGME). As you know from previous conversations, programs that are simply transferred from another hospital are not automatically considered "new" under the Medicare regulations at 42 CFR § 413.86(g)(12).

Each of these discussions confirms that, if a program receives initial accreditation from ACGME then it qualifies as a "new" graduate medical education program for purposes of determining FTEs.

The Board recognizes that the correspondence suggests that a "simple transfer" of programs from one sponsor to another does not qualify as "new." However, the record before the Board

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[60] *See* Intermediary Final Position Paper at 7. *See also* the text accompanying supra note 13 for the discussion from the July 1999 Final Rule.

[61] Provider Exhibits P-17, P-37 (where P-37 is a transcription of P-17).

clearly establishes that the Programs were not "simply transferred" from one sponsor to another.[62]

Other correspondence from the Director of the Division of Acute Care for the CMS Purchasing Policy Group involving another provider confirms that the Board's findings on the interpretation and application of the controlling regulations *during the time period at issue* are correct. Specifically, in a letter dated May 1, 2000, the Director of the Division of Acute Care for the CMS Purchasing Policy Group stated the following in response to an inquiry by another provider concerning whether its internal medicine residency program is considered "new" for GME reimbursement purposes:

> The regulations at 42 CFR § 413.86(g)(9) define a new medical residency training program as one that receives initial accreditation by the appropriate accrediting body ***or*** begins training residents on or after January 1, 1995. Because [the provider]'s internal medicine program received initial accreditation from the Accreditation Council for Graduate Medical Education (ACGME) in 1996, I wrote that I believe it meets the definition of a new program; [the provider] did not also have to begin training residents on or after January 1, 1995. . . .
>
> A member of my staff has spoken informally with a representative of the Internal Medicine department at ACGME to verify that the internal medicine program, was, in fact, accredited as a new program at [the provider], and to determine the exact number of residency slots for which the program was accredited. She was told that, when the sponsor of a program changes, the ACGME considers the program to be new, even though the residents participating in training at the new sponsor may be the same residents that participated in training under the previous sponsor of the program. The representative also confirmed that the program received its initial accreditation at [the provider] in July 1996, and that it was approved for 58 residency slots.
>
> Therefore, based on the regulations at 42 CFR § 413.86 and the information provided by the ACGME, I continue to believe that the internal medicine program at [the provider] qualifies as a new program for GME reimbursement purposes.[63]

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[62] *See, e.g.*, Provider Exhibits P-16, P-26. *See also* ACGME definition of "provisional accreditation." To this end, the Board also rejects the Intermediary's contentions that the Provider double dipped by transferring FTEs from the Fort Lauderdale Hospital to the CFF Cleveland facility while transferring the programs to the Provider and claiming the transferred programs as "new" because: (1) the Provider's GME programs were indeed "new" based on the initial accreditation from ACGME rather than a "transfer"; and (2) Medicare regulations in effect prior to October 1, 2002 allowed for the 2001 contractual transfer of FTEs from the Ft. Lauderdale Hospital to the cap for CFF's Cleveland facility upon the closure of the Ft. Lauderdale Hospital. *See* 67 Fed. Reg. 49982, 50070, 50075-76 (Aug. 1, 2002).

[63] Provider Exhibit P-32 (emphasis in original).

This discussion highlights the agency's reliance on and deference to the findings of the ACGME as to what constitutes a "new" medical residency training program.

In this case, the Provider received initial accreditation from ACGME in 2001 for the colorectal surgery program and 2003 for the internal medicine and neurology programs. The Board therefore finds that the Programs qualify 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 of the August 2009 Final Rule. The Intermediary contends that the definition of a new medical residency program as discussed in the preamble of the August 2009 Final Rule is a clarification of existing evaluation standards. However, the Board examined this discussion and finds that it delineates specific standards for an intermediary's review of residency programs that were neither previously included in the requirements for a new residency program nor communicated to the provider community.

Based on the foregoing, the Board does not consider the preamble discussion in the August 2009 Final Rule to be a clarification, but rather an articulation of a new standard or policy under which medical residency programs are to be evaluated. Accordingly, the Board concludes that the Intermediary improperly applied that new standard/policy to the Provider on a retroactive basis and that the Intermediary improperly disallowed the Provider's resident FTEs associated with the Programs.

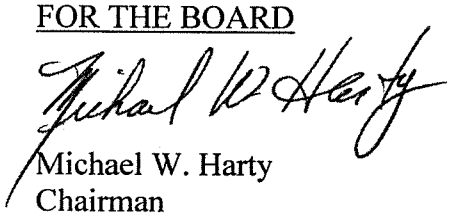
DECISION AND ORDER:

The Intermediary improperly disallowed the Provider's resident FTEs associated with the Programs. The Board directs the Intermediary to set a resident cap for the Provider treating the Programs as "new" programs.

BOARD MEMBERS PARTICIPATING:

Michael W. Harty
J. Gary Bowers, C.P.A
Clayton J. Nix, Esq.
L. Sue Andersen, Esq.

FOR THE BOARD



Michael W. Harty
Chairman

DATE: SEP 09 2014