

**PROVIDER REIMBURSEMENT REVIEW BOARD
DECISION**

2013-D17

PROVIDER -
Alpena Dialysis Services
Alpena, Michigan

Provider No.: 23-2553

vs.

INTERMEDIARY -
Wisconsin Physicians Service

DATE OF HEARING -
October 6, 2010

ESRD Exception Window -
Commencing March 1, 2000

CASE NO.: 09-0234

INDEX

	Page No.
Issue.....	2
Medicare Statutory and Procedural History.....	2
Statement of the Case and Procedural History.....	3
Parties' Contentions.....	6
Findings of Fact, Conclusions of Law and Discussion.....	8
Decision and Order.....	11

ISSUE:

Whether CMS' denial of the Provider's request for an exception to the ESRD composite rate was proper?

MEDICARE STATUTORY AND PROCEDURAL HISTORY:**Background:**

This is a dispute over the proper amount of Medicare reimbursement due to 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 the aged and disabled. 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 (FIs) and Medicare administrative contractors (MACs). FIs and MACs¹ determine payment amounts due providers under Medicare law, regulations and under interpretive guidelines published by CMS.²

Providers are required to submit cost reports annually, with reporting periods based on the provider's accounting year. A cost report shows the costs incurred during the relevant fiscal year and the portion of those costs to be allocated to the Medicare program.³ Each 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).⁴

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); (3) the appeal must be filed with the Board within 180 days of the receipt of the final determination.⁵

Background Related to End Stage Renal Disease

Medicare covers inpatient and outpatient dialysis treatments for ESRD patients.^{6 7} CMS

¹ FIs and MACs are hereinafter referred to as intermediaries.

² See 1395h and 1395kk-1; 42 C.F.R. §§ 413.20 and 413.24.

³ See 42 C.F.R. § 413.20.

⁴ See 42 C.F.R. § 405.1803.

⁵ See 42 U.S.C. § 1395oo(a); 42 C.F.R. §§ 405.1835-1837.

⁶ See 42 U.S.C. § 1395rr(a)

⁷ All citations herein refer to the Code of Federal Regulations provisions in effect at the time Plaintiffs appealed CMS's denial of their exception requests.

reimburses outpatient ESRD treatments through a prospectively-determined “composite rate system” that sets a facility's per-treatment reimbursement rate on the basis of its labor costs, patient population, service intensity, and other relevant factors.⁸ During certain periods of time, called “exception windows,” the Secretary will entertain a facility's request for an “exception” namely, an increase in its composite rate.⁹

To qualify for an exception, the petitioning facility must satisfy a two-prong test through the submission of “convincing objective evidence.” First, it must demonstrate that its total per-treatment costs are reasonable and allowable. Second, it must establish that one of five specified factors causes its actual treatment costs to exceed its composite payment rate.¹⁰ A petitioning facility must satisfy CMS that an exception is appropriate under the applicable regulations and carries the burden of proof at all times.¹¹

TIMELINE OF EVENTS

1. 08/28/2000 ESRD exception request filed by provider.
2. 10/12/2000 CMS denies Provider’s exception request.
3. 01/08/2001 Provider appeals to Board.
4. 12/22/2003 Board issues decision denying Provider’s exception request.
5. 02/12/2004 Provider filed a complaint in the District Court seeking a reversal of the PRRB decision.
6. 09/18/2006 District Court remands to Secretary.
7. 09/26/2006 Secretary files a motion to reconsider remand
8. 11/15/2006 District Court agrees to consider remand. Denies Provider’s exception request.
9. 11/16/2006 Provider appeals to Circuit Court.
10. 12/21/2007 Circuit Court remands to District Court.
11. 02/26/2008 District Court remands to Secretary..
12. 03/11/2008 Administrator remands to CMS.
13. 05/15/2008 CMS issues second denial letter of exception request.
14. 10/29/2008 Provider appeals second CMS denial to the Board.

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

Alpena Dialysis Services (Provider or Alpena) is an independent, free-standing dialysis facility located in Alpena, Michigan. An exception window was opened by CMS commencing on March 1, 2000. The Provider submitted a timely exception request to the composite rate for maintenance dialysis services (\$123.96 per treatment) to United Government Services, LLC (Intermediary). The Provider sought an exception of \$31.85 per treatment on the basis of atypical service intensity and additional nursing service and administrative costs.

⁸ See 42 U.S.C. § 1395rr.

⁹ See 42 C.F.R. § 413.180.

¹⁰ *Id.* § 413.182.

¹¹ *Id.* 413.180(g).

Following a review of the exception, the Intermediary forwarded the request to CMS and recommended approval of a base hemodialysis rate of \$150.61 for atypical nursing and administrative and general costs. On September 25, 2000, CMS denied the Provider's exception request based on its determination that the Provider had failed to justify any increased costs based on its claim of an atypical service intensity and additional nursing service and administrative costs.

On September 25, 2000 and September 28, 2000, respectively, CMS also denied requests for atypical service exceptions to the composite payment rate for Chippewa Dialysis Services (Chippewa), provider number 23-2557, and Northern Michigan Hospital (Northern Michigan), provider number 23-2315, on the grounds that neither provider had substantiated an atypical patient mix, nor had they demonstrated the provision of atypical nursing services based on the 3.0 hours per treatment standard. The Provider, Chippewa and Northern Michigan timely appealed CMS' denials of their exception requests to the Provider Reimbursement Review Board (Board) pursuant to 42 C.F.R. §413.194 and met the jurisdictional requirements set forth in 42 C.F.R. §§ 405.1835-405.1841.

All three appeals were heard at the Board on January 22, 2003. Using identical language in three separate decisions issued on December 22, 2003, the Board affirmed CMS' determination that Chippewa and Northern Michigan did not have an atypical patient mix, and made the same determination with respect to Alpena (notwithstanding the fact that CMS had never made a finding as to whether Alpena had an atypical patient mix) and the Board also affirmed that each of the providers had not demonstrated atypical nursing services based on CMS' 3.0 hour per treatment standard.¹² The CMS Administrator declined review of the decisions, and the Board decisions became the final decisions of the Secretary.

The three providers filed a consolidated appeal from the Board's determinations. In the District Court's initial decision on the consolidated appeal, *Alpena Dialysis Services, Chippewa Dialysis Services and Northern Michigan Hospital v. Levitt*, (D.D.C. Sept. 18, 2006), 2006 WL 2682550, Medicare and Medicaid Guide (CCH) ¶ 301,901, it upheld the use of the 3.0 nursing hour standard in denying each of the provider's exception requests. The District Court's initial decision also upheld the determination that the patient populations for Chippewa and Northern Michigan were not atypical. The District Court, however, found that the Board erred by deciding Alpena's case on the issue of patient atypicality without giving the facility an adequate opportunity to present arguments on that issue.¹³ The District Court noted that the Board notified Alpena that it would hear arguments on the validity of CMS' denial of its exception request and

¹² See *Chippewa Dialysis Servs. v. Blue Cross Blue Shield Ass'n/United Government Servs., LLC-WI*, PRRB Dec. No. 2004-D5, Medicare and Medicaid Guide (CCH) ¶ 81,095 (December 22, 2003), CMS Administrator declined rev. (February 13, 2004); *Northern Michigan Hosp. v. Blue Cross Blue Shield Ass'n/United Government Servs., LLC-WI*, PRRB Dec. No. 2004-D7, Medicare and Medicaid Guide (CCH) ¶ 81,097 (December 22, 2003), CMS Administrator declined rev. (February 13, 2004); and *Alpena Dialysis Servs. v. Blue Cross Blue Shield Ass'n/United Government Servs., LLC-WI*, PRRB Dec. No. 2004-D6, Medicare and Medicaid Guide (CCH) ¶ 81,096 (December 22, 2003), CMS Administrator declined rev. (February 13, 2004).

¹³ See Exhibit P-3

that CMS' determination with respect to Alpena relied solely on its failure to establish excessive labor costs per treatment using CMS' 3.0 nursing hour per treatment standard and did not consider whether its patient population was atypical. The District Court indicated that Alpena reasonably concluded that its hearing before the Board would be confined to the issue of labor costs and when the Board, without prior notice, considered patient atypicality, it was not and could not have been prepared to present arguments on that issue. The District Court concluded that this lack of notice violated provisions of the Administrative Procedure Act (APA) that require proper notice of the scope of a hearing.¹⁴ As a result, the District Court indicated it would "remand the Alpena case so the facility can have an opportunity to address the issue on which the Board made its determination: whether Alpena treats an atypical patient population."¹⁵

On September 29, 2006, the Secretary filed a motion with the District Court requesting that it reconsider its decision to remand the Alpena case to the Board because there was an independent legally sufficient basis for the denial of Alpena's exception request, that is, it had failed to establish atypical nursing services. The District Court agreed and denied Alpena's exception on the basis that Alpena failed to establish atypical nursing services.¹⁶

The three providers appealed to the Court of Appeals for the District of Columbia. In *Chippewa Dialysis Services v. Leavitt*, 511 F.3d 172 (D.C. Cir. 2007), the Court of Appeals decided that 3.0 hours per treatment used by the Secretary to deny the providers request was a guideline of general applicability that had to be, but was not, published in the Federal Register and therefore, could not be used to deny the providers' exception requests.¹⁷ With respect to Chippewa and Northern Michigan, however, the Court of Appeals upheld the Board's determinations that these two providers failed to substantiate an atypical patient mix and that this was an independent basis for upholding the denial of their exception requests. With respect to Alpena, the Court of Appeals noted that the Secretary did not address Alpena's argument that it lacked notice that the Board would address atypical patient mix and therefore, remanded the case to the District Court.

On February 25, 2008, the Secretary filed a Praecipe concerning the anticipated time frame for completing the proceeding on remand of the case.¹⁸ In the Praecipe, the Secretary indicated that the matter would be delegated to the CMS component responsible for rendering decisions on ESRD exception requests, that this component would consider the evidence and render an atypical patient mix determination. The Secretary also indicated that if CMS determined that Alpena had failed to meet its burden of demonstrating its entitlement to an exception from its payment rate, then Alpena would again be permitted to seek administrative review from the Board and the CMS Administrator.¹⁹ On February 26, 2008, the District Court remanded the case to the Secretary for further proceedings consistent with the opinion of the Court of

¹⁴ See 5 U.S.C. § 554(b).

¹⁵ *Supra* note 14, at 10.

¹⁶ See *Alpena Dialysis Services, Chippewa Dialysis Services and Northern Michigan Hospital v. Leavitt*, (D.D.C. November 15, 2006), 2006 WL 3328269.

¹⁷ See Exhibit P-6

¹⁸ See Intermediary Exhibit I-2.

¹⁹ *Id.* Sections 3 and 5.

Appeals.²⁰ On March 11, 2008 the Administrator remanded the case to CMS ordering a determination on the merits of the Provider's request for an exception to the ESRD composite rates based on atypical patient mix.

On May 15, 2008, the CMS component responsible for exception requests issued a denial of Alpena's exception request in which it addressed each of the regulatory requirements for the entitlement of an atypical services exception.²¹ The Provider filed a timely appeal of CMS' denial on October 29, 2008 pursuant to 42 U.S.C. § 1395oo, 42 C.F.R. § 413.194(b) and (c)(1).

The Provider was represented by Jeffrey A. Lovitky, Attorney at Law. The Intermediary's representative was Bernard M. Talbert, Esquire, Associate General Counsel, Blue Cross and Blue Shield Association.

PARTIES' CONTENTIONS:

The Provider contends that CMS' May 15, 2008 denial of its exception request should be overturned for a number of reasons.

First, the Provider asserts that its exception request was timely submitted on August 28, 2000 and that CMS' initial denial, made within the 60 day time period for processing exception requests at 42 U.S.C. § 1395rr(b)(7), was based solely upon atypical costs and the Provider's failure to demonstrate the provision of atypical nursing services.²² The Provider indicates that CMS improperly added the issue of atypical patient acuity to its May 15, 2008 denial and that the addition of new grounds for denial almost 8 years after the initial denial violates the Congressional mandate for the prompt disposition of exception requests. The Provider contends that, in lieu of issuing a new determination, the Secretary could have returned the case to the Board for review of the denial letter dated September 25, 2000 and that the Board should dismiss any new issues which were not raised by CMS in its original denial.

Second, the Provider contends that the May 15, 2008 denial letter was arbitrary and capricious because it relied on the application of national ESRD patient profiles.²³ The Provider asserts that these patient profiles were derived from both outpatient and inpatient data, whereas, the exception request applied only to outpatients. As such, the national ESRD patient profiles do not provide an adequate benchmark against which to determine whether the exception request should be granted. The Provider also asserts that, even assuming the validity of the national ESRD Patient Profile Tables, it demonstrated that its patients were atypical. The age profile for its patients showed significantly higher than normal acuity: patients 75 and older constituted 22% of its patient population, compared to the national average of 14.5%. Further, the percentages of its patients aged 65 and above were significantly higher than the national norm and its mortality rate of 22.8% was also significantly higher than the national mortality rate of 16.0%. The Provider also contends that CMS improperly compared its average inpatient length of stay of

²⁰ Provider Exhibit P-9, at 2.

²¹ Provider Exhibit P-8.

²² Provider's Post Hearing Brief at 13-14; *See also* Provider Exhibit P-1 at 58.

²³ Provider's Post Hearing Brief at 14.

5.11 days with the outdated inpatient average length of stay standard of 8.3 days contained in the ESRD Profiles.

Third, the Provider contends that, the ESRD Patient Profile Tables fell within the publication requirement of 42 U.S.C. § 1395hh(c)(1) and that the Secretary was obligated to provide notice in the Federal Register of the existence of these profiles.²⁴ Since the Secretary failed to provide notice in the Federal Register, they cannot be used as a standard to adjudicate the Provider's exception request, notwithstanding the fact that the Provider was aware of these tables when the exception request was submitted.

Fourth, the Provider contends that CMS improperly used median costs per treatment standards as a basis for adjudicating its exception request for the following reasons: CMS was unable to locate the data upon which it relied in developing the median cost per treatment data and was unable to support the validity of the data; the data it used was from 1983-1984, and as such was outdated and no longer valid; CMS was unable to furnish a breakdown of urban and rural providers and thus reliance on the data was inappropriate; and, hospital based facilities were excluded in developing the median cost per treatment data and therefore reliance on the data is not rational.²⁵ In addition, the Provider points out that use of median cost per treatment figures is inconsistent with the reasonable cost principles of 42 C.F.R. § 413.198 which require a provider's cost be based on a comparison with other facilities "in the same area."

Fifth, the Provider contends that it should be entitled to its additional overhead costs since it demonstrated that its overhead costs resulted directly from higher than average labor costs, and that CMS' assertion that it was due to significant idle capacity was incorrect.²⁶ The Provider claims that CMS should approve its request for the direct labor component of the atypical service request, even if it denies the additional overhead costs.

Sixth, the Provider contends that CMS improperly denied the exception request on the basis that the Provider failed to segregate its home training expenses from its outpatient dialysis costs. The Provider's cost reports clearly indicate that no home CAPD training treatments were provided.

Seventh, the Provider contends that CMS denied its exception request on the faulty basis that it failed to exclude from its outpatient costs any overhead costs associated with inpatient dialysis treatments. The Provider asserts that the cost reports and supporting workpapers submitted with the exception request do not reflect that any inpatient costs (whether direct or indirect) were ever charged to the dialysis unit. Also that associated overhead which could have been charged to the outpatient dialysis treatments, if any, was minimal.²⁷

²⁴ Provider's Post Hearing Brief at 15.

²⁵ Provider's Post Hearing Brief at 15-16.

²⁶ Provider's Post Hearing Brief at 16.

²⁷ The provider has presented seven arguments why CMS' determination should be overturned. Pursuant to the Administrator's remand to CMS, the Board will only address CMS' determination as it relates to the atypical patient mix criteria.

The Intermediary indicates that the Provider's argument that CMS' second denial letter dated May 15, 2008 violates the 60 day time limit for reviewing an ESRD exception requests ignores the procedural history in this case. First, the Intermediary points out that the original determination concerning Alpena's exception request was made within the 60 day period required by the statute at 42 U.S.C. § 1395rr(b)(7) and CMS Pub. 15-1 § 2720. Second, the Intermediary points out that after the Board denied the Provider's request, the Provider appealed to the courts. Eventually, the Court of Appeals ordered the case back to address the issue of patient atypicality. The Intermediary indicates that CMS has fully complied with the Praeceptum and remand order.

With respect to the merits of the Provider's exception request, the Intermediary notes that in order to be entitled to an atypical services exception, the facility must demonstrate by convincing objective evidence that it has an atypical patient mix.²⁸ In its May 15, 2008 review of Alpena's exception request, CMS concluded:

In response to the order of remand issued by the U.S. District Court for the District of Columbia on February 26, 2008, we have reevaluated Alpena's request for an exception to its composite payment rate based on the provision of atypical services. We find that the Provider has not substantiated an atypical patient mix based on the totality of the presented evidence, did not furnish atypical nursing services because its labor costs per treatment did not exceed the amount built into the composite rate, and has failed to demonstrate a clear nexus between its costs in excess of the composite rate and the provision of atypical services. The Provider's excess costs appear to be due to other factors, most notably excess idle capacity stemming from low utilization resulting in higher costs per treatment, particularly overhead costs. In addition, outpatient dialysis costs have been improperly commingled with training and inpatient dialysis overhead expense. Accordingly, Alpena's request for an atypical services exception to its composite payment rate is denied.²⁹

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

The Board, after consideration of the Medicare law and guidelines, the parties' contentions, and evidence presented, finds and concludes as follows:

The Board notes that this case was remanded to CMS to correct a procedural error made in reviewing the Provider's exception request. As outlined in the procedural history above, CMS' initial denial of the Provider's exception request was based on the sole ground that it failed to establish excessive labor costs per treatment. In reviewing CMS' determination, the Board noted that the Provider had sought an exception based on the contention that it served an atypically more acute patient population than the national norm, but that it failed to furnish evidence to support its atypical service exception request. In its previous determination, the Board noted that the Provider had a higher percentage of patients that were aged and diabetic, but that they did not reflect a substantial deviation from the national norms, and that the Provider did not take into

²⁸ 42 C.F.R. § 413.184.

²⁹ Intermediary Exhibit I-1 at 8

consideration other factors in its patient mix analysis which should have been addressed in its exception request (i.e., mortality rate, length of stay for patients requiring inpatient admission, average age of patient population, and individual patient diagnosis). As a result, the Board found that the Provider did not demonstrate that it had a significant deviation from the national averages. In addition, even though the Provider had failed to meet the threshold requirement for patient atypicality, the Board also found that the Provider had not rendered an atypical number of nursing hours per treatment based on CMS' 3.0 hour per treatment standard. The CMS Administrator declined review of the Board's determination.

In the Provider's appeal to the District Court, it argued that the Board exceeded its authority by reviewing the Provider's exception request on a rationale different than that relied on by CMS and that the Board's failure to notify the Provider it would consider the issue of patient atypicality denied it a meaningful opportunity to be heard on this issue. The Board notes that the District Court agreed with the Provider that it had not received proper notice that the Board would consider patient atypicality. The District Court found that the APA, 5 U.S.C. § 554(b), provides that "[p]ersons entitled to notice of an agency hearing shall be timely informed of (1) the time, place, and nature of the hearing; (2) the legal authority and jurisdiction under which the hearing is to be held; and (3) the matters of fact and law asserted."³⁰ The District Court further indicated that this required agencies to give claimants proper notice of the issues on which the hearing would be held and the theories on which the agency might decide the case.³¹

More specifically, the District Court, relying on the APA standard made the following finding:

[T]he Court must conclude that the Board erred by deciding Alpena's case on the issue of patient atypicality without giving the facility an adequate opportunity to present arguments on that issue. The Board notified Alpena that it would hear arguments on that the validity of CMS's denial of its exception request... CMS could not have been clearer that it based its decision on the facility's labor costs, and that it did not consider whether its patient population was atypical... Accordingly, Alpena reasonably concluded that its hearing before the PRRB would be confined to the issue of whether it incurred labor costs that deviated substantially from national norms. Without prior notice that the Board would consider patient atypicality, the facility was not, and could not have been, prepared to present arguments on that issue. Such conduct violates both the letter and spirit of the APA.

Consequently, the Court will remand the Alpena case so that the facility can have an opportunity to address the issue on which the Board made its determination: Whether Alpena treats an atypical patient population.³²

The Circuit Court also indicated that the Secretary had failed to address the Provider's argument

³⁰ *Alpena Dialysis Services, Chippewa Dialysis Services and Northern Michigan Hospital v. Levitt*, (D.D.C. Sept. 18, 2006), 2006 WL 2682550, Medicare and Medicaid Guide (CCH) ¶ 301,901, at 9.

³¹ *Id.*

³² *Id.* at 10.

concerning lack of notice and remanded the case back to the District Court for further proceeding. Prior to the remand, the Secretary submitted a Praecipe in which it indicated that CMS would review the patient atypicality portion of the Providers' exception request and allow, if necessary, a new appeal to the Board. Immediately after the submission the District Court remanded the case to CMS.

The Board notes that the Provider argues it was not appropriate for CMS to reconsider and revise its grounds for denying its exception request as part of the remand because the determination made on May 15, 2008, was made more than 60 days after the submission of the exception request in violation of the statute at 42 U.S.C. § 1395rr(b)(7) that requires that the Secretary make a determination on the exception request within 60 days. The Board finds that this is not a valid objection considering the history of this case. First, the Board notes that the 60 day time limit for completion of the review of an exception request was instituted to prevent delay in the consideration of exception requests. The Board notes that CMS did review the Provider's exception request within the requisite time period and then the appeal of that decision began. The error in this case was the lack of notification to the Provider. The Board finds that the procedure used during the remand has rectified the situation by having both CMS and the Provider fully address the Board's concerns regarding the threshold requirement of patient atypicality.

The Board continues to find that the Provider's request for an exception to the ESRD composite rate should be denied because the Provider failed to meet its burden of proving that it rendered atypical services to its ESRD patients as required under the controlling regulatory provisions.

As stated in the regulation:

A facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients....³³

The Board notes that the Provider sought an exception to the composite rate for atypical nursing and administrative and general costs based on its contention that it served an atypically more acute patient population than the national norms. Pursuant to the regulation at 42 C.F.R. § 413.182(a), CMS may approve such an exception request if the facility demonstrates by convincing objective evidence that: (1) its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles, and (2) its per treatment costs in excess of its payment rate are directly attributable to atypical service intensity. Accordingly, the Provider is responsible for justifying and demonstrating to CMS' satisfaction that the requirements and criteria for an exception request are met in full. It is the Board's conclusion that the Provider has not furnished evidence to support its atypical services exception request, nor has it proven that its excess costs were directly attributable to this factor.

The Board has reviewed the Provider's evidence of atypicality against both the CMS national

³³ See 42 C.F.R. § 413.184.

norms as well as to levels reported by both Chippewa and Northern Michigan in the cases that were merged with the Provider's case³⁴. The data indicates the Provider's percentage of aged patients of 51.8% was greater than the national norm of 36.7%, however, it was not substantially greater than the average of the percentages of both Chippewa and Northern Michigan (53.8% and 54.4%, respectively) who were also found not to be substantially atypical. The Provider's percentage of mortality of 22.8% was also higher than the national norm of 16%, but again, deemed not to be substantially greater. The Board also notes that the Provider was not higher than the national norm for any other category including the percentage of diabetic patients, average length of stay, transplant patients or hypertension rates. Since the Provider has not demonstrated a significant deviation from the national norms, the Board is not able to make a determination that there was an atypical patient mix that justifies the incurrence of additional costs per treatment. The Board, having found that the Provider's patients are not atypical, has not considered whether additional costs reported by the Provider are related to those supposedly atypical patients.

Finally, the Board notes that the Provider claims that it is not proper to utilize the national ESRD patient profiles contained in CMS' May 15, 2008 denial because they were never published in the manner required by 42 U.S.C. § 1395hh. The Board finds that CMS has adequately notified providers in the regulations of the requirements to document atypical service intensity.³⁵ The Board notes that in the preambles of both the proposed and final rules for ESRD Payment Exception Requests and Organ Procurement Costs, CMS indicated that it would compare the data submitted under the regulation to its Patient Profile Tables.³⁶ The Board also notes that the record indicates that the Provider was aware of the ESRD patient profiles and addressed them in its application.

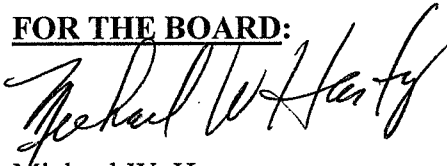
DECISION AND ORDER:

The Board finds that the Provider did not demonstrate that it had an atypical patient mix. CMS' denial of the Provider's exception request was proper, and is affirmed.

BOARD MEMBERS PARTICIPATING:

Michael W. Hartly
Keith E. Braganza, C.P.A.
John Gary Bowers, C.P.A.

FOR THE BOARD:



Michael W. Hartly
Chairman

³⁴ See Intermediary Exhibits I-1 and I-7.

³⁵ See 42 C.F.R. §413.184.

³⁶ See Proposed Rule at 59 Fed. Reg. 44097, 44100 (August 26, 1994), and the Final Rule at 62 Fed. Reg. 43657, 43660 (August 15, 1997).

DATE: **MAY 14 2013**