UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LOMA LINDA UNIVERSITY KIDNEY CENTER,

Plaintiff,

v.

CHARLES E. JOHNSON,
Acting Secretary, United States Department of Health and Human Services,

Defendant.

LOMA LINDA UNIVERSITY MEDICAL CENTER,

Plaintiff,

v.

CHARLES E. JOHNSON,
Acting Secretary, United States Department of Health and Human Services,

Defendant.

Civil Action No. 06-1926
Consolidated with 06-1927
TFH/DAR

REPORT AND RECOMMENDATION[1]

Plaintiffs, Loma Linda University Kidney Center ("LLKC") and Loma Linda University Medical Center ("LLMC"), collectively "Loma Linda," are certified Medicare providers of

[1] The Court has substituted the Acting Secretary as Defendant in place of his predecessor, Michael O. Leavitt, who had been a party to this suit in his official capacity only. *See* Fed.R.Civ.P. 25(d)(1).

service which render hemodialysis services to individuals with end stage renal disease ("ESRD").[2] In this action, Plaintiffs challenge the final decision rendered by the Secretary of the United States Department of Health and Human Services ("Secretary") denying Plaintiffs' requests for an exception to the method for determining the prospective Medicare payment rate for dialysis treatments. Defendant maintains that his decision was proper pursuant to the terms of the applicable statutes and regulations. Pending for consideration by the undersigned United States Magistrate Judge are Plaintiffs' Motion for Summary Judgment (Document No. 19), and Defendant's Motion for Summary Judgment (Document No. 22).

Upon consideration of the motions; the memorandum in support thereof and in opposition thereto; the administrative record, and the entire record herein, the undersigned recommends that Plaintiffs' motion for summary judgment be granted in part, and that Defendant's motion for summary judgment be denied.

I. BACKGROUND

(A) Statutory and Regulatory Framework

This action arises under Title XVIII of the Social Security Act, more commonly known as the Medicare Act, a statutory scheme by which Congress established a federally funded health insurance program for the elderly and disabled. *See* 42 U.S.C. §§ 1395 *et seq*. At issue in this action are provisions which govern the cost reimbursements to providers of service ("Providers") rendering outpatient dialysis treatment to qualified individuals for end stage renal disease

[2] The court (Hogan, J.) consolidated for all purposes Loma Linda University Kidney Center v. Michael O. Leavitt (Civil No. 06-1926), and Loma Linda University Medical Center v. Michael O. Leavitt (Civil No. 06-1927). *See* April 20, 2007 Order (Document No. 12) at 1.

("ESRD"). *See* 42 U.S.C. § 1395rr(b)(7). Reimbursement is administered by the Centers for Medicare and Medicaid Services ("CMS"), formerly the Health Care Financing Administration ("HCFA"),[3] under the direction of the Secretary of the United States Department of Health and Human Services ("Secretary"). 42 C.F.R. § 413.170(a) (2000).[4] Medicare reimbursement payments are determined by

> a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services[.] . . . Such method (or methods) shall provide for the prospective determination of a rate (or rates) for each mode of care based on a single composite weighted formula (which takes into account the mix of patients who receive dialysis services at a facility . . . and the relative costs of providing such services in such setting) for hospital-based facilities . . . or based on such other method or combination of methods . . . which the Secretary determines, after detailed analysis, will more effectively encourage the more efficient delivery of dialysis services[.]

42 U.S.C. § 1395rr(b)(7).[5] Providers are authorized by statute to obtain "exceptions to such methods as may be warranted by unusual circumstances[.]" *Id.*; *see also* 42 C.F.R. § 413.180 (2000).

The Secretary has promulgated regulations enumerating the circumstances warranting an exception to the "method (or methods)" used for "the prospective determination of a rate (or

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[3] Any references to HCFA in cited regulations or the administrative record refers to the entity now known as CMS.

[4] The court cites, where appropriate, the 2000 version of the Regulations that were in effect at the time Plaintiffs filed their requests for payment rate exception.

[5] The reimbursement payments of the cost for services rendered by providers of service are made through private entities, known as fiscal intermediaries. *See* U.S.C. § 1395h; *see also* 42 C.F.R. § 413.180 (2000).

rates)" which determine the amounts of payment to be made for dialysis services.[6] *Id.; see also* 42 C.F.R. §§ 413.182, 413.180 (2000). Providers seeking such a "payment rate exception" must submit to CMS materials specified in the implementing regulations, and at the request of CMS, which are necessary for CMS to "adjudicate each type of exception." *Id.* § 413.180(f). In pertinent part, Providers must request a payment rate exception "within 180 days of . . . the effective date that CMS opens the exceptions process[.]" *Id.* § 413.180(d)(2). The statute provides that "[e]ach application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed." 42 U.S.C. § 1395rr(b)(7); *see also* 42 C.F.R § 413.180(h) (2000) ("An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary.").[7]

In the event that CMS determines that a provider has failed to meet its burden of demonstrating that a payment rate exception is warranted by "convincing objective evidence," the provider may seek administrative review of CMS' decision. 42 C.F.R. § 413.182(b); *see also* §§ 413.180, 413.194(b) (2000). "The [Provider Reimbursement Review Board ("Board")] has the authority to review the action taken by HCFA on the facility's requests. However, the [Board's] decision is subject to review by the Administrator[.]" *Id.* § 413.194(b)(2); *see also* 42 C.F.R. § 405.1875 (2000). "A decision of the Board shall be final unless the Secretary, on its

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[6] The Secretary's implementing regulations authorize "an exception to the prospective payment rate based on atypical service intensity" to a facility that "demonstrates 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." *Id.* § 413.184(a)(1) (2000).

[7] 70 Fed. Reg. 70116, 70331 (November 21, 2005) (redesignated this subsection, in full text, effective January 1, 2006, to 42 C.F.R. § 413.180(g)).

own motion, and within 60 days after the provider of services is notified of the Board's decision, reverses, affirms, or modifies the Board's decision." 42 U.S.C. § 1395oo(f)(1) (2000); *see also* 42 C.F.R. § 405.1875(a)(1) ("The Administrator, at his or her discretion, may review any final decision of the Board[.] . . . on his or her own motion, in response to a request from a party to a Board hearing or in response to a request from HCFA."). Moreover, "the Administrator will promptly notify the parties and HCFA whether he or she has decided to review a decision of the Board and, if so, will indicate the particular issues that he or she will consider." 42 C.F.R. § 405.1875(d)(1). Both CMS and the Provider are afforded an opportunity to submit written materials, as identified by regulation, to the Administrator. *See* § 405.1875(e); *see also id.* § 405.1875(e)(2) ("These submissions shall be limited to issues the Administrator has decided to review and confined to the record of the Board hearing."). A provider of service has the "right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or . . . by the Secretary is received." 42 U.S.C. § 1395oo(f)(1) (2000).

(B) Factual and Procedural Background

Plaintiff Loma Linda University Kidney Center ("LLKC") is a "non-profit free-standing renal dialysis facility . . . [which] operates twenty . . . stations in its outpatient dialysis unit and provides Hemodialysis to mostly adult patients and Peritoneal dialysis to both adult and pediatric patients." LLKC Administrative Record ("LLKC A.R.") 236; *see also* Complaint for Judicial Review of Final Adverse Agency Decision on Medicare Reimbursement ("LLKC Complaint")

(Document No. 1), ¶ 5. Plaintiff Loma Linda University Medical Center ("LLMC") is a "non-profit facility, which operates a hospital-based renal dialysis center . . . [which] operates twelve stations in its outpatient dialysis unit and provides Hemodialysis to both adult and pediatric patients." LLMC Administrative Record ("LLMC A.R.") 522; *see also* Complaint for Judicial Review of Final Adverse Agency Decision on Medicare Reimbursement ("LLMC Complaint") (Document No. 1), ¶ 5.[8] Both facilities, located in Loma Linda, California, are "certified as . . . provider[s] of service[] under the federal Medicare program." LLKC Complaint, ¶ 5; LLMC Complaint, ¶ 6. On August 28, 2000, pursuant to 42 U.S.C. § 1395rr(b)(7), Plaintiffs LLKC and LLMC submitted separate requests for a payment rate exception *(see* LLKC A.R. 235-52, LLMC A.R. 517-44) to "United Government Services, LLC[,]" their fiscal intermediary ("Intermediary").[9] LLKC Complaint, ¶ 16; LLMC Complaint, ¶ 16. Each facility's request for a payment rate exception was predicated upon its contention that it met the atypical service intensity criteria developed by CMS.[10] *See* LLKC A.R. 236, LLMC A.R. 522. According to CMS, the sixtieth working day after August 28, 2000 was November 20, 2000. *See* LLKC A.R. 19, LLMC A.R. 19. Plaintiffs, however, assert that the sixtieth working day after August 28, 2000 was November 24, 2000. *Id*.

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[8] *See* Loma Linda Medical Center v. Michael O. Leavitt (Civil No. 06-1927); *see also* n.2, *supra*.

[9] Despite representations made in their Complaints, Plaintiffs assert in their motion that their requests for payment rate exception "were submitted to Blue Cross of California, which serves as the Secretary's fiscal intermediary." [Plaintiffs'] Memorandum of Points and Authorities in Support of Plaintiff's [sic] Motion for Summary Judgment ("Plaintiffs' Memorandum") (Document No. 19) at 2-3.

[10] LLKC, in its request for a payment rate exception, "sought an additional $51.64 for each outpatient hemodialysis treatment, and an additional $49.43 for each peritoneal dialysis treatment." LLKC Complaint, ¶ 17. LLMC "sought an additional $243.02 for each outpatient hemodialysis treatment." LLMC Complaint, ¶ 17. *See also* n.6, *supra*.

By letters dated November 15, 2000, CMS advised the Intermediary that it denied Plaintiffs' requests for payment rate exception.[11] *See* LLKC A.R. 180-87,[12] LLMC A.R. 192-97.[13] The Intermediary, by letter dated November 29, 2000, advised Plaintiff LLKC that its request for payment rate exception was denied. *See* LLKC A.R. 198.[14] Likewise, by letter dated December 11, 2000, the Intermediary notified Plaintiff LLMC that "[b]ased on HCFA's review of our proposal and your documentation, they denied your request for an exception." LLMC A.R. 202.[15] Plaintiffs appealed CMS' decisions to the Board. *See* LLKC A.R. 874, LLMC A.R. 1023.

The Board, on July 27, 2006 rendered substantially identical decisions on both appeals. *See* LLKC A.R. 25-32 (Provider Reimbursement Review Board Decision); *see also* LLMC A.R. 25-29. In its decisions, the Board defined the issue for adjudication with respect to both Plaintiffs as "[w]hether the denial of the Provider[s'] request[s] for an exception to the end stage renal disease (ESRD) composite rate by the Centers for Medicare and Medicaid Services (CMS) was proper." LLKC A.R. 26, LLMC A.R. 26. The Board further explained that "[these] case[s]

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[11] Plaintiffs allege that "[t]he CMS letter[s] dated November 15, 2000 [were] not sent to the Intermediary until after the expiration of the 60 working day [period] prescribed by 42 U.S.C. § 1395rr(b)(7)." LLKC Complaint, ¶ 23; LLMC Complaint, ¶ 22.

[12] Letter from Joseph Logue, Health Insurance Specialist, Division of Chronic Care Management to Michael S. Foxx, Manager, Provider Audit Department, Medicare Part A Intermediary (November 15, 2000).

[13] Letter from Joseph Logue, Health Insurance Specialist, Division of Chronic Care Management to Brenda Merriweather, Manager, Provider Audit Department, Medicare Part A Intermediary (November 15, 2000).

[14] Letter from Michael S. Foxx, Manager, Provider Audit Department to Corinna Goron, Controller, Loma Linda University Kidney Center (November 29, 2000).

[15] Letter from Brenda Merriweather, Manager, Provider Audit Department to Teresa Day, Sr. V.P. /CFO, Loma Linda University Medical Center (December 11, 2000).

involve[] whether the denial was timely under [42 U.S.C. § 1395rr(b)(7) and 42 C.F.R. § 413.180(g)]." *Id.* The Board rejected CMS' determination on Plaintiffs' requests for a payment rate exception. LLKC A.R. 28, LLMC A.R. 28. In support of its decision, the Board found that (1) "Congressional intent is frustrated if CMS fails to timely send notice of its decision[]"; (2) time limits created in the Medicare regulations should be strictly enforced against CMS, just as they are against providers requesting a payment rate exception; (3) a literal reading or interpretation of the applicable regulation "ignores the reality that notice is essential to the exception process and to fundamental notions of due process." LLKC A.R. 28-29, LLMC A.R. 28-29. Moreover, the Board indicated that "the substantive issue as to whether the exception denial was otherwise proper is moot." *Id*. (footnote omitted).

CMS, by letter dated August 7, 2006, requested the reversal of the Board's decisions contending that "CMS met the requirement of disapproving the Provider[s'] exception request in a timely manner[.]" *See* LLKC A.R. 21, LLMC A.R. 21.[16] On August 9, 2006, the Administrator of CMS notified Plaintiffs and the Intermediary that the Board's decision would be reviewed "to determine whether to reverse, affirm, modify or remand the Board's decision . . . [and] whether the Board's decision is in keeping with the pertinent laws, regulations and other criteria cited by the Board and by the parties in their comments." LLKC A.R. 18, LLMC A.R. 18. On September 12, 2006, the Administrator reversed the Board's decisions upon an examination of the "entire record furnished by the Board . . . including all correspondence, position papers, exhibits, . . . subsequent submissions . . . [and] comments timely received[.]"

[16] Letter from Janet P. Samen, Director, Division of Chronic Care Management, Chronic Care Policy Group to Director, Office of Attorney Advisor (August 7, 2006). *See* LLKC A.R. 19-21, LLMC A.R. 19-21.

See LLKC A.R. 2-8, LLMC A.R. 2-7 (Centers for Medicare and Medicaid Services Decision of the Administrator, dated September 12, 2006). The Administrator found that "CMS' November 15, 2000 disapproval of the Provider[s'] exception request satisfied the statutory and regulatory requirements in that it was made within 60 working days after the request was filed with the Provider[s'] Intermediary." LLKC A.R. 8, LLMC A.R. 7. The Administrator further observed that the applicable statute "does not state that the actual notice of the disapproval must be issued by, or received by, the provider within 60 working days after the application is filed."[17] LLKC A.R. 6, LLMC A.R. 6-7. This decision constituted final agency action from which Plaintiffs seek judicial review. *See* 42 U.S.C. § 1395oo(f)(1).

II. CONTENTIONS OF THE PARTIES

Plaintiffs and Defendant cross-move for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure, alleging that there are no genuine issues as to any material fact and that each is entitled to summary judgment as a matter of law. Moreover, Plaintiffs claim that the Secretary's "denial of their requests for an exception to the Medicare prospectively determined payment rate for dialysis treatments . . . constituted arbitrary and capricious agency action in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A)." Plaintiffs' Memorandum at 1. Plaintiffs, in support of their motion for summary judgment, characterize the issues before the court as:

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[17] In its review of the Board's decision, the Administrator did not make any findings concerning the substantive determination by CMS that Plaintiffs failed to satisfy the criteria for an atypical service intensity exception. *See* LLKC A.R. 2-8, LLMC A.R. 2-7. Indeed, the Administrator asserted that "[i]n this case . . . the parties dispute not the merits of the denial of the Provider's exception request, but rather the interpretation of the pertinent statutory language governing the timing of CMS['] determination on composite rate exception requests." LLKC A.R. 6, LLMC A.R. 6.

> (1) Should the exception request[s] have been deemed approved pursuant to 42 U.S.C. § 1395rr(b)(7)?
> (2) Did the Secretary's failure to furnish a complete administrative record require remand to the [Board]?
> (3) Did the Secretary improperly conclude that [Plaintiffs] abandoned the issue of whether [their] exception request was meritorious?
> (4) Was the Secretary's failure to make a determination on the merits of the exception request[s] a violation of the APA and the requirements of procedural due process?

Id. at 6-7. Plaintiffs offer five grounds in support of their motion: (1) "[t]he exception request[s] filed by Loma Linda should be deemed approved because the Secretary did not provide notification to Loma Linda of its disapproval until after the 60 working day period[]" (*id*. at 8); (2) the Administrator's "rationale" that the statute does not require the Secretary to notify Providers within the sixty-working day period of its decision on a request for payment rate exception is "inconsistent with the underlying purpose of the statute[]" (*id.* at 10); (3) "[t]he [CMS] denial letters [dated November 15, 2000] were subject to the indexing and disclosure requirements of [the Freedom of Information Act ("FOIA")][,] 5 U.S.C. § 552(a)(2)(A)[]" (*id.* at 14); (4) CMS' letter of its decision on Plaintiffs requests for payment rate exception "could not have been '*relied on*' or '*used*' against Loma Linda until such time as the latter received '*actual*' notice thereof[]" (*id.* at 14) (citation omitted); and (5) remand to the agency is required "for further fact finding as to the date upon which the denial letter was signed"[18] (*id*. at 22), and "for a

[18] Plaintiffs, before filing their motion for summary judgment, moved for an order compelling the production of documents. *See* [Plaintiffs'] Motion to Compel Production of Documents (Document No. 15) (Plaintiffs sought "logs reflecting the dates upon which significant actions occur[red] in connection with the processing of renal dialysis exception requests[,]" and any other "documents to establish that the November 15, 2000 denial letter[s] [were] mailed to the Intermediary after the expiration of the 60 working day period." The undersigned denied Plaintiffs' motion to compel without prejudice. *See* October 30, 2008 Minute Entry.

On November 17, 2008, Plaintiffs again filed a motion to compel seeking "any portions of the logs which reflect the date upon which the November 15, 2000 letter was actually signed, and the date upon which the letter was

determination on the substantive merits of the exception request." *Id*. at 20. Plaintiffs assert that a "remand back to the [Board] for a decision on the merits of the exception request[]" is the "appropriate remedy" as "neither the [Board] nor the Administrator rendered any conclusions on the merits of the exception request." *Id*. at 21.

Defendant, in his motion for summary judgment and opposition to Plaintiffs' motion for summary judgment, submits that "the Secretary acted in full compliance with all statutory and regulatory requirements . . . and his interpretation of the Medicare statute was reasonable and should be upheld." *See* Defendant's Memorandum of Points and Authorities in Support of Defendant's Motion for Summary Judgment and in Opposition to Plaintiffs' Motion for Summary Judgment ("Defendant's Memorandum") (Document Nos. 22, 23) at 11. In support of his contention, Defendant asserts that (1) the applicable statute and implementing regulation, by their terms, "requires only that a request [for a payment rate exception] be disapproved, not transmitted and/or delivered to either the intermediary or the provider within the sixty working day limit" (*see id*. at 11-12); (2) CMS notified the Intermediary, by letters dated November 15, 2000 of its decisions to deny Plaintiffs' requests for a payment rate exception (*see id*. at 5); (3) the Secretary's interpretation of 42 U.S.C. § 1395rr(b)(7) is deferential, reasonable and does not undermine the purpose of the Medicare statute (*see id*. at 9-14); (4) Plaintiffs do not, and could not, claim to have been prejudiced by the Intermediary's notification of CMS' decision with

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actually mailed to the fiscal intermediary." [Plaintiffs'] Motion to Compel Production of Documents (Plaintiffs' Motion to Compel") (Document No. 39) at 8. Plaintiffs contended that such discovery was relevant to their claims that "the exception request was not timely processed because it was not mailed to the intermediary within the 60 [working] day period." *Id; see also id*. at 3 ("Plaintiffs are not seeking discovery to demonstrate the existence of a genuine issue of material fact. Rather, [P]laintiffs are seeking to supplement the administrative record[.]"). The undersigned denied Plaintiffs' motion to compel. *See* January 9, 2009 Minute Order. Plaintiffs filed "objections" to the undersigned's order on January 13, 2009 (Document No. 42).

respect to their requests for payment rate exception (*see id.* at 14); and (5) "FOIA is irrelevant to the legal question before this Court[]" *Id*. at 15. Moreover, Defendant asserts that remand is not warranted because Plaintiffs "waived their opportunity to seek a remand . . . [by] fail[ing] to seek [such] alternative relief before the Administrator[]" (*id*. at 16), and that there is "no basis to doubt that the [November 15, 2000] [denial] letters were signed on the date printed upon them[.]" *Id*. at 18. Defendant contends that "there is not a genuine issue of material fact: as a matter of law, the Secretary's actions were not arbitrary or capricious or an abuse of discretion." *Id*. at 11.

In the reply to Defendant's opposition, and opposition to Defendant's motion for summary judgment, Plaintiffs assert that (1) they did not seek a remand of the Board's decision that their requests for a payment rate exception be deemed approved because they were pleased with its decision (*see* [Plaintiffs'] Reply Memorandum in Support of Plaintiffs' Motion for Summary Judgment and in Opposition to Defendant's Cross-Motion for Summary Judgment ("Plaintiffs' Response") (Document Nos. 25, 26) at 2); (2) Plaintiffs do not have the "new, substantial" evidence required as a prerequisite to a remand (*see id*.); (3) remand is warranted to learn the date upon which CMS' denial letters were actually signed (*id*. at 5-7); and (4) arguments and written submissions were limited to issues the Administrator decided to review. *See id.* at 4. Plaintiffs maintain that the Secretary's November 15, 2000 denial of their request for payment rate exception was not final because "the agency did not provide notification of its disapproval until after the 60 working day period." *Id*. at 7; *see also id*. at 11 ("[T]he denial letter(s) [were] still tentative as of November 15, 2000 because the deciding official did not communicate that action to anyone."); *see also id*. at 8 ("The issue to be decided by this Court is

whether a disapproval which has not been communicated can be final."). Plaintiffs also maintained that "[u]nder FOIA, a 'final opinion' or 'order' cannot be 'used' or 'relied on' until the agency has either (a) placed a copy of the denial letter in the agency's electronic reading room, or (b) provided a copy of the denial letter to [Plaintiffs]." *Id*. at 14. Plaintiffs maintain that "the [CMS] November 15, 2000 denial[] [letters] were 'final opinions' or 'orders' within the context of the FOIA[.]"[19] *Id*.

Defendant, in his reply, maintains that his interpretation of 42 U.S.C. § 1395rr(b)(7) is entitled to deference by the court and is within the bounds of reasonable interpretation. *See* Defendant's Reply to Plaintiffs' Opposition to Defendant's Motion for Summary Judgment ("Defendant's Reply") (Document No. 30) at 2-7. Defendant further maintains that consideration of notice requirements under FOIA is irrelevant to the issue before the court because "Plaintiffs have brought a claim pursuant to the Medicare statute, 42 U.S.C. § 1395oo(f)(1), not FOIA[,]" and the "relief which Plaintiffs seek is in no way connected to the relief which may be afforded under FOIA." *See id*. at 8-9. Moreover, remand is unnecessary because Plaintiffs' can not support the assertion that CMS' denial letters were signed on a date other than November 15, 2000, and Plaintiffs "ought to have foreseen the need to notify the Administrator of their intent to pursue the merits of their request[.]" *Id*. at 10-11.

Plaintiffs, in their surreply, argue that "the Administrator's decisions dated September 12, 2006 [also] do not warrant deference under *Chevron* because they were not published as required

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[19] Plaintiffs "acknowledge[] . . . [the] inconsistency between its assertion that the denial letters dated November 15, 2000 were not final, and its assertion that the denial letters constituted a 'final opinion' or 'order' within the context of FOIA." Plaintiffs' Response at 14, n.2. Plaintiffs contend that its alternative arguments will lead to the same conclusion. *See id*. ("[U]nder either legal theory, the denial letters were not effective as of November 15[, 2000]."

by the provisions of [FOIA]."[20] Plaintiff[s'] Surreply (Document No. 37) at 2 (citations omitted).

III. STANDARD OF REVIEW

(A) Motions for summary judgment

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted if the pleadings on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56©. Material facts are those that "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986). There is a genuine issue of material fact "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Id.* In considering a motion for summary judgment, all evidence and inferences to be drawn from the underlying facts must be viewed in the light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). "Additionally, 'in ruling on cross-motions for summary judgment, the court shall grant summary judgment only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not genuinely disputed.'" *American Cargo Transport, Inc. v. Natsios*, 429 F. Supp. 2d 139, 145 (D.D.C. 2006) (quoting *Petchem, Inc. v. United States,* 99 F. Supp. 2d 50, 54 (D.D.C. 2000)) (citations omitted). "In a case involving review of a final agency action under the Administrative Procedure Act, 5 U.S.C. § 706, however, the standard set forth in Rule 56© does not apply because of the limited role of a court in reviewing the administrative

[20] Plaintiffs, on February 27, 2008, moved for leave to file a surreply. *See* Plaintiff's [sic] Motion for Leave to File Surreply (Document No. 31). The undersigned granted Plaintiffs' motion. *See* September 19, 2008 Minute Order.

record." *Baystate Med. Ctr. v. Leavitt*, 545 F. Supp. 2d 20, 34-35 (D.D.C. 2008) (citations omitted).

(B) Judicial Review of Secretary's decision pursuant to the Administrative Procedure Act

Judicial review of Medicare reimbursement disputes is governed by the standards set forth in the Administrative Procedure Act ("APA"). 42 U.S.C. § 1395oo(f)(1); *see also* 5 U.S.C. § 706. To the extent necessary, "the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action." 5 U.S.C. § 706. Further, "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law, unsupported by substantial evidence, arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). "Generally, an agency's decision is arbitrary and capricious 'if the agency . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *Johnson v. U.S. Dep't of Educ.*, 580 F. Supp. 2d 154, 157 (D.D.C. 2008) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)) (internal citations omitted). "As long as an agency has examined the relevant data and articulated a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made, courts will not disturb the agency's action." *Heartland Reg'l Med. Ctr. v. Leavitt,* 511 F. Supp. 2d 46, 51 (D.D.C. 2007) (citing *Motor Veh.*

Mfrs. Ass'n, 463 U.S. at 43). The scope of review of an agency decision accordingly is narrow, and a federal court is not to substitute its judgment for that of the agency. *See Orion Reserves Ltd. P'ship v. Salazar*, 553 F.3d 697, 706 (D.C. Cir. 2009) (citations omitted). When reviewing an administrative decision, "the burden of showing that the agency action violates the APA standards falls on the provider." *Heartland*, 511 F. Supp. 2d at 51(citing *Diplomat Lakewood Inc. v. Harris*, 613 F.2d 1009, 1018 (D.C. Cir. 1979)) (citation omitted).

"The Supreme Court set forth a two-step approach to determine whether an agency's interpretation of a statute is valid under the APA. *Quantum Entertainment, Ltd v. U.S. Dep't of the Interior*, No. CIV.A.07-1295, 2009 WL 401871, at *4 (D.D.C. Feb. 19, 2009) (citing *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.,* 467 U.S. 837 (1984)). Application of the "*Chevron* deference" standard "requires the court to first look to 'whether Congress has spoken to the precise question at issue.' If so, the court ends its inquiry. But, if the statute is ambiguous or silent, the second step requires the court to defer to the agency's position, as long as it is 'based on a permissible construction of the statute.'" *Id*. (internal citation omitted). The Secretary's interpretation of his own regulations is entitled to "substantial deference[,]" and "must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (citation omitted). "Where the regulations involve a complex, highly technical regulatory program such as Medicare, broad deference is 'all the more warranted.'" *St. Anthony's Health Ctr. v. Leavitt,* 579 F. Supp. 2d 115, 119 (D.D.C. 2008) (quoting *Thomas Jefferson Univ.,* 512 U.S. at 512) (internal quotations omitted).

IV. DISCUSSION

(A) Remand is warranted for the Administrator's consideration of whether Plaintiffs requests for payment rate exception were deemed approved pursuant to 42 U.S.C. § 1395rr(b)(7).

Plaintiffs, in the memorandum in support of their motion for summary judgment, state that they "challenge[] the denial of their requests for an exception to the Medicare prospectively determined payment rate for dialysis treatments[,]" and maintain that such denial "constituted arbitrary and capricious agency action in violation of the [APA]." Plaintiffs' Memorandum at 1. Plaintiffs submit that the first issue presented is "[s]hould the exception request have been deemed approved pursuant to 42 U.S.C. § 1395rr(b)(7)?" *Id*. at 6; *see also* LLKC Complaint, ¶ 34, LLMC Complaint, ¶ 33 ("Defendant incorrectly held that 42 U.S.C. § 1395rr(b)(7) requires only that the exception request be denied with [sic] the 60 working day period without regard to when CMS provided notice of said denial to the Intermediary, and without regard to when the Intermediary provided notice of said denial to the Plaintiff."). Plaintiffs contend that "the Secretary's disapproval [should] be given effect . . . [at] such time as the provider has been notified." *Id.* at 12.

Defendant contends that "Plaintiffs' requests were timely disapproved by the November 15, 2000 letters." Defendant's Memorandum at 12. Additionally, Defendant asserts that "there is not a genuine issue of material fact: as a matter of law, the Secretary's actions were not arbitrary or capricious or an abuse of discretion[,]" and that "his interpretation of the Medicare statute was reasonable and should be upheld." *Id*. at 11.

In pertinent part, the Medicare Act provides that

> [e]ach application for . . . an exception shall be deemed to be

> approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed.

42 U.S.C. § 1395rr(b)(7). The implementing regulation is markedly similar. *See* 42 C.F.R § 413.180(h) ("An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary.").

It is undisputed that Plaintiffs, pursuant to 42 U.S.C. § 1395rr(b)(7), submitted requests for a payment rate exception to their Intermediary on August 28, 2000 (*see* LLKC A.R. 235-52, LLMC A.R. 517-44); CMS, by letters dated November 15, 2000, advised the Intermediary that it denied Plaintiffs' requests for a payment rate exception (*see* LLKC A.R. 180-87, LLMC A.R. 192-97); the Intermediary, by letters dated November 29, 2000 and December 11, 2000, advised Plaintiff LLKC and LLMC, respectively, of CMS' decision (*see* LLKC A.R. 198, LLMC A.R. 202), and Plaintiffs appealed CMS' decisions to the Board (*see* LLKC A.R. 874, LLMC A.R. 1023). In adjudicating Plaintiffs' appeal, the Board initially defined the issue as "[w]hether the denial of the Provider[s'] request[s] for an exception to the end stage renal disease (ESRD) composite rate by the [CMS] was proper." LLKC A.R. 26, LLMC A.R. 26. However, without explanation, the Board later characterized the dispute as "case[s] involv[ing] whether the denial was timely under [42 U.S.C. § 1395rr(b)(7) and 42 C.F.R. § 413.180(g)]." *Id*. On July 27, 2006, the Board rendered its decisions reversing CMS' determinations of Plaintiffs' requests for a payment rate exception.

The undersigned finds that the Board's decision is ambiguous. Specifically, in the "Findings of Fact, Conclusions of Law and Discussion" section of its decisions, the Board "[found] . . . pursuant to 42 U.S.C. § 1395rr(b)(7) and 42 C.F.R. § 413.180(h), [that] the

[Plaintiffs'] exception request[s] [were] automatically deemed approved as CMS' determination[s] [were] sent to the *Intermediary* after the 60 working day deadline." LLKC A.R. 28, LLMC A.R. 28 (emphasis added). Notwithstanding this finding, the Board in the "Decision and Order" section of its decision, concluded that "[a]s a result of the failure of CMS to notify the *Provider* of the determination within 60 working days as required by 42 U.S.C. § 1395rr(b)(7), the Provider's exception request is deemed approved." LLKC A.R. 29, LLMC A.R. 29 (emphasis added).

Additionally, the undersigned finds that the Administrator made no findings with respect to the ambiguity in the Board's decision or provided a rationale for the Administrator's sole review of the Board's finding regarding notification to the *Provider*. *See* LLKC A.R. 2-8, LLMC A.R. 2-7. Instead, the Administrator reversed the Board's decisions and concluded that a proper interpretation of 42 U.S.C. § 1395rr(b)(7) is that by its terms "[t]he statute does not require that the *Provider* receive the disapproval, or have notice of the disapproval, within [the] statutory time period." *Id*. at 6. Moreover, the administrative record reveals that Plaintiffs argued–in written submissions before the Administrator–that

> "[p]er the Board's decision, CMS did not send its notification to the intermediary until after the 60 day deadline expired. As such, even assuming *arguendo* that notification of the Provider is not subject to the 60-day time limit, CMS has not satisfied its requirement to provide notification to the Intermediary within the 60 day period."

[LLKC's] Provider Comment, A.R. 12; *see also* [LLMC's] Provider Comment, A.R. 12. The Administrator's decision is notably silent with respect to the Board's finding that "the [Plaintiffs'] exception request[s] [were] automatically deemed approved as CMS'

determination[s] [were] sent to the *Intermediary* after the 60 working day deadline." LLKC A.R. 28, LLMC A.R. 28 (emphasis added).

The court does not have the authority, consistent with *Chevron* deference, to make a determination of what the Board meant by the use of the conflicting language in its decision, or to resolve the conflict. Thus, the undersigned's narrow judicial review is thwarted by the ambiguity of the administrative record, and the court cannot substitute its own judgment for that of the agency. *See Orion Reserves Ltd. P'ship v. Salazar*, 553 F.3d 697, 706 (D.C. Cir. 2009) (citations omitted). Additionally, the undersigned observes that "'[t]he focal point for judicial review under the [APA] should be the administrative record already in existence[.]'" *Colorado Wild Horse & Burro Coalition, Inc. v. Kempthorne*, 527 F. Supp. 2d 3, 7 (D.D.C. 2007) (citation omitted). Further, "[i]f the record is too scant for a decision to be made, courts will, 'except in rare circumstances,' remand to the agency for additional investigation or explanation.'" *Id*. (citations omitted). Thus, the undersigned recommends that the matter be remanded for resolution of the ambiguity.[21]

(B) Remand is also warranted for consideration of the merits of Plaintiffs' request for payment rate exception.

Plaintiffs contend that "this matter should be remanded "for a determination on the substantive merits of the exception request." Plaintiffs' Memorandum at 20. Plaintiffs assert

[21] To the extent that Plaintiffs request remand "for further fact finding as to the date upon which the denial letter was signed" (Plaintiffs' Memorandum at 22), the undersigned does not so recommend. Plaintiffs, in their motion to compel, conceded that "[r]emand is especially inappropriate in the present case, as there are no longer any fact finding procedures available at the administrative level to determine the date upon which the November 15, 2000 letter was either signed or mailed." Plaintiffs' Motion to Compel at 11; *see also* n.18, *supra*.

that a "remand back to the [Board] for a decision on the merits of the exception request[]" is the "appropriate remedy" as "neither the [Board] nor the Administrator rendered any conclusions on the merits of the exception request[s]." *Id*. at 21. Defendant maintains that a remand is not warranted because Plaintiffs "waived their opportunity to seek a remand . . . [by] fail[ing] to seek [such] alternative relief before the Administrator[]" (Defendant's Memorandum at 16); and Plaintiffs "ought to have foreseen the need to notify the Administrator of their intent to pursue the merits of their request[.]" Defendant's Reply at 10-11. However, Defendant's arguments do not withstand scrutiny; indeed, the undersigned finds that no findings were articulated with respect to Defendant's review of the substantive merits of Plaintiffs requests for a payment rate exception.

The administrative record is clear that before the Board, the parties disputed whether the Plaintiffs met the criteria for atypical service intensity. *See* LLKC A.R. 91-152 (June 10, 2004 Transcript of Proceedings, Provider Reimbursement Review Board); *see also* LLMC A.R. 99-160 (June 10, 2004 Transcript of Proceedings, Provider Reimbursement Review Board). However, the Board, in making its determination that Plaintiffs' requests for payment rate exception were "deemed approved[,]" also held that "the substantive issue as to whether the exception denial was otherwise proper is moot." *See* LLKC A.R. 29, LLMC A.R. 29 (footnote omitted). In its September 12, 2006 decisions, the Administrator summarily stated that "the parties dispute not the merits of the denial of the Provider's exception request, but rather the interpretation of the pertinent statutory language governing the timing of CMS['] determination on composite rate exception requests." LLKC A.R. 6, LLMC A.R. 6. However, the Administrator neither made any findings, nor provided an explanation regarding this conclusion

which disregarded the arguments made by the Plaintiffs before the Board. Moreover, the Administrator made no findings regarding its consideration of the Board's decision to find as moot the merits of Plaintiffs' requests for payment rate exception. Consequently, the Plaintiffs lack a final decision regarding the merits of their requests for payment rate exception.

The undersigned finds that the Administrator's decision is devoid of any findings with respect to whether Plaintiffs' requests for a payment rate exception were meritorious. "In cases where a reviewing court is unable to make a determination because of the agency's failure to explain the grounds for its decision, the proper remedy is a remand for further proceedings." *Merck & Co., Inc. v. Food & Drug Admin.*, 148 F. Supp. 2d 27, 31 (D.D.C. 2001) (citation omitted). Thus, a remand to the Administrator is warranted for consideration consistent with the applicable statutes and regulations.

© *The requirements of the Freedom of Information Act are immaterial to the issues before the court*

Plaintiffs contend that the November 15, 2000 denial letters "were subject to the indexing and disclosure requirements of 5 U.S.C. § 552(a)(2)(A) [of the Freedom of Information Act ("FOIA")][,]" but "were not indexed or published in the publication known as CMS Rulings[.]" *See* Plaintiffs' Memorandum at 14. Further, Plaintiffs contend that because CMS failed to index or publish its November 15, 2000 denial letters in the publication known as CMS Rulings, the denial letters "could not have been '*relied on*' or '*used*' against Loma Linda until such time as the latter received '*actual*' notice thereof." *Id*. Defendant maintains that "FOIA is irrelevant to the legal question before this Court[,]" and that "the timeliness of ESRD exception request

denials is to be determined pursuant to the Medicare statute, not FOIA." Defendant's Memorandum at 15. Defendant further maintains that "[t]he Secretary complied with the Medicare statute because he disapproved the exception request within sixty working days[,]" and "FOIA cannot be read to . . . impose a stricter deadline for agency action than the Medicare statute itself." *Id*.

The undersigned finds that Plaintiffs' invocation of FOIA is entirely misplaced. FOIA is an enactment which "requires agencies of the federal government to release records to the public upon request, unless one of nine statutory exemptions applies." *Moore v. Bush*, No. CIV.A.07-107, 2009 WL 504623, at *7 (D.D.C. Feb. 23, 2009); *see also Ubunger v. U.S. Citizenship and Immigration Services*, No. CIV.A.08-673, 2009 WL 504680, at *3 (D.D.C. Mar. 2, 2009) ("FOIA provides public access to government records as a means for exposing and examining government conduct[.]"). No authority supports the proposition that an agency's compliance–or lack thereof–with any "indexing and disclosure requirements of [FOIA]" (*see* Plaintiffs' Memorandum at 14) is either relevant or material to a request for APA review of a final agency decision.

V. CONCLUSION

For the foregoing reasons, the undersigned finds that (1) the administrative record is ambiguous with respect to the decision rendered by the Board and subsequently by the Administrator; (2) the Administrator's decision is devoid of any findings with respect to whether Plaintiffs' requests for a payment rate exception were meritorious; and (3) any "indexing and disclosure requirements" of the Freedom of Information Act are neither relevant nor material to

any of the issues presented in this action. It is, therefore, this 17th day of March, 2009,

RECOMMENDED that Plaintiffs' Motion for Summary Judgment (Document No. 19) be **GRANTED IN PART,** and that this matter is remanded for further consideration and findings consistent with the instant Report and Recommendation; and it is

FURTHER RECOMMENDED that in all other respects, Plaintiffs' Motion for Summary Judgment be **DENIED**; and it is

FURTHER RECOMMENDED that Defendant's Motion for Summary Judgment (Document No. 22) be **DENIED**.

_____/s/_____
DEBORAH A. ROBINSON
United States Magistrate Judge

Within ten days of the filing of the instant report and recommendation, either party may file written objections. Such objections shall identify with specificity the portions of the findings and recommendations to which objection is made, and the basis for the objection. In the absence of timely objections, further review of issues addressed herein may be deemed waived.