UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DIALYSIS CLINIC, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 05-604 (GK)**
	)	
MICHAEL O. LEAVITT,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM OPINION

Plaintiff Dialysis Clinic, Inc. ("DCI") brings this action against Defendant Michael O. Leavitt, Secretary of the U.S. Department of Health and Human Services ("HHS"),[1] pursuant to Title XVII of the Social Security Act, 42 U.S.C. §§ 1395 et seq. ("the Medicare Act"). DCI is a Tennessee non-profit corporation that owns and operates Medicare-certified end stage renal disease ("ESRD") facilities throughout the United States. Pursuant to Medicare's cost reimbursement program, DCI filed Medicare cost reports on behalf of a number of those ESRD facilities for periods ending September 30, 1994, September 30, 1995, and September 30, 1996 ("Relevant Periods"). DCI included in those cost reports bad debts that it was unable to collect from Medicare recipients for whom the facilities had provided ESRD treatment. The cost reports included $1,033,628 in bad debts relating to the provision of "separately billed items" to Medicare patients. AR 19.

[1] Michael O. Leavitt is sued in his official capacity.

DCI seeks judicial review of a final agency decision to deny reimbursement to those ESRD facilities for a portion of the deductible and coinsurance payments that they were unable to collect from Medicare patients. Specifically, DCI challenges the decision of the Administrator of the Centers for Medicare and Medicaid Services ("CMS") to deny reimbursement pursuant to 42 C.F.R. § 413.170(e) ("§413.170(e)") for bad debts relating to the "separately billed items" category of services.

This matter is now before the Court on the parties' cross-motions for summary judgment. Upon consideration of the Motions, Oppositions, Replies, and the entire record herein, and for the reasons stated below, DCI's Motion for Summary Judgment [Dkt. No. 15] is **granted**, and Defendant's Cross-Motion for Summary Judgment [Dkt. No. 18] is **denied**.

I. BACKGROUND AND PROCEDURAL HISTORY

A. Statutory and Regulatory Framework

Congress created the Medicare program in 1965 to pay for certain specified, or "covered," medical services provided to eligible elderly and disabled persons. See 42 U.S.C. §§ 1395 et seq. Under the program, health care providers are reimbursed for a portion of the costs that they incur treating Medicare beneficiaries pursuant to an extremely "complex statutory and regulatory regime." Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 404 (1993). That regime is administered by the Centers for

Medicare & Medicaid Services ("CMS" or "the agency") under the supervision of the Secretary of HHS ("the Secretary") and through a network of fiscal intermediaries, private entities with which the Secretary contracts to review and process Medicare claims in the first instance.

The Medicare Act provides for reimbursement of the "reasonable cost" of services furnished to Medicare beneficiaries. 42 U.S.C. § 1395x(v)(1)(A). "Congress authorized the Secretary of Health and Human Services (Secretary) to issue regulations defining reimbursable costs and otherwise giving content to the broad outlines of the Medicare statute. That authority encompasses the discretion to determine both the 'reasonable cost' of services and the 'items to be included' in the category of reimbursable services." Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 506-07 (1994) (citing 42 U.S.C. § 1395x(v)(1)(A)).

The Medicare program reimburses Medicare-certified ESRD facilities for two categories of items and services provided to program beneficiaries: (1) those items and services contained within the Medicare "composite rate," which is a pre-determined payment for dialysis treatment based on past reasonable costs for such treatment; and (2) separately billed items, which are "add-on" items and services outside of the composite rate. 42 U.S.C. § 1395rr(b)(7), (b)(11). The separately billed items, such as provision of the drug Epoietin, are paid on a charge or flat fee

schedule, rather than a reasonable cost or reasonable cost-based prospective payment methodology. A deductible and coinsurance applies to both the composite rate services and the separately billed items.

If, after making reasonable collection efforts, a facility is unable to collect the deductible or coinsurance from the patient, that outstanding amount is treated as a Medicare bad debt. 42 C.F.R. § 413.80(b). Medicare bad debts are "amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services [to Medicare beneficiaries]." Id.

Pursuant to the authority granted by the Medicare statute, the Secretary, by regulation applicable during the Relevant Periods, permitted reimbursement for "allowable Medicare bad debts." 42 C.F.R. § 413.170(e) (1996). Specifically, the ESRD regulation in effect during the Relevant Periods provided, in pertinent part:

> (1) HCFA [Health Care Financing Administration] will reimburse each facility its allowable Medicare bad debts, up to the facility's costs as determined under Medicare principles, in a single lump sum at the end of the facility's cost reporting period.
> . . .
> (3) A facility must request reimbursement for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list of all specific noncollections related to covered services.

42 C.F.R. § 413.170(e) (1996).[2] Defendant concedes that "covered

[2] All citations herein refer to the Code of Federal Regulations provisions in effect at the time Plaintiffs appealed

services" includes both composite rate and separately billed items. Def.'s Cross-Mot. at 7.

The regulations also define "allowable bad debt." In a section titled "Criteria for allowable bad debt," the regulations provided that for a Medicare bad debt to be allowable, it must meet the following criteria:

> (1) The debt must be related to covered services and derived from deductible and coinsurance amounts.
> (2) The provider must be able to establish that reasonable collection efforts were made.
> (3) The debt was actually uncollectible when claimed as worthless.
> (4) Sound business judgment established that there was no likelihood of recovery at any time in the future.

42 C.F.R. § 413.80(e) (1996)[3] ("§ 413.80(e)"); AR 138; see also Provider Reimbursement Manual § 308 (reiterating those four

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CMS's denial of their exception requests and filed this case. Section 413.170(e)(3) was amended on August 15, 1997. That section, which has been redesignated as 42 C.F.R. § 413.178(c), now states that "[a] facility must request payment for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list that specifically enumerates all uncollectable amounts related to covered services under the composite rate." 42 C.F.R. § 413.178(c) (emphasis added).

Even though the agency has changed the governing regulation, the Court is required to review DCI's appeal based on the regulation applicable during the Relevant Periods, which in this case is § 413.170. See Nat'l Mining Ass'n v. Dep't of Labor, 292 F.3d 849 (D.C. Cir. 2002).

[3] Since the Relevant Periods, 42 C.F.R. § 413.80(e) has been redesignated as 42 C.F.R. § 413.89(e). 69 Fed. Reg. 48916 (Aug. 11, 2004, effective Oct. 1, 2004). The text of the redesignated regulation is identical to the original version.

criteria).[4]

B. Procedural History

DCI filed Medicare cost reports with the fiscal intermediary (Blue Cross and Blue Shield of Georgia) for the Relevant Periods seeking reimbursement for the bad debts of its ESRD facilities. The fiscal intermediary found that, pursuant to the Medicare Provider Reimbursement Manual ("PRM"),[5] ESRD facilities were only entitled to reimbursement for bad debts related to composite rate services, not to separately billed items. See AR 44 (citing Medicare Provider Reimbursement Manual § 2714.2(i)). Relying on the PRM, the fiscal intermediary denied DCI's request for reimbursement for the $1,033,628 of bad debts relating to separately billed items during the Relevant Periods.

On September 18, 1996, DCI filed a request for appeal with the Provider Reimbursement Review Board (the "PRRB") on behalf of four of the facilities. DCI later added additional facilities to the appeal. On November 18, 2004, the PRRB issued a decision reversing

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[4] Defendant concedes that "[t]he appropriateness of DCI's efforts, if any, to collect the outstanding amounts from beneficiaries is not an issue in this litigation." Def.'s Cross-Mot. at 4 n.6. Accordingly, only the first criterion--that the debt be related to covered services and be derived from deductible and coinsurance amounts--is at issue in this case.

[5] CMS (formerly HCFA) issues a Provider Reimbursement Manual that sets forth its interpretations of its Medicare and Medicaid rules and regulations. The PRM is not promulgated pursuant to notice and comment rulemaking procedures under the Administrative Procedure Act ("APA"), 5 U.S.C. § 553.

the fiscal intermediary's denial of DCI's bad debts claims. Specifically, the PRRB held that

> The regulation [42 C.F.R. § 413.170(e)] in effect during the cost report periods appealed is controlling over contrary manual provisions that do not have the force of law. Christensen v. Harris County, 529 U.S. 576, 587 (2000). The regulation clearly provides reimbursement for bad debts relating to all covered ESRD items and services. It is undisputed that the separately billed items in issue are covered under Medicare. Whether the covered services relate to Medicare's composite rate or to separately billed but nonetheless allowable services or items is irrelevant under the regulation. The Board concludes that the Providers' claimed bad debts are reimbursable.

Provider Reimbursement Review Board Decision, Nov. 18, 2004, AR 22.

On December 2, 2004, the fiscal intermediary requested that the CMS Administrator ("Administrator") review the PRRB's decision. In her ruling on January 13, 2005, the Administrator reversed the PRRB, stating that the relevant portions of the Code of Federal Regulations and the PRM provide that bad debts are reimbursable only to the extent they relate to services falling within the composite rate. AR 2-7.

In her decision, the Administrator relied upon (1) the 1997 amendment to § 413.170(e), whose preamble indicated that HHS's policy had always been to allow bad debt reimbursement only for covered services under the composite rate, AR 5-6; and (2) Section 2710.2 of the PRM, which states that "[r]eimbursable bad debts . . . relate to composite rate services and are not for separately billed items," AR 6. She found "that longstanding CMS policy does

not allow for the payment of bad debts related to these services, such as the administration of [Epoietin]." Id. Accordingly, she found that "bad debts related to services which are separately [sic], such as the administration of [Epoietin], at issue in this case are not reimbursable as part of the Providers' Medicare bad debts." Id.

In this case, DCI appeals the Administrator's January 13, 2005 decision and asks the Court to reverse and remand for reinstatement of the PRRB's decision.

II. STANDARD OF REVIEW

Summary judgment should be granted if the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits or declarations, 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. See Fed. R. Civ. P. 56. The parties agree that there are no disputed material facts and this case presents a pure question of law.

Title 42 U.S.C. § 1395oo(f) provides for judicial review of final Medicare provider reimbursement decisions under the terms of the Administrative Procedure Act, 5 U.S.C. § 701 et seq. The APA commands reviewing courts to "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

In reviewing an agency's interpretation of its own

regulations, the Court must defer to that interpretation as long as it is reasonable. Shalala v. Guernsey Memorial Hosp., 115 S. Ct. 1232, 1236 (1995). The Court must "give substantial deference to an agency's interpretation of its own regulations." Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 506-07 (1994) (internal citations omitted). "An agency's interpretation of the meaning of its own regulations is entitled to deference 'unless plainly erroneous or inconsistent with the regulation.'" Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 127 S. Ct. 2518, 2537-38 (2007) (quoting Auer v. Robbins, 519 U.S. 452, 461 (1997)). The Court of Appeals for this Circuit has made clear that "in framing the scope of review, the court takes special note of the tremendous complexity of the Medicare statute. That complexity adds to the deference which is due to the Secretary's decision." Methodist Hosp. of Sacramento v. Shalala, 38 F.3d 1225, 1229 (D.C. Cir. 1994).

This deference, however, is not without limitation. Although the Court should not "disregard an agency's interpretation of its own regulation 'unless an alternative reading is compelled by the regulation's plain language,'" PNC Fin. Servs. Group v. Comm'r, No. 06-1034, 2007 U.S. App. LEXIS 20182, at *32 (D.C. Cir. Aug. 24, 2007) (quoting Air Transp. Ass'n of Am., Inc. v. F.A.A., 291 F.3d 49, 53 (D.C. Cir. 2002)), a court does not defer to the administrative construction of the regulation if that construction

"is plainly erroneous or inconsistent with the regulation." Bowles v. Seminole Rock Co., 325 U.S. 410, 414 (1945). Deference "is warranted only when the language of the regulation is ambiguous." Christensen v. Harris County, 529 U.S. 576, 588 (2000).

III. ANALYSIS

The dispositive question in this case is whether the Administrator's interpretation of the applicable regulations to deny reimbursement for bad debts relating to separately billed items is a reasonable construction of the regulatory language or is "plainly erroneous or inconsistent with the regulation." Auer, 519 U.S. at 461. The Court concludes that the Administrator's interpretation is inconsistent with the applicable regulations.

Section 413.170(e)(1) provides that HCFA (now CMS) will reimburse each facility its "allowable Medicare bad debts." 42 C.F.R. § 413.170(e)(1) (1996). Section 413.80(e) plainly provides that "debt . . . related to covered services and derived from deductible and coinsurance amounts" is allowable bad debt, provided it meets certain collection criteria not at issue in this case. 42 C.F.R. § 413.80(e) (1996). To request reimbursement, a facility must "submit[] an itemized list of all specific noncollections related to covered services." 42 C.F.R. § 413.170(e)(3) (1996) (emphasis added).

None of the regulations governing reimbursement for bad debts carve out any exception for separately billed items. To the

contrary, §§ 413.170(e)(3) and 413.80(e) expressly encompass "covered services." Interpreting "covered services" to encompass only "composite rate services" would effectively amend the regulation, thereby circumventing the notice-and-comment procedures required by the APA. See 5 U.S.C. § 553(b).[6] Reading §§ 413.170(e) and 413.80(e) together, their plain language clearly provides that HCFA will reimburse facilities their bad debts relating to covered services, which includes separately billed items, up to the facilities' costs.

Defendant's arguments in support of the Administrator's interpretation of the regulations are unpersuasive. First, Defendant argues that the PRM, unchanged since 1983, clearly states that bad debts are reimbursable only where they "relate to Composite Rate services and are not for separately billed items." Def.'s Cross-Mot. at 13 (quoting PRM § 2714.2). The Administrator relied on this provision of the PRM in its reversal of the PRRB decision. AR 6.[7]

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[6] As indicated above, § 413.170(e) was amended pursuant to notice-and-comment rulemaking on August 15, 1997. Since that amendment occurred after the Relevant Periods, however, the amended regulation does not apply to the reimbursements requested in this case.

[7] The Administrator cited to PRM Section 2710.2, which states that "[r]eimbursable bad debts . . . relate to composite rate services and are not for separately billed items." AR 6. It appears from the parties' submissions that they are referencing the same section cited by the Administrator, although they do not indicate whether CMS has redesignated Section 2710.2 as 2714.2.

It is well-settled that the guidelines cannot "trump" the language of a regulation when the regulation is clear on its face. Christensen, 529 U.S. at 588 (citing Auer, 519 U.S. at 461). To defer to the agency in the face of those regulations' unambiguous language "would be to permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation." Id. In this case, the language of the regulations unambiguously provides for reimbursement of covered services. The Administrator's reliance on the PRM to deny reimbursement for a certain class of covered services, i.e. separately billed items, was therefore improper under Christensen.

Second, Defendant argues that DCI ignores the discretion granted by the term "allowable" Medicare bad debts. Def.'s Cross-Mot. at 17-18 (emphasis in Defendant's Mem. of Law). It is Defendant that ignores the language of the regulations, however, not Plaintiff. As discussed above, 42 C.F.R. § 413.80(e) sets forth the criteria for allowable bad debt. Section 413.80(e) does not leave the definition of allowable bad debt to the Secretary's discretion.

Third, Defendant raises, for the first time in his Reply brief, a similar argument regarding the second clause of § 413.170(e)(1). Specifically, Defendant argues that the clause providing for reimbursement up to the facility's costs "as determined under Medicare principles" is ambiguous with respect to

which precise "Medicare principles" were being referenced. Def.'s Reply at 6. Nor, Defendant argues, does the provision specify how the agency would measure the "facility's costs" under "Medicare principles." Id. at 7. Since agency interpretations of ambiguous regulations are granted deference, Defendant argues, the Court should defer to CMS's interpretation of those ambiguous provisions of § 413.170(e)(1).

The Medicare principle that Defendant would apply is the "anti-cross subsidization principle," i.e. that individuals not covered by Medicare should not have to bear the costs of services provided to Medicare patients. The regulations, in explaining the rationale for Medicare's reimbursement of bad debts, also reference the concern that unpaid portions of "covered services" not be subsidized by non-Medicare patients. See 42 C.F.R. § 413.80(d) (1996). Specifically, the regulations explain that

> Under Medicare, costs of covered services furnished to beneficiaries are not to be borne by individuals not covered by the Medicare program, and conversely, costs of services provided for other than beneficiaries are not to be borne by the Medicare program . . . . The failure of beneficiaries to pay the deductible and coinsurance amounts could result in the related costs of covered services being borne by other than Medicare beneficiaries. To assure that such covered service costs are not borne by others, the costs attributable to the deductible and coinsurance amounts that remain unpaid are added to the Medicare share of allowable costs.

42 C.F.R. § 413.80(d).

Defendant argues that "[b]ecause the available evidence suggests that ESRD outpatient facilities are receiving

reimbursement [via other Medicare payment provisions] for separately-billed services which exceeds their costs and covers the lost revenue associated with their bad debts, there is no reason for the costs of these services to be shifted to non-Medicare persons. Accordingly, there is little statutory authority for bad debt reimbursement in this instance." Def.'s Reply at 16-17 (citing 42 U.S.C. § 1395x(v)(1)(A)).

Defendant's argument "is forfeit because [he] did not raise it earlier." La. PSC v. FERC, 482 F.3d 510, 521 (D.C. Cir. 2007) (citing Grant v. U.S. Air Force, 197 F.3d 539, 542 n.6 (D.C. Cir. 1999) ("[O]ur caselaw makes clear that an argument first made in a reply comes too late."). Moreover, and most significantly, it was not the basis for the Administrator's decision. The Court "'may not supply a reasoned basis for the agency's action that the agency itself has not given.'" Dithiocarbamate Task Force v. E.P.A., 98 F.3d 1394, 1401 (D.C. Cir. 1996) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). The Court may consider only the rationale an agency gives for its actions at the time they occur and not "post hoc rationalizations by . . . government agency counsel." Ace Motor Freight, Inc. v. I.C.C., 557 F.2d 859, 864 (D.C. Cir. 1977).

Even if the Court were to consider Defendant's belated argument, however, it is unconvincing. Assuming, arguendo, that the anti-cross subsidization principle is a reasonable basis for

treating composite rate services and separately billed items differently,[8] Defendant's argument simply cannot overcome the plain language of the regulation to justify denying all reimbursement for bad debts relating to separately billed items. As discussed above, §§ 413.170(e) and 413.80(e) are clear that reimbursement will be provided for Medicare bad debts related to covered services.

Even if the Court interpreted the language Defendant cites--"up to the facility's costs, as determined under Medicare principles"--to leave to the Secretary's discretion what "Medicare principles" apply in determining the facility's costs, that interpretation merely permits the Secretary to set a limit on the amount of the facility's costs for separately billed items. The plain language of §§ 413.170(e) and 413.80(e) requires

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[8] DCI argues that the anti-cross subsidization principle supports reimbursement for separately billed items. See Pl.'s Opp'n at 7-9. Our Court of Appeals has expressed a broader concern with § 413.170(e)'s limit on reimbursement. In Kidney Ctr. v. Shalala, 133 F.3d 78, 87 (D.C. Cir. 1998), the Court of Appeals, discussing § 413.170(e), concluded that "the Secretary has provided an incoherent justification for her decision to cap reimbursement for bad debts. The only statutory authorization the Secretary relied upon in the rulemaking record for her decision to cap reimbursement for bad debts is the prohibition of crosssubsidization in 42 U.S.C. § 1395x(v). . . . [W]e conclude that the Secretary's explanation for the cap upon bad debt reimbursement [i.e. the prohibition of crosssubsidization] . . . is inconsistent with the prospective rate scheme of the [Medicare] statute." Because this Court finds that the Administrator's decision to deny reimbursement for all bad debts relating to separately billed items was unreasonable independent of the anti-cross subsidization principle, it does not reach the question of the validity of treating separately billed items differently on the basis of that principle.

reimbursement for separately billed items up to that limit. Whether or not the Secretary may limit the reimbursement pursuant to § 413.170(e)(1), that Section clearly does not allow wholesale elimination of reimbursements for separately billed items, which is what the agency purports to have done in the PRM.

Finally, Defendant's construction of §§ 413.170(e)(1) and 413.80(e), permitting denial of all reimbursement for bad debts relating to separately billed items, renders the term "covered services" meaningless and turns it into nothing more than a synonym for "composite rate services." "It is 'a cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'" TRW Inc. v. Andrews, 534 U.S. 19, 31 (2001) (internal citation omitted). If the Secretary meant that allowable Medicare bad debts were to include only bad debts related to composite rate services, the regulation would not state that allowable Medicare bad debts include "debt . . . related to covered services." 42 C.F.R. § 413.80(e) (1996). CMS's reading of §§ 413.170(e) and 413.80(e) to exclude bad debts relating to separately billed items conflicts directly with the language of those sections.

The regulations at issue in this case cannot bear the meaning that the Defendant assigns to them, i.e. that "covered services" does not mean "covered services," but rather only "composite rate

services." Because the Administrator's interpretation of the regulations to allow for such an exception was inconsistent with the plain language of the regulation, it was improper under Seminole Rock, 325 U.S. at 414.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's Motion for Summary Judgment [Dkt. No. 15] is **granted**, and Defendant's Cross-Motion for Summary Judgment [Dkt. No. 18] is **denied**.

An Order will issue with this Memorandum Opinion.

/s/
Gladys Kessler
United States District Judge

October 30, 2007