PROVIDER REIMBURSEMENT REVIEW BOARD
HEARING DECISION

ON THE RECORD
2002-D34

PROVIDER –
Medical Center of Garden Grove
Garden Grove, California

Provider No. 05-0230

vs.

INTERMEDIARY –
Blue Cross Blue Shield Association/
United Government Services, LLC--CA

DATE OF HEARING-
January 24, 2002

Cost Reporting Periods Ended - February 28, 1981 , February 28, 1982 and February 28, 1983

CASE NO. 89-1181R

INDEX

ISSUES:

1. Did CMS invalidly apply pre-composite rate ESRD Screens to limit the Provider's reimbursement for the reasonable costs it incurred for the treatment of ESRD patients?

2. Whether and to what extent the Provider is entitled to an exception from the $138 per treatment ESRD screens for fiscal years 2/28/81, 2/28/82, and 2/28/83.

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

The Medical Center of Garden Grove ("Provider") is an acute care hospital located in Garden Grove, California. It also operates a hospital based outpatient dialysis center, established in 1967, which was one of the first in Orange County, California. The issues in this appeal center around whether the Secretary of Health and Human Services ("Secretary") improperly limited the reimbursement requested by the Provider for treatment of End Stage Renal Dialysis ("ESRD") patients for the fiscal years noted above.

This appeal was originally heard by the Provider Reimbursement Review Board ("Board") on June 4 and 5, 1996, and the Board issued its decision on September 26, 1997 See, The Medical Center of Garden Grove v. Blue Cross and Blue Shield Association/Blue Cross of California, PRRB Dec. No. 97-D106, September 26, 1997, Medicare & Medicaid Guide (CCH) ¶ 45,696. In that decision the Board found that: 1. the Secretary's application of the pre-composite ESRD rate screens to limit reimbursement for the Provider's ESRD costs was improper, and therefore the Provider should be reimbursed its reasonable costs, and 2. the denial of the Provider's request for exceptions was improper; exception requests were approved in the amounts set forth in the individual exception requests.

On November 28, 1997 the Centers for Medicare and Medicaid Services ("CMS") (formerly referred to as the Health Care Financing Administration ("HCFA") Administrator issued a decision vacating the Board Decision. See CMS Administrator, November 28, 1997, Medicare and Medicaid Guide (CCH) ¶45,946. The Administrator disagreed with the Board's finding that the pre-composite rate ESRD fee screens were arbitrary and capricious, and therefore invalid.[1] However, the Administrator did not address the basis of the Board's decision regarding the validity of the fee screens. Moreover, the Administrator's remand did not reverse or modify the Board's decision on this issue. The Administrator did state that this case should be remanded to CMS for evaluation of the Provider's exception request under the pre-composite rate standards as set forth in 42 C.F.R. § 405.402(g) and Intermediary Letters 78-9 and 82-1, and under general reasonable cost provisions and documentation requirements of the statute and regulations.

On February 11, 1998 the Board issued a Notice of Reopening Pursuant to the Administrator's

[1] Provider Exhibit P-76.

Order for Remand.[2] In that Notice the Board ordered:

> 1. that, within 120 days, the Intermediary and CMS were to render a determination of whether the Provider's costs that are in excess of the applicable ESRD payment screens are reasonable and justifiable in accordance with applicable regulations and program criteria; and
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> 2. that if the Intermediary and CMS deny any of the exception requests, and the Provider wishes to pursue this appeal, then within 60 days of written notification of the CMS denial(s) to the Provider, the parties are to file position papers with the Board concerning the CMS denials.

On January 1, 1998 the Provider filed a lawsuit in U.S. District Court contesting the CMS Administrator's remand order. The Board agreed to a stay of proceedings pending the outcome of the Provider's lawsuit. On February 25, 1999 the U.S. District Court dismissed the Provider's lawsuit, thereby moving the case back to the Board for disposition.

On November 10, 1999 pursuant to the Administrator's and Board's remand orders, the Secretary issued its redetermination of the reimbursement due to the Provider for dialysis services rendered to ESRD patients. Payment rates of $152.57, $147.96 and $147.77 were approved for the fiscal years ending 2/28/81, 2/28/82 and 2/28/83, respectively.[3]

On February 9, 2000 the Provider filed its position paper regarding CMS' denial of its requests. It is seeking payment rates of $178.45, $199.41 and $271.45 for the fiscal years ending 2/28/81, 2/28/82 and 2/28/83, respectively. The approximate amount of Medicare reimbursement in controversy is $1,106,270.

The Board determined that the Provider met the jurisdictional requirements of 42 C.F.R. §§ 405.1835-.1841 and established a December 27, 2000 hearing date. However, both parties agreed that the hearing could be completed "on the record." The Provider is represented by Laurence D. Getzoff, Esquire, and Gina M. Reese, Esquire, of the law firm of Hooper, Lundy & Bookman, Inc. The Intermediary is represented by Bernard M. Talbert, Esquire, of the Blue Cross and Blue Shield Association.

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[2] Provider Exhibit P-77.

[3] Provider Exhibit P-78

Legislative History of the ESRD Pre-Composite Rate Screens:

During the cost reporting years at issue, the Providers were reimbursed by Medicare for the "reasonable costs" incurred for the provision of services to Medicare beneficiaries. Title XVIII of the Social Security Act, section 1861, codified at 42 U.S.C. § 1395x(v)(1)(A). The regulations implementing this statute appear at 42 C.F.R. § 405.451 (redesignated at 42 C.F.R. § 413.9).

In October, 1972 Congress established the ESRD program by extending Medicare coverage to insured individuals who required hemodialysis or renal transplantation for this disease. Social Security Act Amendments of 1972, Pub. L. No. 92-603, §2991, 1972 U.S.C.C.A.N (Stat.) 1463, 1713 (codified at 42 U.S.C. § 426(e), (f), and (g)). The pertinent section of the statute for purposes of this appeal was to be effective on July 1, 1973 and read, "the Secretary [of Health and Human Services ("Secretary") is authorized to limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers that meet such requirements as he may by regulation prescribe. . . ." 42 U.S.C. § 426(e), (f), and (g).

The implementing regulations for the ESRD program were designated as "interim" regulations and implemented without notice and comment. 38 Fed. Reg. 17,210 (June 29, 1973).

Next, the Bureau of Health Insurance ("BHI"), predecessor to the HCFA, issued Intermediary Letters ("ILs") stating the interim policies and procedures concerning chronic renal disease. The ILs issued on June 29, 1973 were effective as of July 1, 1973 and established specific dollar limits of $150 and $145 to all provider and non- provider facilities rendering ESRD services. See ILs Part A 73-25 and Part B 73-22 (June 1973). A year later, additional ILs were issued altering the reimbursement rate to $138 per treatment. This is the rate in dispute in this appeal. See ILs Part A 74-26 and Part B 74-24 (August 1974). The interim reimbursement screens remained in effect until the establishment of the composite rate reimbursement system in August, 1983. 48 Fed. Reg. 21,254 (May 11, 1983).

Litigation ensued over the subject ESRD screens wherein the Federal District Court for the District of Columbia invalidated the 1973 ILs in an action brought by a non-provider. First the court found that the ESRD reimbursement policies set forth in the 1973 ILs constituted substantive rules not promulgated in accordance with the Administrative Procedure Act, 5 U.S.C. § 553 et seq. ("APA"). The court went on to invalidate the 1973 ILs "insofar as it imposes a formula for the calculation of an estimated customary charge for non-providers under the chronic renal disease Medicare program." Schupak v. Matthews, [1976 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,987, at 10,007 (D.D.C. Sept 17, 1976) ("Schupak").

Fifteen years later, the same court addressed the validity of ESRD screens in Cleveland Clinic Foundation v. Sullivan, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,519 (D.D.C. July 30, 1991) ("Cleveland"). The District Court noted that the subject screens were "adopted" without publication or explanation . . . "[and] there is no evidence in the record of the basis for or methodology by which the Secretary derived the $138.00 screen in 1973." Id. at

27,487. The Court, after noting the lack of substantive justification for the screens, set aside the HCFA Administrator's ruling and remanded to the Secretary "in order that he may supplement the administrative record to explain the basis and justification for the $138.00 screen." Id. at 27,488. There is no record of further litigation of the issue evidencing that the Secretary provided a justification for the screens.

On June 13, 1978 Congress enacted the End Stage Renal Disease Program Improvements which are codified at 42 U.S.C. § 426-1, 1395rr. This law mandated that HCFA determine the amount of payment for ESRD services under Part A of the Medicare program "in accordance with section 1861(v) and required regulations to establish the programs used in setting limits on. . . . costs . . . of specific items or services to be recognized as reasonable. . . ." 42 U.S.C. § 1395x(v)(1)(A).

With respect to the process for requesting an exception from the pre-composite rate ESRD screens, the Secretary's instructions were contained in ILs. Specifically, IL 78-9 and IL 82-1 required providers to submit an ESRD cost questionnaire with its annual cost report. If a provider incurred cost above the ESRD screens, the provider was responsible for submitting documentation to support the reasonableness of the additional reimbursement. The letters instructed the intermediaries to examine the reasonableness of the costs as compared to peer group facilities. Id.

PROVIDER'S CONTENTIONS:

ISSUE 1:

The Provider challenges the pre-composite rate ESRD screens on three primary grounds. First, the Provider contends that the screens were established without notice and comment, violating the procedural requirements of the APA. Second, that the 1973 interim regulation was without statutory authority when promulgated, was expressly repealed, and thus, invalid with the enactment of the 1978 Act. Finally, the Provider asserts that the screens were established in a manner that was arbitrary, capricious, an abuse of discretion, and contrary to the law, and therefore violated the substantive requirements of the APA.

With respect to the Provider's contention that the screens violated the procedural requirements of the APA, the Provider argues that the ILs established the screens without the required notice and comment, and as such, are invalid. 5 U.S.C. § 553(b), (c). United States v. Picciotto, 850 F. 2d 345, 346 (D.C. Cir.1989); Mt. Diablo Hospital District v. Bowen, 860 F. 2d 951, (9th Cir. 1988); and Linoz v. Heckler, 800 F. 2d 871, 878 (9th Cir. 1986). Moreover, the directives contained in those letters do not qualify under the APA exceptions for interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice. See 5 U.S.C. § 553(b). The Provider argues that interpretive rules are those that clarify or explain existing law or regulations and are by that "non-binding" and do not foreclose alternate courses of action or conclusively affect the rights of private parties. Flagstaff Medical Center, Inc. v. Sullivan, 962 F. 2d 879 (9th Cir. 1992) ("Flagstaff") and Batterton v. Marshall, 648 F. 2d 694 (D.C. Cir. 1980). Conversely,

substantive rules are those that effect a change of existing law or policy. Powderly v. Schweiker, 704 F. 2d 1092 (9th Cir. 1983) and Flagstaff, 962 F. 2d at 866.

The Provider contends that because the ILs at issue constituted an entire reimbursement scheme for outpatient dialysis, they amounted to substantive rules under the APA and the controlling case precedent. The limits and requisite justifications were clearly substantive because they affected a provider's ability to seek reimbursement for dialysis services. The Provider also asserts that the District Court for the District of Columbia specifically found partially invalid the 1973 IL because it amounted to a substantive rule and was not promulgated in accordance with the APA. Schupak, supra, at 10,007. Specifically, the court stated that the 1973 IL "directly controls the reimbursement to be paid to dialysis facilities, . . . is definitive, new and controlling, and is precisely the sort of regulation required to be imposed only pursuant to the rule making requirements of the APA." Id.

The Provider also contends that the interim regulation was not meant to remain in effect for ten years. Further, the language of the regulation stated that "rules may be developed for establishing limits on costs and services above which reimbursement shall be made only upon appropriate justification." 38 Fed. Reg. 17,210, 17,211-212 (June 29, 1973), (codified at 20 C.F.R. § 405.402(g) (emphasis added). Moreover, the regulation authorized the issuance of "temporary instructions modifying the provisions of this subpart . . ." in order to implement the ESRD Program. Id. Therefore, the Provider asserts that the regulation was temporary by its own terms and required that rules be developed for formulating ESRD reimbursement limits.

Next, the Provider contends that the regulation was without statutory authority when promulgated and expressly invalid as of October, 1978. First, the statute did not authorize the Secretary to promulgate a regulation allowing for temporary screens. Second, Congress repealed section 2991 in 1978, removing the only statutory authority for the 1973 regulation. Further, the 1978 amendment expressly mandated new regulations to implement the ESRD reimbursement mechanism. Therefore, if the Board concludes that the 1973 interim regulation provides support for the promulgation of the ESRD screens without following the notice and comment provisions of the APA, the 1973 regulation could not do so after Congress repealed the only statutory basis for the 1973 regulation. See Bowen v. Georgetown University Hospital, 109 S. Ct. 468, 471 (1988). Accordingly, the Provider claims that there is no statutory authority for the interim regulation after 1978, and therefore the Board must rule application of the interim regulations to the Provider was unlawful.

Finally, the Provider contends that the pre-composite rate ESRD screens were established in violation of the substantive requirements of the APA. See Motor Vehicle Mfrs. Ass'n. v. State Farm Mutual Auto Ins. Co., 103 S. Ct. 2856 (1983) ("Motor Vcehicle Mfrs Ass'n"). The APA requires that an agency must "examine the relevant data and articulate a satisfactory explanation for its action . . ." Id. at 2866. To this end, the Provider argues that during the ten years that the pre-composite rate ESRD screens were in effect, CMS provided no information regarding the basis for its methodology for the establishment of the screens. Thus, the Provider argues the pre-

composite rate ESRD screens were improperly established. Moreover, the District Court for the

District of Columbia findings concerning the ILs at issue here, clearly support its position. Specifically, the court found that the ESRD screens were "adopted without publication or explanation . . . [and] there is no evidence in the record of the basis for or methodology by which CMS derived the $138 screen." Cleveland Clinic Foundation v. Sullivan, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,519 (D.D.C. July 30, 1991) (emphasis added).

ISSUE 2:

The Provider contends that its costs should be judged solely under the reasonableness standard contained in the regulations at 42 C.F.R. § 413.9. Further, the Provider argues that it has demonstrated that the costs it incurred were reasonable, necessary, prudent, and directly related to the provision of atypically intense dialysis services to its complex ESRD patient population. Disallowances under the reasonableness standard require that the Intermediary prove the Provider's costs are "substantially out of line" with the costs of comparable providers. 42 C.F.R. §413.9(c)(2). The Provider further contends that the record shows that the costs claimed were audited and found reasonable.[4] Accordingly, since the Intermediary has not offered any evidence that the ESRD costs at issue are substantially out of line when compared to similar providers, the disallowances are improper.

The Provider also asserts that there is Board precedent for exception requests prior to August 1, 1988 to be judged solely on reasonable cost standards. See St. Alphonsus Regional Medical Center (Boise, Idaho) v. Blue Cross and Blue Shield Association/Blue Cross of Oregon, PRRB Dec. No. 89-D28, March 15, 1989, [1989-2 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 37,804, aff'd, HCFA Administrator, May 19, 1989 [1989-2 Transfer Binder], Medicare & Medicaid Guide (CCH) ¶ 37,868 ("St. Alphonsus"). The Board upheld the same reasoning in two other decisions. See Sutter General Hospital v. Blue Cross and Blue Shield Association/Blue Cross of California, PPRB Dec. No. 96-D34, June 7, 1996, Medicare & Medicaid Guide (CCH) ¶ 44,482, CMS Administrator declined review, July 16, 1996, (" Sutter General") and Sutter Memorial Hospital v. Blue Cross and Blue Shield Association/Blue Cross of California, PRRB Dec. No. 96-D35, June 7, 1996, Medicare & Medicaid Guide (CCH) ¶ 44,485, HCFA Administrator declined review July 16, 1996 ("Sutter Memorial").

PROVIDER RESPONSE TO HCFA RECONSIDERATION:

Pursuant to the Board Order, CMS reevaluated the Provider's exception request and issued its redetermination of the reimbursement due for dialysis services in a letter dated November 10, 1999.[5] In summary, CMS approved the following payment rates:

	FY 1981	FY 1982	FY1983

[4] Tr. at 520-521 of PRRB Dec. No. 97-D106.

[5] See complete CMS letter identified as Intermediary Exhibit 1.

Payment Screen	$138.00	$138.00	$138.00
Salaries	0	.50	.31
Supplies	14.57	9.46	9.46
Total	$152.57	$147.96	$147.77

The Provider contends that CMS' findings are without merit. It asserts that the CMS denials should be overturned, and that the Provider should be reimbursed for the reasonable costs it incurred for the provision of ESRD services to Medicare beneficiaries. The Provider request is summarized as follows:[6]

	FY1981	FY1982	FY1983
Direct Costs	$105.81	$123.32	$135.54
Indirect Costs	72.64	76.09	135.61
Total	$178.45	$199.41	$271.15

General Comments:

The Provider disagrees with CMS' position that the amounts requested for outpatient maintenance hemodialysis for FYEs 1982 and 1983 by the Provider in its narrative were taken from the wrong column in the cost report documentation. (CMS stated that, for purposes of the reconsideration, it prepared its own analysis of the outpatient maintenance hemodialysis costs based on the cost report documentation supplied by the Provider with its exception requests.) The Provider contends that CMS does not clarify in its reconsideration whether it is claiming that the Provider used the "wrong" numbers in the initial exception requests or in the requests submitted by the Provider during the hearing process, as contained in the Provider's position papers and other documents contained in the hearing record. Furthermore, it is unclear which cost reports CMS used to prepare its analysis. In particular, CMS does not indicate whether it used the most recent revised cost reports available to perform this analysis. In any case, the reimbursement requested by the Provider is based on the actual costs incurred by the Provider in furnishing ESRD services to Medicare beneficiaries. The amounts requested are based on the reconciliation of the revised, audited cost reports with the Intermediary's ESRD audit schedules and have been corrected by virtue of such reconciliations and revised cost reports.

Specific Comments:

Direct Costs

[6] Provider Position Paper, dated February 9, 2000 at 78-79.

The major components of direct costs are: 1) labor costs (and associated benefits) and 2) supply costs. CMS denied all but a small amount of the reimbursement requested in the Provider's Exception Requests for Direct Costs. However, as discussed below, the Provider contends that the costs it incurred for these fiscal years are reasonable and directly related to the provision of atypically intense dialysis treatments.

Labor Costs

CMS did not allow any of the amount requested for salaries and employee benefits for FYE 2/28/81, because the amount it calculated as the Provider's salary and employee benefit costs for 1981 ($46.60) was allegedly less than the national median labor CPT for 1982 and 1983 ($47.00). No national median labor cost per treatment ("CPT") for 1981 was provided in the reconsideration. The amount calculated as the Provider's costs for salaries and employee benefits over $47.00 was allowed for FYs 1982 and 1983. However, CMS claimed that the Provider had not furnished an explanation of the increase in the CPT for registered nurses ("RN") salaries from 1982 to 1983 and had not explained what action had been taken to hold its salary costs down. Therefore, the increase in RN salary costs from 1982 to 1983 was disallowed.

The Provider contends, however, that all of the labor costs incurred and requested in its exception requests were reasonable and should be allowed. As demonstrated at the prior hearing and in the Provider's various submissions, the labor costs incurred were reasonable and necessary to treat its atypical patient population, and the Provider fully explained all increases in labor costs.

The Provider also contends that the Medicare regulations (which remained in effect until after the end of the Provider's 1983 fiscal year) do not require that providers undertake time studies to substantiate the reasonableness of their labor costs, and therefore do not list any specific requirements for any such time studies that are performed.[7] However, in order to further support the reasonableness of its labor costs, the Provider submitted with its exception requests the results of time studies which clearly delineate that the patients it treats consume an additional amount of labor for unusually intensive and complex care, above and beyond that required by the typical ESRD patient ("atypical labor CPT"). See "Patient Classification," "Base Time Calculation," "Time Determination," "Frequency of Occurrence," "Computation of Incremental Labor," and "Reconciliation" in each exception request.[8]

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[7] Tr. at 412-414.

[8] Provider Exhibits P-54, P-55, and P-56.

The Provider submits that its time studies, therefore, demonstrate that its high labor CPT in the fiscal years at issue herein was justified and is directly related to the atypical labor CPT required for the Provider's unusually complex and ill patient population.

Based on these studies, the Provider calculates that the atypical labor CPT it incurred in these fiscal years is approximately 64%, 68%, and 72% of its total actual direct labor costs (salaries only) for fiscal years 1981, 1982, and 1983, respectively. Without these atypical labor costs, the Provider would not have incurred such high labor costs for these fiscal years. Since these additional costs have been shown by the Provider's time studies to be directly and clearly related to the provision of specific, unusually complex care for its atypical patient population, these costs must be considered reasonable and should not be subjected to the rate screens.

The Provider further contends that it did explain the overall increase in labor costs between 1981, 1982, and 1983. There was an increase in labor costs in the area of $20.00 per treatment from the earlier years to the later years. The increase, however, is attributable solely to the increases in the total costs of the Provider's RN salaries; costs actually decreased or stayed even in all other categories of salaries and benefits.[9] The increase in overall RN salaries does not appear to have been caused by an increase in the hourly rate levels of nurses' wages. The average hourly salaries for RNs increased, over a three year period, from only $0.40 to $0.98 per hour, which is a more than reasonable amount of increase for cost of living raises from year to year. What changed is that the Provider was forced to use a richer skill mix as its patients became more atypical, complex and difficult to treat.

Finally, with respect to the Provider's 1981 labor cost, the Provider disagrees with CMS' reconsideration assessment wherein it was stated that the Provider's actual salary cost per treatment was below a national median. Such a median was never a part of the pre-composite rate process and did not come into play until August 1983. Thus, CMS' denial of relief is invalid.

2. Supply Costs

In the reconsideration, CMS determined that the national median CPT for supplies was $33, without indicating any difference in CPT between 1981, 1982 and 1983. Based on that finding, CMS allowed a small amount in reimbursement for supplies in each of the three fiscal periods, based on the amounts calculated as the Provider's supply CPT for those fiscal periods. However, the Secretary claimed that there was no documentation to explain the significant increase in the supply CPT from 1982 to 1983, and therefore disallowed reimbursement for these increased costs.

The Provider contends that all of the requested costs for supplies must be reimbursed. As demonstrated in the Provider's Initial Position Paper, at the hearing, and in the Provider's Post-

[9] Provider Position Paper at 87.

Hearing Brief, the costs the Provider incurred for supplies were all reasonable and necessary for the treatment of its atypical patient population.

The supply CPT included in the Provider's exception requests included the component prices of all supplies used during the hemodialysis outpatient treatments. The major component of the supply costs, the dialyzer, is a large surface area dialyzer that was prescribed for efficient removal of small and medium toxic molecules. The Provider's patient population required dialyzers that were highly efficient because they were so gravely ill when referred to the facility.

Other Direct Costs

Medical Director fees are included in other direct costs. As may be seen in the exception requests, there was an increase in these fees every year between 1981 and 1983.[10] As the Provider demonstrated at the hearing, during those years more freestanding units were opened and there was a concomitant increase in demand for medical directors for these units, while there was a shortage of qualified nephrologists for these positions. As the demand rose, the salary demanded by the Medical Directors also rose. The Provider felt that it was imperative to have a highly qualified medical director for its unit, due to the extremely ill population of ESRD patients it serviced. Therefore, the Provider found it necessary and reasonable to pay higher Medical Director salaries each year to maintain the quality Medical Director in his position at the hospital. Other direct costs included medications and laboratory tests. As described previously, the Provider's atypically ill dialysis patients required a higher number of medications and laboratory tests than would a more typical patient population in order to treat the high number of complications and severe co-morbidities these patients experienced.

Indirect Costs

In the reconsideration, CMS determined that the national median CPT for overhead, excluding employee benefits, was $47 and did not allow any additional reimbursement.

In the reconsideration, CMS did agree that the Provider should receive additional reimbursement for the use of isolation rooms and for providing dietary and social services for its atypical ESRD patients. However, no additional reimbursement was granted, based on CMS' claim that the Provider did not provide any documentation or computations that could be used to make that determination. No additional reimbursement was granted in the areas of admissions, medical records, accounts receivable and collections, laundry and housekeeping, capital buildings and capital movable, employee benefits, or central supply, based on CMS' claim that the Provider failed to relate the excess costs to the "exception criterion" or state how these costs related to the special needs of its atypical ESRD patients.

However, the Provider contends that it has demonstrated in its Initial Position Paper, at the

10 Provider Exhibits P-54, P-55, and P-56.

hearing, and in its Post-Hearing Brief that all of these costs were directly related to the treatment of its atypical ESRD patient population.

The Provider points out that the major components of its indirect CPT are: 1) capital; 2) administrative and general costs; 3) central services; 4) maintenance, repairs, laundry and housekeeping; and 5) miscellaneous overhead costs, including employee benefits, social services, dietary and medical records. As discussed in detail below, each of these costs are reasonable and should be allowed.

1. Capital Costs

The Provider contends that capital costs were allocated to the outpatient dialysis center on a time-weighted square foot basis. There was a significant increase in capital costs from 1982 to 1983, from $8.35 CPT to $26.80 CPT. As the Provider demonstrated at the hearing, this increase was largely due to the construction of a new hospital facility which was occupied in 1983 and the demolition of the old hospital, with the resultant increase in depreciable costs and amortization of the loss on disposal of the old hospital building over three and one half years, which were allocated to the appropriate cost centers, including outpatient dialysis.

The outpatient dialysis unit, however, occupied less square footage in the new hospital than in the old, which is evidence of the Provider's determination to operate the dialysis unit as efficiently as possible. The Provider accordingly allocated a smaller percentage of the capital costs to the new unit than to the old unit. Thus, it is apparent that although the capital CPT increased in 1983, this increase was solely attributable to the construction of a new and necessary hospital facility, which was a prudent and economical decision at the time. The Intermediary has audited these costs and found them to be reasonable.

2. Administrative and General Costs

The Provider contends that its role as a back-up unit for the surrounding freestanding dialysis centers caused it to experience a very high patient turnover rate, to admit a high number of new or "starter" dialysis patients and to admit a high number of more severely ill patients as inpatients. This in turn caused increased administrative and general ("A&G") costs to provide needed services for those patients. For example, the high patient turnover rate resulted in a significant increase in billing, collection and admitting services, as well as other administrative services. The Provider submits that such additional costs are the direct result of its atypical patient population.

In addition, according to Medicare cost accounting principles, A&G cost allocation is based on the accumulated cost of the department at the point of the allocation. As demonstrated throughout, the Provider incurred higher direct costs for the outpatient dialysis unit due to the provision of atypically intense dialysis treatments. Therefore, the Provider reasonably allocated a greater amount of A&G costs to the dialysis cost center based on the higher level of departmental

costs. Again, the Intermediary audited these costs on the cost reports and found them to be reasonable.

3. Central Services

The Provider contends that the costs incurred in this category were reasonable and directly related to the provision of care in the ESRD unit. First of all, the Provider actually incurred less costs in this category in 1982 than in 1981. In reviewing the most recently audited cost reports for 1983, the Provider discovered four pieces of information that appear to explain this increase in Central Services costs, as follows:

1. The Medicare auditor reclassified certain costs previously classified as "Medical Supplies Charged to Patients" to the Central Supplies cost center. After allocation to the ESRD cost center, this resulted in an increased CPT of approximately $8.23. These were reasonable costs pursuant to the auditor's findings.

2. A portion of the costs associated with the construction of the new building and the resultant loss on disposal of the old building was allocated to the Central Supplies cost center. After allocation to the ESRD cost center, this resulted in an increased CPT of approximately $3.28.

3. There was a decrease in the number of treatments in 1983, which caused an increased CPT for Central Supplies cost of approximately $3.50.

4. There was apparently an error in the posting of RN salaries to the Central Supplies cost center which caused an increased CPT of approximately $10.94. This error was not noted prior to this time either by the auditor or the Provider.

As demonstrated, except for item 4, the reasons for the increased Central Supplies CPT are all reasonable and related to the provision of patient care. The Provider has decreased the CPT it is requesting herein for 1983 by the amount of the apparent error in posting in RN salaries (item 4); the amount requested for 1983 for Central Supplies after deduction for this error is $35.70. This would cause a concomitant decrease in the total CPT requested for 1983 to $271.15.

4. Maintenance, Repairs, Laundry and Housekeeping

The Provider contends it incurred a higher CPT in these categories than typical dialysis units as a direct result of its provision of atypically intense dialysis treatments. As a back-up unit, the Provider was required to maintain all of its dialysis stations ready at all times, since the stations may be required at a moment's notice when a severely ill patient is referred into the facility. Maintenance, repair, laundry and housekeeping costs are therefore incurred on a daily basis, even

for stand-by dialysis stations, in order to maintain them ready for patient admissions.

In addition, two of the Provider's dialysis stations were designated as isolation rooms and used on a frequent basis for its complicated patients with hepatitis and other major infections. Maintenance of these stations, which is more complicated than maintenance of a normal station, was required on a daily basis, since these rooms must also be ready immediately if required for an urgent dialysis treatment.

As described previously, the Provider's patients experienced a high rate of complications, such as vomiting and bleeding, and required a large number of complicated procedures, such as dressing changes, foot soaks, blood administration, IV medications and medical procedures involving arterial access. Therefore, the Provider reasonably incurred higher laundry costs for the increased linens used as a result of these complications.

5. Other Indirect Costs

The Provider also reasonably incurred a higher CPT for medical records and social services as a direct result of the medical needs of its atypical patient population. The extremely complicated nature of the patients and the high turnover rate created an increased need for medical record services. In addition, the complicated social, economic and emotional consequences involved with all of these dialysis patients caused the need for social services to be greater than in a more typical hospital or freestanding unit.

Employee benefits costs include the personnel and employee benefits department space allocation. These costs are allocated according to Medicare stepdown principles, based on salaries. Since the Provider reasonably incurred higher salary costs, as discussed above, based on its atypical patient population, the allocation of employee benefits is also justified.

The dietary costs allocated to the dialysis unit are also justified based on the Provider's atypical patient population. Because these patients were more elderly and more severely ill than the typical ESRD population, they required more consultations and interventions by the dietician to address their complex dietary needs, and hence more dietary costs should be allocated to the unit for these services than in a more typical dialysis unit.

Conclusion:

As the Provider has demonstrated herein, the pre-composite rate ESRD screens, established in a 1973 Intermediary Letter, violate the procedural and substantive requirements of the APA and conflict with the clear Congressional requirement that such limits be promulgated through formal rulemaking. As such, the Secretary invalidly used these screens to limit the Provider's reimbursement for ESRD dialysis treatments for FYEs 2/28/81, 2/28/82 and 2/28/83. Therefore, the Secretary's denials of the Provider's exception requests should be overturned and the Provider should be reimbursed for the reasonable costs it incurred for the provision of these

dialysis services to Medicare beneficiaries.

Even if the Board determines that the pre-composite rate ESRD screens were properly applied for the cost reporting years in question, the Provider has demonstrated herein and in its exception requests that the costs it incurred above the screen were reasonable and necessary and were directly related to its provision of atypically intense dialysis treatments for its unusually complicated and ill ESRD population. Accordingly, the Provider requests that it be reimbursed for all of these costs.

INTERMEDIARY'S CONTENTIONS:

ISSUE 1:

The Intermediary contends that the Secretary had the statutory authority to fix the ESRD rate under the Social Security Act Amendments of 1972, which were codified at 42 U.S.C. § 426(e), (f), and (g). Specifically, the amendment authorizes the Secretary to "limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers which meet such requirements as he may by regulation prescribe . . ." 42 U.S.C. § 426(g) (emphasis added). The Intermediary contends that Congress' use of the phrase "may by regulation" rather than the term "shall," declares the Secretary's clear authority to limit reimbursement for ESRD services.

The Intermediary contends that the Secretary's actions in not promulgating final regulations until 1983 did not breach the provisions of the APA. The interim regulations clearly stated that HCFA had no experience with the delivery of ESRD services. Moreover, the regulations specifically described the services as very complex. Accordingly, the Intermediary maintains that an interim period for the regulation at issue was appropriate under the circumstances.

The Intermediary also claims that during the interim period, limits on reimbursement would be applied to "amounts and services covered beyond which payment will be made, i.e. will be considered reasonable and necessary, only if adequate justification is provided." 38 Fed. Reg. 17,210 (June 29, 1973), (codified at 20 C.F.R. § 405.402 (emphasis added). Therefore, if the Provider was dissatisfied with its reimbursement, it should have availed itself of the exception process to justify the costs of furnishing ESRD services.

The Intermediary contends that the methodology of communicating the establishment of the ESRD rates was pursuant to statute, at the option of the Secretary. The Intermediary claims that communicating the rates through Intermediary Letters was appropriate, and the Provider's challenge of the same based on both procedural and substantive provisions of the APA is without support. The regulation stipulated the method of reimbursement through the interim period with the exception for providers whose costs exceeded the limit. Accordingly, the Intermediary maintains that setting the rates through Intermediary Letters did not violate the APA.

With respect to the Provider's challenge premised on the notice and comment provisions of the

APA, the Intermediary asserts that those provisions are inapplicable. The Intermediary Letters at

issue clearly come under the exception for "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(3)(A) (emphasis added). As such, publishing the pre-composite rates through the subject Intermediary Letters fell within the notice and comment provisions of the regulations.

ISSUE 2:

The Intermediary contends that CMS, rather than the Intermediary, determines a provider's qualifications for ESRD exception relief. The Intermediary claims that in accordance with the program instructions, its assessment and recommendation are only secondary to CMS' final determination. See CMS Pub. 15-1 § 2723ff. Further, the regulations are specific, in that CMS is the approving body for ESRD exception requests, as per 42 C.F.R. § 413.170(f)(2). See also CMS Pub. 15-1 § 2724. The Intermediary's role in the exception process involves the initial processing and review of exception requests and the verification of supporting data.

The Intermediary points out that CMS has stated that based on the Provider's documentation it is agreed that the Provider is furnishing renal services to a patient population that is different from other renal facilities. Additionally, CMS has agreed that the Provider has an atypical patient mix, and there is no need to revisit that issue.

Therefore, pursuant to the Board's remand, CMS has reevaluated the Provider's ESRD exception requests and offers the following general comments:

CMS contends that the amounts requested for outpatient dialysis for FYs 1982 and 1983 by the Provider were taken from the wrong column in the cost report documentation. In requesting its exception amount for FY 1982 and FY 1983, the Provider requested the total CPT shown in column 24 of the Supplemental Worksheet I-2, Part 3, which is for all outpatient treatment modalities, rather than the total CPT shown in column 12, which is for outpatient maintenance dialysis only. Then the Provider made reference to the cost components shown in columns 12 and 24 in the remainder of its narrative for FYs 82 and 83. Due to these inconsistencies, CMS prepared an analysis of the outpatient maintenance hemodialysis cost based on the cost report documentation furnished by the provider with its exception requests. CMS' analysis is as follows:

OUTPATIENT MAINTENANCE HEMODIALYSIS

DESCRIPTION	FY 81	FY 82	FY 83
RN	$ 186,254	$ 288,071	$ 289,647
LPN	49,498	27,226	26,290
TECH	9,602	24,038	21,554
OTHER(EB)	49,246	43.786	43,462
TOTAL SALARIES	294,600	383,121	380,953
SUPPLIES	300,803	223,782	285,465

OVERHEAD	527,250	557,350	670,175
TOTAL COSTS	$1,122,653	$1,164,253	$1,336,593
Total Treatments	6,322	5,270	5,059
Medicare Treatments	5,432	4,350	4,652

DESCRIPTION	CPT	CPT	CPT
RN	$ 29.46	54.66	$ 57.25
LPN	7.83	5.17	5.20
TECH	1.52	4.56	4.26
OTHER (EB)	7.79	8.31	8.59
TOTAL SALARIES	46.60	72.70	75.30
SUPPLIES	47.57	42.46	56.43
OVERHEAD	83.39	105.76	132.47
TOTAL CPT	$177.56	$ 220.92	$ 264.20

With respect to specific categories of expenses, CMS provides the following analysis:

Salaries and Employee Benefits

Based on audited Medicare cost report data for FYs 1982 and 1983, the national median CPT for salaries and employee benefits is $47. Based on CMS' CPT analysis, the Provider's salary and employee benefits CPT is $46.60, $72.70, and $75.30 for FY 81, 82, and 83, respectively.

In reviewing the salary CPT, it was noted that the CPT for the RNs, went up, while the number of treatments went down. There was no documentation in the Provider's narrative for FY 82 and FY 83 explaining the significant increase in the RN CPT for FY 82 (86% increase - $54.66/$29.46) and FY 83 (94% increase - $57.25/$29.46) over the FY 81 RN CPT. Further, there was no documentation explaining what action had been taken by the Provider to hold its salary costs down. Therefore, CMS is holding the Provider's RN CPT for FY 82 and FY 83 to the FY 81 amount. CMS is approving the following amounts for salaries:

FYE	Amount	Computation
1981	$ 0	($46.60 - $47)
1982	$ .50	($29.46 + $5.17 + $4.56 + $8.31 = $47.50 - $47)
1983	$ .31	($29.46 + $5.20 + $4.26 + $8.39 = $47.31 - $47)

Supplies

The national median CPT for supplies is $33. Based on CMS' CPT analysis, the Provider's supply CPT is $47.57, $42.46 and $56.43 for FY 81, 82, and 83, respectively.

In reviewing the supplies CPT, it was noted that the supply CPT for FY 83 increased significantly (33% increase - $56.43/$42.46) over the FY 82 supply CPT. There was no documentation in the Provider's narrative for FY 83 explaining the significant increase in the supply CPT for FY 83 over the FY 82 supply CPT. Therefore, CMS is holding the Provider's supply CPT for FY 83 to the FY 82 amount. CMS is approving the following amounts for supplies:

FYE	Amount	Computation
1981	$14.57	($47.57-$33)
1982	$ 9.46	($42.46-$33)
1983	$ 9.46	($42.46-$33)

Overhead - Additional Accumulated Costs

The national median CPT for overhead, excluding employee benefits, is $47. Based on CMS' CPT analysis, the Provider's overhead CPT is $83.39, $105.76 and $132.47 for FY 81, 82, and 83, respectively. The Provider's overhead exceeded the national data by $36.39, $58.76 and $85.47 for FY 81, 82 and 83, respectively.

The Provider requested that additional overhead costs be approved based on the total costs accumulated by the renal department based on the accumulated costs that were allocated to its renal department from the support departments. Cost reporting requirements reflect a cost accounting protocol that includes the allocation of overhead costs from support departments to revenue-producing departments.

The cost accounting protocol used for the Medicare cost reporting is not appropriate in identifying the costs directly attributable to a provider's atypical ESRD patients. For example, if a provider incurred additional nursing (salaries) costs because of its atypical ESRD patients, these additional nursing (salaries) costs would result in an "automatic" increased allocation of A&G costs to the renal dialysis department. However, the additional A&G costs allocated to the renal dialysis department do not necessarily represent the incremental costs incurred as a result of the additional nursing (salaries) costs for services rendered to a provider's atypical ESRD patients. They may represent the additional costs allocated, but they do not represent the incremental costs incurred as a result of, or specifically and directly attributable to, the additional nursing (salaries) for atypical ESRD services. Further, it must be noted that the cost accounting protocol used for cost reporting is separate and distinct from the act of identifying costs that are directly attributable to the atypical services furnished to a provider's atypical ESRD patients. Consequently, fixed overhead costs from a provider's support departments stepped down to a provider's revenue-producing departments, based on a statistical allocation due to a cost accounting protocol, are not directly attributable to the atypical services furnished to a provider's

atypical patients.

CMS' analysis of the Provider's overhead CPT showed that the overhead CPT kept increasing, while the number of maintenance outpatient hemodialysis treatments kept decreasing. Also, the

Provider merely identified its overhead cost components for all three fiscal years without explaining what management action it had taken in holding down its overhead costs. CMS believes that the Provider has not exercised prudent managerial action in keeping its overhead costs down.

Isolation Rooms

The Provider requested an additional exception amount because it incurs costs for isolation rooms due to the special needs of certain atypical patients. While CMS agrees with this point, the Provider did not furnish any computations or documentation on which CMS could make an exception amount determination. Therefore, CMS is unable to grant an exception amount for depreciation for isolation rooms.

Admission, Medical Records, Accounts Receivable and Collections

The Provider requested additional exception amounts because it incurs costs for admission, medical records, accounts receivable and collections. All ESRD providers, both freestanding and hospital-based, incur costs for these types of A&G services whether or not they have an atypical patient population. The Provider did not furnish any computations or documentation on which CMS could make an exception amount determination. Also, the Provider did not explain how these A&G services related to the special needs of its atypical ESRD patients. While costs may be reasonable and necessary, the Provider must relate the excess costs to the exception criterion for an exception amount to be granted. Therefore, CMS is unable to grant an exception amount for admission, medical records, accounts receivable and collections.

Laundry and Housekeeping

The Provider requested additional exception amounts for laundry and housekeeping because of their ESRD patient population. All ESRD providers, both freestanding and hospital-based, would incur costs for laundry and housekeeping whether or not they have an atypical patient population. Also, the Provider did not furnish any computations or documentation on which HCFA could make an exception amount determination. Therefore, CMS is unable to grant an exception amount for laundry and housekeeping.

Dietary and Social Services

The Provider requested additional exception amounts for dietary and social services because the Provider incurs costs for dietary and social services due to the special needs of certain atypical ESRD patients. While CMS agrees with this point, the Provider did not furnish any

computations or documentation that relates those costs to the atypical nature of its patient mix. Therefore, CMS is unable to grant an exception amount for dietary and social services.

Capital Buildings and Capital Movable

The Provider stated that these costs have been allocated on a time-weighted square foot basis. While these costs may be reasonable and necessary, the Provider must relate the costs to the exception criterion for an exception amount to be granted. The intent of the exception process is to provide relief to a provider that justifies its higher costs and relates those costs in excess of its payment rate to the exception criterion. The Provider has not explained how these costs related to the special needs of its atypical ESRD patients. Therefore, CMS is unable to grant an exception amount for capital buildings and capital movable.

Employee Health and Welfare for FY 1981

The Provider did not identify these costs and did not furnish any documentation explaining how these costs related to the special needs of its atypical ESRD patients. Therefore, CMS is unable to grant an exception amount for employee health and welfare.

Other Directs for FY 1981

The Provider did not furnish a breakout of these costs and did not furnish any documentation explaining how these costs related to the special needs of its atypical ESRD patients. Therefore, CMS is unable to grant an exception amount for these costs.

Employee Benefits Line 19 for FY 1982 and 1983 Space in the Personnel Department

The Provider stated that these costs are for space in the personnel and employee benefits department and have been allocated based on salaries under the Medicare step-down principles. The intent of the exception process is to provide relief to a provider that justifies its higher costs and relates those costs in excess of its payment rate to the exception criterion. The Provider has not explained how these costs related to the special needs of its atypical ESRD patients. Therefore, CMS is unable to grant an exception amount for a cost allocation for space in the personnel and employee benefits department. Further, the narrative description presented by the Provider appears to be more like “Plant and Fixtures” rather than “Employee Benefits.”

Central Supply

The Provider stated that these costs have been allocated based on treatments. While these costs may be reasonable and necessary, the Provider must relate the costs to the exception criterion for an exception amount to be granted. The intent of the exception process is to provide relief to a provider that justifies its higher costs and relates those costs in excess of its payment rate to the exception criterion. The Provider has not explained how these costs related to the special needs

of its atypical ESRD patients. Therefore, CMS is unable to grant an exception amount for central supply.

Laboratory and Medications

For FY 81, the Provider’s narrative did not discuss laboratory and medications. For FYs 82 and

83, the Provider stated in its narrative that it placed the laboratory and medication costs on line 15, column 23, Other. The Provider did not place the laboratory and medication costs on lines 27 (Pharmacy) and 29 (Laboratory) in Column 12, Outpatient Maintenance Dialysis. Consequently, these costs are not broken out between the various modalities and CMS is unable to make a comparison with national data. Therefore, an exception can not be granted.

CMS SUMMARY:

Based on the above, CMS is approving the following payment rates for outpatient maintenance dialysis:

Description	2/28/81	2/28/82	2/28/83
Payment Screen	$138.00	$138.00	$138.00
Salaries	0	.50	.31
Supplies	14.57	9.46	9.46
Total	152.57	147.96	$147.77

CITATION OF LAW, REGULATIONS AND PROGRAM INSTRUCTIONS:

1. Law:

5 U.S.C. § 553 et seq.	-	Administrative Procedure Act
5 U.S.C. § 706 (2)(A)	-	Administrative Procedure Act
42 U.S.C. § 426	-	ESRD Program Improvements
42 U.S.C § 426(e), (f) & (g)	-	ESRD Coverage/ SSA Amendments of 1972
42 U.S.C. § 1395rr	-	ESRD Program Improvements
42 U.S.C. § 1395x(v)(1)(A)	-	Reasonable Costs

2. Regulations:

§ 405.402	-	Cost Reimbursement
§ 405.1835-.1841	-	Board Jurisdiction
§ 413.9 et seq.	-	Cost Related to Patient Care
§ 413.170 et seq.	-	Payments for Covered Outpatient Maintenance Dialysis Treatments

3. Program Instructions- Provider Reimbursement Manual, Part 1 (CMS Pub. 15-1):

§ 2723 - Responsibility of Intermediaries

§ 2724 - HCFA Central Office Responsibilities

4. Program Instructions – Intermediary Letters:

73-22 Chronic Renal Disease - Interim Policies/ Procedures PT B

73-25 Chronic Renal Disease - Interim Policies/ Procedures PT A

74-26 Chronic Renal Disease - Reimbursement Screen PT A

74-24 Chronic Renal Disease - Reimbursement Screen PT B

78-9 Submission of Renal Dialysis Facility Cost and Statistical Information

82-1 End Stage Renal Disease Facilities - Documentation for Exception to Payment Screens

5. Case Law:

Batterton v. Marshall, 648 F. 2d 694 (D.C. Cir. 1980).

Bowen v. Georgetown University Hospital, 109 S. Ct. 468, (1988).

Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

Cleveland Clinic Foundation v. Sullivan, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,519 (D.D.C. July 30, 1991).

Flagstaff Medical Center, Inc. v. Sullivan, 962 F. 2d 879 (9th Cir 1992).

Linoz v. Heckler, 800 F. 2d 871 (9th Cir. 1986).

Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co., 103 S. Ct. 2856 (1983).

Mt. Diablo Hospital District v. Bowen, 860 F. 2d 951 (9th Cir. 1988)

Powderly v. Schweiker, 704 F. 2d 1092 (9th Cir. 1983).

St. Alphonsus Regional Medical Center (Boise, Idaho) v. Blue Cross and Blue Shield Association/Blue Cross of Oregon, PRRB Dec. No. 89-D28, March 15, 1989, [1989-2

Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 37,804, aff'd, HCFA Administrator, [1989-2 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 37,868 (May 19, 1989).

Schupak v. Matthews, [1976 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,987 at 10,007 (D.D.C. September 17, 1976).

Sutter General Hospital (Sacramento, California) v. Blue Cross and Blue Shield Association/Blue Cross of California, PRRB Dec. No. 96-D34, June 7, 1996, Medicare & Medicaid Guide (CCH) ¶ 44,482, HCFA Administrator declined review, July 16, 1996.

Sutter Memorial Hospital (Sacramento, California) v. Blue Cross and Blue Shield Association/Blue Cross of California, PRRB Hearing Dec. No. 96-D35, June 7, 1996, Medicare & Medicaid Gide (CCH) ¶ 44,485, HCFA Administrator declined review, July 16, 1996.

The Medical Center of Garden Grove v. Blue Cross and Blue Shield Association/ Blue Cross of California, ¶ 45,696, vacated and remanded, CMS Administrator, November 28, 1997, Medicare and Medicaid Guide CCH ¶ 45,946.

United States v. Picciotto, 850 F. 2d 345 (D.C. Cir. 1989).

6. Other:

38 Fed. Reg. 17,210 (June 29, 1973) codified at 20 C.F.R. § 405.402(g).

48 Fed. Reg. 21,254 (May 11, 1983).

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

The Board, after consideration of the facts, parties' contentions, and all evidence presented finds and concludes as follows:

ISSUE 1 – Application of pre-composite rate ESRD screens limiting the Provider's reimbursement for reasonable costs.

The Board finds that on November 28, 1997 the CMS Administrator issued a decision vacating the previous Board decision on this issue rendered in Board Decision No. 97-D106. However, the Administrator did not address the basis of the Board's decision relative to the validity of the pre-composite rate ESRD screens. Nor did the Administrator's remand reverse or modify the Board's decision on this issue. For these reasons, the Board has revisited this issue and includes its findings in this new decision.

After a thorough review of the prior record and the current contentions and evidence, the Board finds that it concurs with its previous decision on this issue as stated in Board

Decision No. 97-D106. Specifically, the Board finds that the screens were implemented by substantive rule rather than an interpretive rule. This position is supported by the Federal District Court's ruling in Schupak, supra, at 10,007. The District Court held that a portion of the 1973 IL, at issue here, was invalid as a substantive rule not promulgated in accordance with the APA. The Court stated that the 1973 IL "directly controls the reimbursement to be paid to dialysis facilities . . . has a substantial impact on the rights of those facilities[,] . . . is definitive, new, and controlling, and is precisely the sort of regulation required to be imposed only pursuant to the rule making requirements of the APA." Id. Accordingly, the Board concludes that the screens were established in violation of the procedural requirements of the APA and therefore, are invalid.

The Board also finds that the subject ESRD screens were established in violation of the substantive requirements of the APA. The APA declares unlawful any agency action which is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law . . ." See 5 U.S.C. § 706(2)(A), see also the Motor Vehicle Mfrs. Ass'n., supra, wherein the Court stated the agency must "examine the relevant data and articulate a satisfactory explanation for its action." The Board also points to Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc. 467 U.S. 867 (1984), wherein the Court noted that if Congress has "explicitly left a gap for the agency to fill," the agency's regulations, pursuant to the gap, are not given controlling weight if "they are arbitrary, capricious, or manifestly contrary to the statute." The Board also notes the Court's finding in Cleveland, supra, that there was no evidence of the basis for the methodology by which CMS derived the 1973 screens. Further, the Board observes that CMS was unable to produce the data used to determine the screen amount even though a Freedom of Information Act request was made.[11] This factor, together with the facts in the Cleveland case, support the Board's conclusion that the data was insufficient to set the screens and limit reimbursement for a ten year period.

ISSUE 2 - Exception to the $138 ESRD screen

The Board notes that the CMS Administrator's November 28, 1997 remand vacated the Board's original decision on this issue. (PRRB Decision No. 97-D106). The

Administrator then remanded the case to CMS for further evaluation of the Provider's exception request under the pre-composite rate standards set forth in 42 C.F.R. § 405.402(g), Intermediary Letters 78-9 and 82-1 and under general reasonable cost provisions and documentation requirements of the regulations.

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[11] Provider Exhibit P-36.

The Board finds that two key factors need to be addressed. First, the Board has to determine if CMS' reevaluation of the Provider's ESRD costs was in accordance with the guidance offered in the Administrator's November 28, 1997 remand. Secondly, the Board must determine whether and to what extent the Provider is entitled to an exception from the $138 per treatment ESRD screen.

With respect to the CMS reevaluation, the Board finds that CMS appears to continue to use the composite rate criteria to evaluate the Provider's request for additional costs in the areas of salaries, benefits and supply costs. The Board notes that this criteria was not applicable until fiscal years subsequent to those at issue. Accordingly, the Board finds that CMS can not retroactively apply the composite rate rules to requests for exceptions for fiscal periods prior to the implementation of those rules. The Board points to its prior decisions in Saint Alphonsus, Sutter General Hospital, and Sutter Memorial Hospital, supra, wherein it held that exception requests for pre-1984 providers should be based solely on reasonable cost reimbursement standards and the Secretary could not retroactively apply current criteria to prior years.

Secondly, the Board notes that in its reevaluation CMS indicated that it was unable to recognize additional requested costs in the various overhead areas, as the Provider was unable to relate the excess costs to the exception criteria. However, the Board finds that the interim regulations and ILs were very vague in their guidance to providers seeking to recover costs above the screen.

The Board finds that evidence in the original hearing revealed that the Provider serviced a patient population that was sicker, more elderly and with more complications than other facilities in the area. In fact, CMS agreed that the Provider had an atypical patient mix. The Board notes that the Provider prepared a detailed response to the CMS reevaluation which addressed each category of cost and fully explained why its atypical patient mix led to additional costs. This was supplemented by unrefuted testimony at the original hearing.

Based on the above, the Board finds that the Provider's exception requests justified and substantiated the necessity for exceptions in accordance with the rules in effect (reasonable costs) for the fiscal years at issue. The Board notes that the Provider requested total costs per treatment of $178.45, $199.41, and $271.15 for the fiscal years 1981, 1982, and 1983, respectively. These amounts were asserted to be derived from the most recently revised, audited costs reports. The Board notes that CMS computed different amounts in its reevaluation/analysis as indicated in the Intermediary's

contentions. However, the amounts are very similar and do not result in a material difference.

DECISION AND ORDER:

ISSUE 1:

The Board finds that the pre-composite rate screens established through the 1973 intermediary letter violated the procedural and substantive requirements of the APA. Accordingly, the Board concludes that CMS' application of the screens to the Provider's ESRD costs was improper, and therefore the Provider should be reimbursed its reasonable costs.

ISSUE 2:

The Board concludes that CMS' denial of the Provider's request for exceptions to its ESRD cost per treatment was without merit. CMS' determination is reversed. Provider exception requests are approved in the amounts set forth in the Provider's most recent position paper.[12]

Board Members Participating:

Irvin W. Kues
Henry C. Wessman, Esquire
Stanley J. Sokolove
Dr. Gary Blodgett
Suzanne Cochran, Esquire

Date of Decision: August 21, 2002

For The Board

Irvin W. Kues
Chairman

[12] Provider Position Paper dated February 9, 2000 at 77-79.