CENTERS FOR MEDICARE & MEDICAID SERVICES

Decision of the Administrator

In the case of:	Claim for:
The Milton S. Hershey Medical Center **Provider** **vs.** **Blue Cross/ Blue Shield Association** **Veritus Medicare Services** **Intermediary**	**Provider Cost Reimbursement Determination ESRD Window** **Date: 06/20/2001** **Review of:** **PRRB Dec. No. 2006-D45** **Dated: September 1, 2006**

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision of the Provider Reimbursement Review Board (Board). The review is during the 60-day period in Section 1878(f) (1) of the Social Security Act (Act), as amended (42 USC 1395oo (f)). The CMS Center for Medicare Management (CMM) submitted comments requesting that the Administrator reverse the Board's decision. Accordingly, the parties were notified of the Administrator's intention to review the Board's decision. Comments were also received from the Provider requesting that the Administrator affirm the Board's decision. Accordingly, this case is now before the Administrator for final agency review.

ISSUE AND BOARD'S DECISION

The issue is whether the CMS denial of the Provider's request for an exception to the end-stage-renal disease (ESRD) composite rates based on atypical service intensity and patient mix was correct.

A majority of the Board held that CMS improperly denied the Provider's request for an atypical services exception to its ESRD composite payment rate. The Board found that CMS relied on stale data from an undisclosed source. The Board majority

ruled that CMS' atypical services exception determination was improperly based on the analysis of the Provider's patient population, rather than on the analysis of the Provider's outpatient maintenance dialysis treatments, as required by 42 C.F.R. § 413.184. The Board majority remanded the case to the Intermediary for a determination of whether the Provider qualified for an atypical services ESRD exception based on it furnishing a substantial proportion of outpatient dialysis treatments in accordance with the regulations.

One member of the Board dissented finding that CMS properly denied the Provider's exception request. The dissenter noted that CMS performed a diligent review. The Dissenter found that any finding that a substantial proportion of a facility's outpatient maintenance dialysis treatment involve atypical intensity dialysis services must be based on analysis of each and every patient's condition and the additional time, supplies, etc., that it takes to provide the dialysis. Although the Provider's exception request was flawed, CMS elected to perform a detailed review. The dissenting Board member noted that at the hearing the Provider improperly introduced evidence that was neither considered by the Intermediary nor CMS when its exception was submitted, in violation of 42 C.F.R. §413.194(c) (2). The exception regulation places the burden on the provider to support every aspect of its exception request, which the Dissenter stated, the Provider failed to do in this case.

SUMMARY OF COMMENTS

CMM commented, requesting that the Administrator review and reverse the Board's decision. CMM argued that the Provider's exception request should be denied because the Provider failed to include home patients in its atypical services exception request analysis submitted to the Intermediary in violation of 42 C.F.R.§§413.170(a) and 413.184(b)(1). Notwithstanding the Provider's omission of home patients in its atypical services exception request, CMM argued that, even when these patients are included in the Provider's atypical services exception request, the evidence revealed that the Provider's patient population was not atypical in comparison to the national average.

With regard to the Board's directive for the Intermediary to perform an atypical services exception analysis based on the number of treatments, CMM argued that the Board's finding and remand order was moot. The Provider failed to submit the required number of treatments documentation for its home dialysis patients for the pertinent fiscal period. In addition, CMM argued that it would be impossible for the Intermediary to perform such an analysis, since the Provider's home dialysis treatments for FYE 6/30/2000 have been commingled with treatment counts from pervious years. Finally, CMM requested that the Administrator strike from the

administrative record Provider's Exhibits P-22 through P-25, as they were not part of the Provider's exception request to the Intermediary, and therefore, in violation of 42 C.F.R. §413.194(c)(2). CMM argued that these documents may not be subsequently used in support of the Provider's exception request.

The Provider commented requesting that the Administrator affirm the Board's decision, or in the alternative, grant the Provider's exception request. The Provider argued that sufficient documentation was presented in its exception request to substantiate that a number of its outpatient maintenance dialysis treatments involved atypically intense services. The Provider argued that the Intermediary erred in denying its exception request based on the grounds that the Provider did not demonstrate an atypical patient mix. The Provider stated that 42 C.F.R. §413.184, requires the Provider to demonstrate that a substantial proportion of its outpatient maintenance dialysis treatments involved atypically intense dialysis services. Therefore, excluding transient patients from the analysis was appropriate, since they represented such a small percentage of total treatments and otherwise distorted the evaluation of the atypicality of the treatments.

The Provider argued that it should not be punished because CMS lacks normative data to evaluate the atypicality of treatments, as opposed to the atypicality of the patients. CMS should not rely on its own failure to develop normative data as a basis for avoiding the valid evaluation of the atypicality of the treatments provided.

The Provider maintained that information regarding home patient treatments was contained within its exception request contrary to the assertions in CMM's comments. The Provider argued that this information was on the final page of Attachment 10 to its exception request found at Provider Exhibit 2.10 and listed the home patients as well as the number of treatment days for each patient. The Provider maintained that the only remaining thing to do was to convert the number of treatment days to the equivalent number of in-facility hemodialysis treatments.

With regard to PRM §2725.1, the Provider argued that it needed to meet only one of the criteria in order to show atypicality. However, the Provider argued that it is moot since the Board did not rule on this issue, and there is no reason to address the issue prior to the Intermediary's determination on remand. Finally, the Provider argued that CMM's motion to strike Provider Exhibits P-22 through P-25 is unfounded since those exhibits merely contained statistical recapitulations of information that was located within its exception request. 42 C.F.R. 413.194(c) (2), prohibits a provider from submitting new information that was not included in the exception request. It does not prevent the Provider from making all available arguments based upon information that was supplied with the exception request.

DISCUSSION

The entire record, which was furnished by the Board, has been examined, including all correspondence, position papers, and exhibits. The Administrator has reviewed the Board's decision. All comments received timely are included in the record and have been considered.

The Medicare Act provides for payment for services furnished to individuals suffering from kidney failure, or ESRD. Since 1983, hospital-based and freestanding ESRD facilities have been reimbursed for outpatient dialysis services under the "composite rate" system, as required by §1881(b) of the Social Security Act (Act) and the regulations at 42 C.F.R. 413.170, et seq. 2001.[1] Under this system a provider of dialysis services receives a prospectively determined payment for each dialysis treatment that it furnishes. An ESRD facility must accept the composite payment rate established by CMS as payment in full for covered outpatient dialysis.[2]

The Secretary has broad authority under §1881(b) (2) (B) of the Act to prescribe methods and procedures governing the ESRD prospective reimbursement system and to encourage the efficient delivery of dialysis services. Section 1881(b) (7) of the Act further requires the Secretary to provide for such exceptions to the composite payment rate "as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities."[3] Pursuant to this statutory

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[1] Congress established the Medicare ESRD program under §2991 of the Social Security Amendments of 1972 (Pub. L. 92-603). Medicare paid hospital-based ESRD facilities under Medicare cost reimbursement rules and independent facilities on the basis of Medicare reasonable charge principles. Section 2145 of the Omnibus Budget Reconciliation Act of 1981 (OBRA '81), (Pub. L. 97-35) amended §1881 of the Act to require the Secretary to develop a prospective reimbursement system for outpatient maintenance dialysis that promotes home dialysis. The Secretary promulgated the ESRD prospective payment regulations pursuant to OBRA '81 and the ESRD Program Amendment of 1978 (Pub. L. 95-292). The regulations originally codified at 42 C.F.R. §405.439, became effective August 1, 1983. See also 45 Fed. Reg. 64008 (1980); 47 Fed. Reg. 6556 (1982). The regulations were re-designated to 42 C.F.R. §413.170 in 1986. See 51 Fed. Reg. 34790 (1986) and later reorganized to their current codification in 1997. See 62 Fed. Reg. 43657 (1997)

[2] See 42 C.F.R. §413.172 (b).

[3] Section 422 of the Budget Improvement and Protection Act and section 623 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) made major changes to allow only pediatric ESRD facilities that did not have an approved exception rate as of October 1, 2002, to file for an exception to its updated prospective payment (or composite) rate. See also Change Request (CR) 4188

mandate, the Secretary has promulgated regulations which provide procedures and criteria for ESRD facilities to request exceptions to the composite rate.

The regulation at 42 C.F.R. §413.180(b) explains that, to qualify for an exception, an ESRD facility must anticipate higher allowable costs than its prospective payment rates, attributable to factors related to certain specified criteria such as atypical service intensity. The regulation that provides for an exception based on "atypical service intensity" is set forth at 42 C.F.R. §413.182 (a) and 42 C.F.R. §413.184(a) (1). The regulation at 42 C.F.R. §413.184(a) (1) states, in pertinent part, that:

> A facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. Examples that may qualify under this criterion are more intense dialysis services that are medically necessary for patients such as:
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> > (i) Patients who have been referred from other facilities on a temporary basis for more intense care during a period of medical instability, and who return to the original facility after stabilization;
> >
> > (ii) Pediatric patients, who require a significantly higher staff-to-patient ratio than typical adult patients; or
> >
> > (iii) Patients with medical conditions that are not commonly treated by ESRD facilities, and that complicate the dialysis procedure.[4]

In addition, the regulation at 42 C.F.R. §413.184(b)(1) states, with respect to the atypical patient mix, that:

> A facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year showing—

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effective January 1, 2006; Transmittal 781, CMS Medicare Claims Processing (Pub. 100-04) (Revised Manual Instructions for Processing End Stage Renal Disease (ESRD) Exceptions under the Composite Rate Reimbursement System.)

[4] 42 C.F.R. §413.184(a)(1)

> (i) Patients who received transplants, including the date of transplant;
> (ii) Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, and projected transplants;
> (iii) Home patients;
> (iv) In-facility patients, staff-assisted, or self dialysis;
> (v) Individual patient diagnosis;
> (vi) Diabetic patients;
> (vi) Patients isolated because of contagious disease;
> (vii) Age of patients;
> (ix) Mortality rate, by age and diagnosis;
> (x) Number of patients transfers, reasons for transfers, and any related information; and
> (xi) Total number of hospital admissions for the facility's patients, reason for, and length of stay of each session.

The Secretary explained, in promulgating the atypical patient mix criteria, the requirement for the above listed patient information in evaluating the exception request. The Secretary specifically stated that:

> When adjudicating exception requests, to determine if a substantial proportion of the facility's outpatient maintenance dialysis treatments involve more intense dialysis services and special dialysis procedures, [CMS] will compare the above data submitted by providers to data contained in [CMS'] Patient Profile Tables. The information in the Tables is developed annually and represents information on persons with end-stage renal disease covered by Medicare. While the number of treatments is used when determining whether a facility furnishes a substantial proportion of treatments to atypical patients, it is the typical or the atypical patient mix that generates the total treatment count used in this determination. In determining whether a facility's patients are atypically sick, each patient category is individually compared to its corresponding specific norm (national average). Various combinations of factors might lead to a determination that a facility has an atypical patient mix. For example, a facility might qualify for an exception for atypical patient mix if the percentage of its diabetic patients, older patients, and mortality rate were significantly higher than national averages.
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> By its very nature, an exceptions process addresses situations that are not anticipated, and because of the myriad combinations of factors that are possible, we cannot articulate a single specific standard that encompasses

> all these situations. Instead [CMS] will evaluate each request on a case-by-case basis to determine if the characteristic of the patient population are such that it might be beyond the facility's control to incur higher costs. (Facilities will still have to demonstrate that the atypical patient mix, in fact caused higher costs.)[5]

The regulation at 42 C.F.R. §413.180 (g) provides that it is a provider's burden to show:

> [T]hat the requirements of this section and the criteria in §413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.[6]

CMS will approve an exception based upon convincing objective evidence that a facility meets the requisite criteria, pursuant to 42 C.F.R. §413.182, which explains:

> CMS may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant costs reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria.

A provider dissatisfied with CMS' determination has a right to appeal that denial under 42 C.F.R. §413.194(b). 42 C.F.R. §413.194(c) (2) states that:

> The facility may not submit to the reviewing entity, whether it is the intermediary or the PRRB, any additional information or cost data that had not been submitted to CMS at the time CMS evaluated the exception request.

Thus, the pertinent data and documentation under review in this case are the Provider's initial ESRD exception request with its supporting documentation.

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[5] 59 Fed. Reg. 44097, 44099-44100 (Aug. 26, 1994).

[6] Section 2721 of the Provider Reimbursement Manual (PRM) provides: "The facility is responsible for justifying and demonstrating to [CMS] satisfaction that the requirements and the criteria listed in these instructions are met in full. That is, the burden of proof is on the facility to show that one or more of the criteria are met, and that the facility's costs, in excess of the composite rate, are justifiable under reasonable cost principles…."

In this case, by letter dated June 20, 2001, the Provider requested an exception to the prospective payment ESRD composite rate for outpatient maintenance hemodialysis, based on a claim of atypical patient mix.[7] The rate in question was the December 1, 2000, ESRD composite rate of $128.72 per treatment.[8] The Provider sought an exception amount of $168.08 or an increase of $39.36 per treatment.[9] In its exception request, the record shows that the Provider submitted an amended Worksheet I-series for the FYEs 6/30/98, 6/30/99 and 6/30/2000 cost reports. The record further shows that on June 27, 2001, the Intermediary notified the Provider that this amended data would not be accepted and instructed the Provider of the procedures for submitting a reopening request. The Intermediary explained that it accepted amended cost report under very limited circumstances. On July 26, 2001, the Intermediary recommended to CMS that the Provider's ESRD request be denied.

By letter dated August 23, 2001, CMS denied the Provider's request on the grounds that the submitted documentation did not satisfy the atypical patient mix criteria. CMS noted that a provider must submit a listing of all outpatient dialysis patients including home patients treated during the most recently completed fiscal calendar year. CMS found that the Provider prepared a patient population analysis attempting to demonstrate that it treats an atypical patient mix. The Provider claimed that 46 percent of its patients were over 65 (aged), 52 percent diabetic and that it had a mortality rate of 19 percent. However, these percentages were based on 100 outpatients and did not include data for the 35 home patients (Provider Exception Request Exhibit 10). CMS found that these home patients are to be included in the determination of whether a provider treats an atypical patient mix. When the data is recast including home dialysis patients, the data shows that 38.5 percent of the Provider's patients were aged and 59 patients or 45.4 percent were diabetic.

CMS noted that the national average (based on latest available CMS data from 1997) are 36.7 percent for aged, 33.3 percent diabetic, and 8.5 percent mortality. When the Provider's transient patients are excluded (that is, those that dialyzed less than a week Exhibit 8) the Provider's mortality rate was 12.4 percent, still less than the 16 percent national mortality rate. In addition, the Provider's new patient rate was 7.7 percent, while the national rate was 26.3 percent. The average length of stay (LOS) was 6.22, while the national rate was 8.30 (based on 1994 data).

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[7] Intermediary's Exhibit I-9. In its exception request, the Provider submitted amended Worksheet I-series for its FYE 6/30/98, 6/30/99 and 6/30/2000 cost reports.

[8] Intermediary's Position Paper at 4.

[9] $33.10 for labor costs and $6.26 for employee benefits. See also, Provider's Position Paper at 3.

CMS noted that the Provider's transplant rate was overstated as it had excluded home dialysis patients and that the rate is closer to 3.1 percent, not significantly different from the national average of 2.9 percent. With respect to the transfer patients, CMS found that in contrast to the allegations in the Provider's narrative claiming sicker patients as transfers, Exhibit 10 reveals only one patient transferred due to medical instability. This data is not supportive of an atypical patient mix based on referrals to the Provider due to medical acuity.

CMS found that the Provider's outpatient ESRD population, including home dialysis modalities, is not substantially different (38.5 percent) from the national average of 36.7 percent with respect to aged patients. The Provider is marginally atypically (45.4 percent) compared to the national average of 33.3 percent for diabetics. When home dialysis patients are properly included in the analysis, all indicators of atypicality with respect to the Provider's patients do not show that its patients are atypical compared to national data.

CMS found that the Provider's Exhibit 2 has created patient categories for its 100 hemodialysis outpatients that require extra treatment. However, CMS found that the data is largely antidotal and lacked national normative data for a determination of atypicality and was limited to in-facility patients. Thus, CMS concluded that based on a totality of the presented evidence, that the Provider had not demonstrated an atypical patient mix justifying entitlement to an atypical services exception. As CMS found that the Provider's failure to demonstrate that it had an atypical patient mix was dispositive of the exception request, CMS did not rule on whether the Provider had justified the excessive costs.

However, a majority of the Board found that CMS' denial of the Provider's exception request was improper and that it should be remanded to the Intermediary for a determination based on the atypical nature of the outpatient maintenance dialysis treatments instead of CMS' use of national patient statistics. In particular, the Board rejected CMS' use of the national ESRD patient tables to evaluate the Provider's patient population and ordered that the Provider's exception request be evaluated using the Provider's atypical treatment instead of atypical patients.

After a review of the pertinent laws and the record, the Administrator disagrees with the Board Majority decision. The Administrator concludes that the Board erroneously found that the national data used by CMS was seriously outdated and of an undisclosed source. Furthermore, the Administrator concludes that the Board was incorrect to order the use of atypical treatments, instead of patients, in determining whether the Provider met the criteria for an atypical patient mix exception.

The Administrator finds that CMS used 1997 national data to evaluate the Provider's patient mix for the June 2001 window. The Administrator finds that the use of that data was appropriate. In accurately compiling any national data, there can be expected to be a time lag in any national data used. In addition, contrary to the Board's finding, the data is from a disclosed source and, thus, verifiable. CMS has publicly noted that the data is derived from all patients for whom CMS receives a Form 2728 and are Medicare entitled as of December 31, 1997. Finally, there is no indication that this national data does not accurately reflect the normative standards against which a provider's patient population may be properly evaluated, nor is there any indication.

In addition, the Secretary published in the Federal Register, on August 26, 2004, pursuant to notice and comment rulemaking, how the atypical patient exception requests would be evaluated and that the CMS National Profile Tables would be to be used in that evaluation.[10] The Secretary explained that, while the number of treatments is used when determining whether a facility furnishes a substantial proportion of treatments to atypical patients, it is the typical or the atypical patient mix that generates the total treatment count used in this determination. Therefore, CMS evaluates a provider's patient population to determine if it meets the atypical patient mix criteria. In determining whether a facility's patients are atypically sick, each patient category is individually compared to its corresponding national average. The Secretary explained that various combinations of factors might lead to a determination that a facility has an atypical patient mix. As an example, a facility might qualify for an exception for atypical patient mix if the percentage of its diabetic patients, older patients, and mortality rate were "significantly higher" than national averages.

Notably no public comments were received with respect to the methods of evaluating the atypical patient exception request using patient statistics and the national data to be used in making the determination. In addition, contrary to the Provider's contention, the Secretary's discussion makes clear that an exception is not anticipated to be granted based on one atypical characteristic in a provider's patient population, but rather would be granted when there is a combination of atypical characteristics in a provider's patient population that are significantly higher than the national averages.

In addition, to qualify for an exception to the prospective payment rate based on atypical service intensity (patient mix), a provider must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year. The record shows that the Provider, while including a list of these patients, failed to include home patients undergoing peritoneal dialysis in its exception request analysis submitted to the Intermediary and in its computation of the various percentages of atypical categories of patients.

[10] See 59 Fed. Reg. 44097 44099-44100.

When these home dialysis patients were correctly included with the in-facility hemodialysis patients analysis and percentages, CMS found that the Provider's patient population was not atypical in comparison to the national average. As noted above, the record shows that based on the Provider's 100 hemodialysis and 30 peritoneal dialysis outpatients, a total of 50 or 38.5 percent of the Provider's patients were aged (65 and over), and 59 or 45.4 percent were diabetic compared to the national average based on CMS 1997 data, of 36.7 percent for aged patients (65 and over) and 33.3 for diabetics.[11] In addition, the Provider's mortality rated based on 130 ESRD outpatients was 8.5 percent compared to approximately 16 percent in CMS' data for patients who underwent dialysis in 1997 and died in 1998. Further, CMS' evaluation of other factors, such as transfers, transplants, LOS, also showed that the Provider's patient percentages for atypical indicators were similar to those of the national norm. Based on the totality of the presented evidence, the Administrator agrees that CMS properly found that the Provider did not demonstrate an atypical patient mix justifying entitlement to an atypical services exception.[12] CMS' determination properly relied on CMS national ESRD patient data and properly evaluated the Provider's exception request based on its patient statistics. CMS also properly required, in this case, for more than one indicator of atypicality to be presented in order to demonstrate an atypical patient mix.

Finally, the Provider argued that the Board properly required the use of treatments, not patients, in evaluating the request as the transient patients dilute all those patient characteristics indicating atypicality.[13] However, an initial review of the characteristics of the transient patients shows a population with characteristics very similar to the Provider's overall patients. The Administrator notes that CMS took into consideration the Provider's transient patient population in evaluating the Provider's mortality rate in the exception request as it was therein raised and found that even after removing them, the Provider's mortality percentage was not significantly outside the national percentage. In addition, of the approximately 40 transient patients identified by the Provider, about 14 patients (35 percent) were aged[14] and about 16 patients (40 percent were diabetic). These statistics are not

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[11] Intermediary's Exhibit I-10.

[12] The Administrator finds that the Board is limited to the record as presented in the original exception request. The Board should not consider evidence not before CMS and should give it no weight in its deliberations.

[13] The Provider suggested in its exception request that the Provider's mortality rate would be diluted by transient patients.

[14] This is an approximation. The number of transient patients does not include home dialysis patients that dialyzed less than seven times. In addition, the Provider's Exhibit P-1-9, (Exception Request Exhibit 2, which indicates, inter alia, the age,

significantly lower than those of the Provider's total statistics with the transients patients (38.5 aged and 45 diabetic) and without the transients patients (36 percent aged and 47 percent diabetic). The Administrator finds the record does not support the Provider's argument that the transient patient population significantly dilutes the number of overall sicker patients and therefore this argument does not support the use of "treatments" as the measure for the atypical patient mix, instead of patients.

Pursuant to 42 C.F.R. §413.180(g), the Administrator finds that the Provider "must demonstrate to CMS' satisfaction that the requirements in §413.182 are fully met." The Provider has the burden of proof "to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part. CMS' reasonably required the Provider to show a combination of atypical characteristics in order to demonstrate that it serviced an atypical patient mix. CMS was reasonable to evaluate the exception request by use of patient data including that of the Provider's home patients and, finally, CMS reasonably relied on the latest available CMS ESRD Patient Table to adjudicate the request. Thus, the Administrator concludes that CMS properly found that the Provider did not meet the required "convincing objective evidence" to justify approval of an exception under the atypical service intensity criterion.

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whether the patient was diabetic and the number of treatments for that patient is difficult to accurately read with respect to the ages listed.

DECISION

The decision of the Board is reversed consistent with the foregoing opinion.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: 11/1/06

/s/
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services