Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Center for Organ Recovery and Education,	)	DATE: May 3, 1994
	)	
Petitioner,	)	Docket No. C-94-020
	)	Decision No. CR313
- v. -	)	
	)	
Health Care Financing Administration.	)	
	)	

DECISION

On October 29, 1993, Petitioner, the Center for Organ Recovery & Education (CORE), filed a request for a hearing pursuant to 42 C.F.R. Part 498.[1] CORE asserted that it was a qualified organ procurement organization ("OPO"), and, therefore, a "supplier" of health care items or services as defined by 42 C.F.R. § 498.2. CORE averred that it had applied in 1992 to the Health Care Financing Administration ("HCFA") for designation as the OPO for the entire State of West Virginia, with the exception of one county served by a Kentucky-based OPO. In its request for hearing, CORE asserted that HCFA had approved CORE's application to serve as an OPO for the entire state of West Virginia, the only exceptions being that HCFA had denied CORE's application with respect to nine counties in southern and eastern West Virginia, four counties in the northern panhandle of West Virginia and one county in the eastern panhandle of West Virginia. HCFA had allocated the nine counties in southern and eastern West Virginia to a Virginia-based OPO. HCFA had allocated the four northern panhandle counties and one eastern panhandle county to an Ohio-based OPO.

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[1] CORE was known originally as Pittsburgh Transplant Foundation. Some of the correspondence and other documents which are exhibits in this case were written on Pittsburgh Transplant Foundation's letterhead, and others were written under CORE's letterhead. For purposes of simplicity, I refer to Petitioner as "CORE" throughout this decision.

CORE averred that HCFA had denied CORE's request for reconsideration of its application for all of the counties mentioned above. Therefore, according to CORE, it was entitled to a hearing pursuant to 42 C.F.R. § 498.5(d)(2), to contest HCFA's determination to award the 14 counties in West Virginia which it had not awarded to CORE to OPOs other than CORE.

The case was assigned originally to Administrative Law Judge Charles Stratton. On December 16, 1993, Judge Stratton held a prehearing conference in which the parties participated by telephone. On January 13, 1994, Judge Stratton issued a prehearing order, based on the issues discussed at the prehearing conference. Order and Schedule for Filing Briefs and Documentary Evidence, January 13, 1994. The order identified a number of issues and directed the parties to brief those issues. Id. at 4 - 5. In accordance with that Order, the parties filed the following: On February 4, 1994, HCFA filed a motion for summary disposition; on March 7, 1994, Petitioner filed an opposition to HCFA's motion; and on March 22, 1994, HCFA filed a reply brief.[2] On March 9, 1994, the case was reassigned to me. On March 28, 1994, I conducted a telephone conference at which I heard oral argument as to the issues which Judge Stratton had identified and as to additional issues which I identified during the conference. I provided the parties the opportunity to file supplemental briefs concerning the additional issues which I identified. These were filed by the parties on April 8, 1994.

I have considered the applicable law, the parties' arguments, and the undisputed material facts. I conclude that CORE withdrew its request for a hearing concerning HCFA's allocation of the three West Virginia counties of Marshall, Mineral, and Ohio to an OPO other than CORE. P. Opp. at 3 - 4, n. 3.[3] I dismiss Petitioner's request for a

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[2] The filing date reflects the date the submission was mailed.

[3] I cite the parties' briefs, exhibits, attachments and my Findings of Fact and Conclusions of Law as follows:

Petitioner's exhibit . . . . . P. Ex. (number at page)

HCFA's exhibit . . . . . HCFA Ex. (number at page)

HCFA's motion . . . . . HCFA MSD at (page)

Petitioner's opposition . . . . . P. Opp. at (page)

(continued...)

hearing concerning those three counties, pursuant to 42 C.F.R. § 498.68(a) and (b). I conclude that CORE is not entitled to a hearing concerning HCFA's determination to allocate the West Virginia counties of Brooke and Hancock to an OPO other than CORE. I dismiss Petitioner's request for a hearing concerning those two counties, pursuant to 42 C.F.R. § 498.70(b).

I conclude that HCFA did not consider CORE's request for reconsideration concerning the remaining nine West Virginia counties which HCFA awarded to another OPO pursuant to the standards for reconsideration contained in 42 C.F.R. § 498.24(a) and (b). Accordingly, I am vacating HCFA's reconsideration determination and remanding this case to HCFA in order that it may reconsider CORE's application in accordance with the standards contained in section 498.24(a) and (b).

ISSUES

The issues in this case are whether:

1. There is a need in this case for an evidentiary hearing involving live testimony.

2. CORE withdrew its request for a hearing concerning whether HCFA should have allocated the West Virginia counties of Marshall, Mineral, and Ohio to CORE.

3. CORE is entitled to a hearing concerning whether HCFA should have allocated the West Virginia counties of Brooke and Hancock to CORE.

4. HCFA applied the criteria contained in 42 C.F.R. § 498.24(a) and (b) to decide CORE's reconsideration request.

5. Assuming HCFA failed to apply the criteria contained in 42 C.F.R. § 498.24(a) and (b) to decide

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[3](...continued)

HCFA's reply brief . . . . . HCFA R. Br. at (page)

Petitioner's supplemental brief . . P. Supp. Br. at (page)

HCFA's supplemental brief . . . . HCFA Supp. Br. at (page)

Findings of Fact and Conclusions of Law . . Finding (number)

Administrative Law Judge Exhibit . . . ALJ Ex. (attachment)

CORE's reconsideration request, do I have authority to direct a remedy, and if so, what authorized remedy is appropriate here.

The parties raise additional issues. CORE asserts that it is entitled to a de novo hearing which, in effect, supersedes the initial and reconsideration determinations made by HCFA. CORE contends that I should join as parties to this case other OPOs who submitted competing applications for portions of West Virginia. It argues that it should be provided the opportunity to take discovery, including depositions, of HCFA officials. Although these additional issues are not central to my decision, I discuss them herein.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. CORE is an agency which procures organs for transplant. See HCFA Ex. 11; P. Ex. 1 at 1.[4]

2. Prior to October, 1991, Mountain State Organ Procurement Agency (MSOPA) had been approved by HCFA to serve as an OPO in a service area which included portions of the State of West Virginia. HCFA Exs. 11, 12; P. Ex. 4.

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[4] HCFA submitted 43 exhibits with its motion for summary disposition. CORE submitted four exhibits and two attachments with its memorandum in opposition to HCFA's motion for summary disposition.

CORE objected to HCFA Exs. 1, 4, 6, 7, 8, 12, 16, 18, 20, 22, 31, and 34, on various grounds. These included objections to allegedly extraneous handwritten notations on some of the exhibits and to the authenticity of some of the exhibits. CORE contended also that HCFA failed to prove that some of these exhibits, consisting of correspondence, had been mailed by HCFA or had been received by CORE.

It is not necessary for me to admit all of the exhibits submitted by the parties in order for me to decide this case. I have admitted into evidence and rely on HCFA Exs. 1, 8, 11, 12, 13, 14, 16, 18, 28 and 37; P. Exs. 2 and 4; and CORE's October 26, 1992 reconsideration request and the attachments which CORE submitted to HCFA in conjunction with its request, which I have marked for identification as ALJ Exs. 1 and 2, respectively. ALJ Ex. 2 consists of 16 attachments. I reject all other exhibits and attachments submitted by the parties as irrelevant. I have addressed and resolved all of CORE's objections to the HCFA exhibits which I have admitted, and I discuss my ruling as to these exhibits where appropriate.

3. Effective September, 1991, MSOPA ceased operating in West Virginia, and CORE entered into an agreement with MSOPA to assume all of the activities previously conducted by MSOPA in West Virginia. HCFA Ex. 11 at 1.

4. On October 18, 1991, CORE notified HCFA that it had assumed the activities previously conducted by MSOPA and applied for approval from HCFA to conduct its activities in the counties in West Virginia that were previously served by MSOPA. HCFA Ex. 11.

5. In its October 18, 1991 application to HCFA, CORE identified the counties previously served by MSOPA as: Barbour, Brooke, Doddridge, Fayette, Gilmer, Greenbrier, Hancock, Harrison, Lewis, McDowell, Marion, Marshall, Mercer, Monogalia, Monroe, Nicholas, Ohio, Pocahontas, Preston, Raleigh, Randolph, Ritchie, Summers, Taylor, Tucker, Tyler, Upshur, Webster, Wetzel, and Wyoming. HCFA Ex. 11.

6. In a letter dated December 5, 1991, HCFA advised CORE that it was giving CORE temporary authority, effective October 18, 1991, to assume the organ procurement activities of MSOPA. HCFA Ex. 12; P. Ex. 4.

7. In the December 5, 1991 letter, HCFA advised CORE that, before it could designate a replacement OPO for MSOPA, it was required to consider applications from all entities which applied to replace MSOPA. HCFA Ex. 12; P. Ex. 4.

8. In the December 5, 1991 letter, HCFA advised CORE that it would shortly issue a public notice that the MSOPA service area would be an "open" service area for consideration of applications from OPOs to service that area, and that HCFA would accept CORE's October 18, 1991 letter as a statement of its intention to compete to be the OPO for the specific counties which had been served by MSOPA. HCFA Ex. 12; P. Ex. 4.

9. In the December 5, 1991 letter, HCFA advised CORE that the West Virginia counties of Brooke and Hancock were not part of the MSOPA service area, but were part of a Metropolitan Statistical Area that had been assigned to another OPO, Lifeline of Ohio Organ Procurement Organization ("LOOP"). HCFA Ex. 12; P. Ex. 4.

10. In the December 5, 1991 letter, HCFA advised CORE that it could not permit the West Virginia counties of Brooke and Hancock to be part of the interim agreement between CORE and MSOPA. HCFA Ex. 12; P. Ex. 4.

11. CORE received a copy of the December 5, 1991 letter from HCFA in early January 1992. HCFA Ex. 14; P. Ex. 4.[5]

12. In a letter dated December 11, 1991, HCFA advised CORE that it had designated LOOP to be the OPO for the Steubenville-Weirton Ohio-West Virginia Metropolitan Statistical Area. HCFA Ex. 8; P. Ex. 2.

13. CORE received the December 11, 1991 letter from HCFA. P. Ex. 2.

14. The Steubenville-Weirton Ohio-West Virginia Metropolitan Statistical Area includes the West Virginia counties of Brooke and Hancock. P. Ex. 1; HCFA Ex. 8.

15. CORE knew no later than January 2, 1992 that HCFA had not given it approval to operate in Brooke and Hancock counties and that Brooke and Hancock counties were not part of MSOPA's service area. Findings 9 - 14.

16. In December 1991, HCFA published a notice which formally notified interested parties that there was an open service area for an OPO, consisting of all counties in West Virginia except Mineral, Hancock, Brooke, Ohio, Marshall, Cabell, Wayne, and Wood. HCFA Ex. 13.

17. The December 1991 notice invited interested parties to apply to be the OPO for the open service area and established a January 31, 1992 deadline for applications. HCFA Ex. 13.

18. On January 2, 1992, CORE advised HCFA that it was modifying its application, so that it would consist of an application for approval by HCFA to serve as the OPO for all counties in West Virginia served previously by MSOPA. HCFA Ex. 14; P. Ex. 4.

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[5] CORE initially contended that it had not received a copy of HCFA Ex. 12, which is a copy of the December 5, 1991 letter from HCFA to CORE. At the March 28, 1994 oral argument, counsel for CORE stated that CORE did receive a copy of the December 5, 1991 letter from HCFA, on January 7 or 8, 1992, after CORE requested that HCFA send it a copy of the letter. Letter by direction of the administrative law judge, March 31, 1994. However, as is evident from HCFA Ex. 14 and P. Ex. 4, CORE actually received a copy of the letter a few days prior to January 8, 1992.

19. On January 28, 1992, LOOP applied to HCFA for designation as the OPO for the service area in West Virginia previously designated to MSOPA. HCFA Ex. 16. [6]

20. On January 29, 1992, the Virginias' Organ Procurement Agency (VOPA) applied to HCFA for designation as the OPO for the West Virginia counties of Morgan, Jefferson, Fayette, Monroe, Mercer, Berkeley, Raleigh, Greenbrier, and Summers. HCFA Ex. 18.[7]

21. On July 21, 1992, HCFA advised CORE that it was approving its application as the OPO for all counties in the West Virginia open service area vacated by MSOPA, except the nine counties of Morgan, Jefferson, Fayette, Monroe, Mercer, Berkeley, Raleigh, Greenbrier, and Summers. HCFA Ex. 28 at 1 - 2.[8]

22. HCFA advised CORE that it and VOPA met the basic requirements contained in 42 C.F.R. § 485.304 to qualify an entity as an OPO. HCFA Ex. 28 at 1 - 2.

23. HCFA advised CORE that, under 42 C.F.R. § 485.308, the Secretary of the United States Department of Health and Human Services (the Secretary) may designate only one OPO for any service area. HCFA Ex. 28 at 1 - 2.

24. HCFA advised CORE that where two or more OPOs apply for the same service area, and where both meet the basic qualifying requirements for OPOs, HCFA is required to determine the best qualified OPO for the service area by applying tie-breaker factors contained in 42 C.F.R. § 485.308. HCFA Ex. 28 at 1 - 2.

25. HCFA advised CORE that it had applied the tie-breaker factors for the nine West Virginia counties at issue and had determined that VOPA was better qualified to serve as the OPO for the nine West Virginia counties of Morgan,

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[6] CORE objected to HCFA Ex. 16 on the basis that it contains extraneous handwritten notations. My findings are not based on the notations.

[7] CORE objected to HCFA Ex. 18 on the ground that it contains extraneous handwritten notations. My findings are not based on these notations.

[8] CORE objected to pages 3 and 4 of HCFA Ex. 28 as an unsigned letter not printed on HCFA letterhead. I do not base any of my findings in this decision on pages 3 and 4 of HCFA Ex. 28.

Jefferson, Fayette, Monroe, Mercer, Berkeley, Raleigh, Greenbrier, and Summers. HCFA Ex. 28 at 1 - 2.

26. HCFA advised CORE that it could apply for reconsideration of HCFA's determination, pursuant to 42 C.F.R. Part 498. HCFA Ex. 28 at 1 - 2.

27. On October 26, 1992, CORE filed a request for reconsideration with HCFA. ALJ Exs. 1, 2.[9]

28. In its request for reconsideration, CORE presented facts concerning its performance in West Virginia both prior and subsequent to January 31, 1992. ALJ Exs. 1, 2.

29. On August 31, 1993, HCFA advised CORE that it was denying its request for reconsideration. HCFA Ex. 37.

30. In its denial, HCFA informed CORE that it did not consider to be relevant to the reconsideration facts concerning CORE's performance in West Virginia after January 31, 1992. HCFA Ex. 37.

31. Reimbursement may be made under Medicare or Medicaid to an agency which procures organs for transplant only if that agency meets the qualifications for an OPO set forth in section 1138(b) of the Social Security Act and is designated by the Secretary as an OPO. Social Security Act, section 1138(b)(1); see, section 371(b) of the Public Health Service Act.

32. The Secretary may not designate more than one OPO for each service area within which an OPO may operate. Social Security Act, section 1138(b)(2); 42 C.F.R. § 485.308(a).

33. Where more than one qualified OPO applies for a designated service area, the Secretary (or her delegate, HCFA) will consider additional factors and will allocate the service area based on a comparison of the OPOs, using those factors as a basis for comparison. 42 C.F.R. § 485.308(a).

34. The factors that HCFA will consider in deciding which OPO will be awarded a designated service area where more

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[9] The reconsideration request and the appendix to that request were not offered as exhibits. In order to ensure that the record is complete, I have identified the reconsideration request as ALJ Ex. 1 and admit it into evidence. Cf. Footnote 4. I have identified the appendix to that request, consisting of 16 attachments, as ALJ Ex. 2 and admit it into evidence. Id.

than one qualified OPO applies for that service area consist of:

> (1) Prior performance by each OPO, including the previous year's experience in terms of the number of organs retrieved and wasted and the average cost per organ;
>
> (2) Actual number of donors compared to the number of potential donors;
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> (3) The nature of relationships and the degree of involvement by each OPO with hospitals in that OPO's service area;
>
> (4) Bed capacity associated with the hospitals with which the OPOs have working relationships;
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> (5) The willingness and ability of each OPO to place organs within the designated service area;
>
> (6) The proximity of each OPO to donor hospitals.

42 C.F.R. § 485.308(a)(1) - (6).

35. An organization that applies to HCFA to be the designated OPO for a service area, which is not designated by HCFA for that service area, has no statutory right to a hearing. See, Social Security Act, section 1138(b).

36. An organization that applies to HCFA to be the designated OPO for a service area, which is not designated by HCFA for that service area, may appeal its non-designation under the regulations contained in 42 C.F.R. Part 498. 42 C.F.R. § 485.308(b).

37. An OPO is a "supplier" within the meaning of the regulations contained in 42 C.F.R. Part 498. 42 C.F.R. § 498.2.

38. HCFA's determination to allocate the part of MSOPA's service area to CORE and part of MSOPA's service area to VOPA was an "initial determination" within the meaning of 42 C.F.R. § 498.20(a).

39. CORE was entitled to apply for reconsideration of HCFA's initial determination. 42 C.F.R. § 498.22(a).

40. The West Virginia counties of Brooke and Hancock were not part of the open service area formerly assigned to MSOPA for which HCFA solicited applications from OPOs. Findings 9, 10, 12, 14.

41. CORE knew no later than early January 1992, that Brooke and Hancock counties were not part of MSOPA's service area. Findings 10, 11, 12, 13.

42. HCFA's initial determination to reallocate the designated service area formerly allocated to MSOPA did not include the West Virginia counties of Brooke and Hancock. HCFA Ex. 13, 28.

43. CORE was not entitled to reconsideration as to the assignment of the West Virginia counties of Brooke and Hancock to an OPO other than CORE because those counties were not part of the open service area formerly assigned to MSOPA and were not involved in HCFA's initial determination. Findings 41, 42.

44. CORE is not entitled to a hearing as to HCFA's allocation of the West Virginia counties of Brooke and Hancock to an OPO other than CORE, because CORE did not timely request reconsideration of this allocation. Findings 10 - 14; 42 C.F.R. § 498.22(b)(3).

45. In reconsidering its initial determination, HCFA was required to consider any written evidence submitted by CORE which related to CORE's activities in the service area previously assigned to MSOPA subsequent to the date of the initial determination. 42 C.F.R. § 498.24(b).

46. In reconsidering its initial determination, HCFA did not consider written evidence submitted by CORE which related to CORE's activities in the service area previously assigned to MSOPA subsequent to the date of the initial determination. HCFA Ex. 37; ALJ Exs. 1, 2.

47. HCFA failed to conduct a redetermination of the assignment of the nine West Virginia counties sought by CORE, which HCFA had assigned to VOPA, in accordance with the requirements contained in 42 C.F.R. § 498.24(b).

48. The appropriate remedy in this case is to remand it to HCFA to conduct a reconsideration in accordance with the requirements of 42 C.F.R. § 498.24(b).

RATIONALE

This is a case of first impression involving the application of section 1138(b) of the Social Security Act and the implementing regulations contained in 42 C.F.R. Part 485. The case involves also interpretation and application of the regulations contained in 42 C.F.R. Part 498. The law and material facts are as follows.

I. This case is governed by section 1138(b) of the Social Security Act, and by the regulations at 42 C.F.R. Parts 485 and 498.

Section 1138(b) of the Social Security Act establishes a mechanism whereby agencies which procure organs for transplant may qualify for reimbursement under Titles XVIII (Medicare) and XIX (other federally-funded health care programs, including Medicaid). This section specifies that, in order to qualify for reimbursement as an OPO, an organization must either be qualified under section 371(b) of the Public Health Service Act, or must be certified or recertified by the Secretary as meeting qualifying standards within the previous two years. It specifies further that the Secretary may not select more than one OPO to provide organ procurement services to each designated service area.

The implementing regulations contained in 42 C.F.R. Part 485 set forth the qualifications necessary for an agency to be designated as an OPO. 42 C.F.R. § 485.304. They reiterate the statutory requirement that only one OPO may be selected by the Secretary to serve a designated service area. 42 C.F.R. § 485.308(a). They provide that, where more than one OPO applies to serve a designated service area, and where the competing OPOs meet the basic qualifying requirements contained in 42 C.F.R. § 485.304, the Secretary will select one of the competing OPOs based on consideration of certain "other factors." These factors are enumerated in 42 C.F.R. § 485.308(a)(1) - (6). The regulations thus envision that qualified OPOs may compete for the franchise in a designated service area, and they establish tie-breaker criteria to be applied in order to resolve competitions for territory among OPOs.

Section 1138(b) does not provide hearing or appeal rights to agencies that are dissatisfied with determinations concerning their applications to be designated as OPOs or for territorial rights to designated service areas. This section therefore differs from other sections of the Act which specifically confer hearing and appeal rights pursuant to section 205(b) of the Act on individuals and entities who are dissatisfied with determinations made by the Secretary or her delegate, HCFA. See, e.g., Social Security Act, section 1866(h)(1) (which provides for a hearing pursuant to section 205(b) where the Secretary determines that an institution or an agency is not a provider of services, or where the Secretary terminates or refuses to review an agreement with a provider), and Social Security Act, section 1869(b)(1) (which provides for a hearing pursuant to section 205(b) for an individual who is dissatisfied with the Secretary's determination as to coverage for Medicare benefits).

However, the regulations provide that an organization which applies to HCFA for designation as an OPO for a service area, and which is not designated by HCFA, may appeal its non-designation under the regulations contained in 42 C.F.R. Part 498. 42 C.F.R. § 485.308(b). CORE's appeal rights in this case thus arise from regulations, including the regulations contained in 42 C.F.R. Part 498.

Under the Part 498 regulations, a supplier which is dissatisfied with an initial determination by HCFA may request reconsideration of that determination. 42 C.F.R. § 498.22. The standards by which reconsiderations are to be conducted are set forth in 42 C.F.R. § 498.24. The regulations provide further that a prospective supplier who is dissatisfied with a reconsidered determination is entitled to a hearing before an administrative law judge. 42 C.F.R. § 498.5(d)(1).

II. The parties do not disagree as to the factual background of this case.

Prior to October 1991, the State of West Virginia, with the exception of the counties of Mineral, Hancock, Brooke, Ohio, Marshall, Cabell, Wayne, and Wood, comprised a service area which HCFA had assigned to MSOPA. In September 1991, MSOPA ceased operating in West Virginia. It entered into an agreement with CORE under which CORE assumed responsibility for MSOPA's service area in West Virginia.[10] On October 18, 1991, CORE advised HCFA of the agreement. It told HCFA that it wished to apply to be designated as the OPO for the counties in West Virginia which had been designated as MSOPA's service area. It described those counties as including the counties of Brooke and Hancock.

On December 5, 1991, HCFA replied to CORE, advising it that HCFA had designated it temporarily as the OPO for the MSOPA service area, effective October 18, 1991. HCFA told CORE that it would have to consider applications from all OPOs interested in the MSOPA service area before it could designate a replacement OPO for MSOPA. Furthermore, it advised CORE that the West Virginia counties of Brooke and Hancock were not part of MSOPA's service area and that they had been assigned previously to another OPO, LOOP. HCFA advised CORE that, therefore, it could not approve even a temporary designation of CORE as the OPO for Brooke and Hancock counties.

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[10] At that time, CORE was known as Pittsburgh Transplant Foundation. Footnote 1.

CORE contends that it did not receive the December 5, 1991 letter from HCFA. However, it did receive a copy of that letter in early January 1992. HCFA Ex. 14; P. Ex. 4.

On December 20, 1992, HCFA published a notice advertising that there was an open service area. It described the service area as including all counties in the State of West Virginia except the counties of Mineral, Hancock, Brooke, Ohio, Marshall, Cabell, Wayne, and Wood. It invited interested entities to apply for designation as the OPO for the service area.

CORE applied to be designated as the OPO for all West Virginia counties that were served previously by MSOPA. LOOP applied to be designated as the OPO for the entire open service area. Another OPO, VOPA, applied for nine counties of the MSOPA service area. The counties for which VOPA applied were Morgan, Jefferson, Fayette, Monroe, Mercer, Berkeley, Raleigh, Greenbrier, and Summers.

On July 21, 1992, HCFA informed CORE, VOPA, and LOOP that it had decided to award to CORE all of the MSOPA service area except for the nine counties for which VOPA had applied. HCFA's July 21 letter further informed CORE, VOPA, and LOOP that it had awarded Morgan, Jefferson, Fayette, Monroe, Mercer, Berkely, Raleigh, Greenbrier, and Summers to VOPA. HCFA advised the OPOs that it had based its determination on a consideration of the parties' applications pursuant to the tie-breaker criteria contained in 42 C.F.R. § 485.308.

On October 26, 1992, CORE filed a request for reconsideration with HCFA.[11] In its request, CORE asserted that it had planned to serve the "entire state of West Virginia," based on MSOPA's cessation of operations. Request for Reconsideration of Designation of Certain Counties in West Virginia, ALJ Ex. 1 at 2. CORE asserted that HCFA had failed to acquire from it all relevant information necessary to evaluate its performance and experience, when compared against that of LOOP and VOPA, pursuant to the tie-breaker criteria of 42 C.F.R. § 485.308. CORE asserted that a proper application of the tie-breaker criteria established that it would do a better job than VOPA in the nine counties HCFA awarded to VOPA. CORE contended also that had HCFA properly applied the tie-breaker criteria to the counties it had awarded to LOOP, HCFA would have determined that CORE's performance was superior to LOOP's.

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[11] CORE had requested and received from HCFA an extension of time within which to file a reconsideration request.

CORE's request for reconsideration contained information concerning its performance, both in West Virginia and elsewhere. CORE sought to contrast this performance with that of other OPOs, particularly VOPA. To that end, CORE provided HCFA with information concerning its performance in 1992 and with information concerning VOPA's performance during the same time period. Specifically, CORE provided HCFA with information concerning the total organs recovered by CORE in the first six months of 1992, compared with VOPA's performance during the same period of time. ALJ Ex. 1 at 9.

Additionally, CORE provided HCFA with information concerning its organ recovery performance in the period between July and October, 1992, compared with VOPA's performance during the same time period. Id. at 10. CORE provided HCFA with a letter attesting to its efforts in 1992 to increase eye tissue donations. Id. at 10 - 11; ALJ Ex. 2, Attachment 3. CORE provided HCFA with information concerning the nature of the relationships it had developed during 1992 with hospitals in West Virginia. ALJ Ex. 1 at 14 - 16; ALJ Ex. 2, Attachments 6, 7. CORE provided HCFA with information concerning the total number of beds in West Virginia hospitals with which it had developed relationships, compared to those with which VOPA had developed relationships. ALJ Ex. 1 at 16 - 17; ALJ Ex. 2, Attachments 12, 13. This information is ambiguous in that CORE's reconsideration request does not state clearly whether the information includes 1992 information. CORE provided HCFA with information concerning its efforts to place organ procurement coordinators in reasonably close proximity to hospitals in West Virginia. This information included information as to CORE's efforts in 1992 to establish coordinators in West Virginia.

On August 31, 1993, HCFA advised CORE that it had affirmed its original determination to award nine counties in West Virginia to VOPA. In denying the reconsideration request, HCFA made it plain that it had not considered information supplied by CORE concerning its performance, or that of other OPOs, after January 31, 1992, the deadline for the original application for the service area vacated by MSOPA. HCFA asserted specifically that it would not consider organ procurement cost information supplied by CORE covering a period of time after January 31, 1992 "because . . . [the information] was issued after the evaluation period used to determine the filling of open service area." HCFA Ex. 37 at 2.[12]

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[12] Also, HCFA questioned the relevance of this information.

Furthermore, HCFA asserted that CORE's efforts to place organ procurement coordinators in West Virginia were not relevant because "we have discerned that not all CORE coordinators were in place at the time of the initial application; therefore there is no merit to this concern in the appeal." Id. at 3. HCFA did not discuss the other information which CORE had supplied to it concerning its performance in 1992 or that of other OPOs during the same period of time.

CORE then filed a request for a hearing before an administrative law judge. In its request, CORE contended that the proper scope of the hearing should include HCFA's determination to award the nine counties in West Virginia to VOPA and also HCFA's alleged determination to award to LOOP an additional five counties (Marshall, Mineral, Ohio, Brooke, and Hancock).

III. There is no need for an in-person hearing.

In his January 13, 1994 prehearing order, Judge Stratton questioned whether an in-person hearing was necessary. He established a schedule whereby the parties could brief issues in dispute, including the issue of whether an in-person hearing would be needed. Judge Stratton scheduled a hearing to commence on May 3, 1994, in the event that he decided that such a hearing was needed. Based on the law, the undisputed material facts, and the parties' arguments, I concluded that there was no need in this case for an in-person hearing. I therefore canceled the May 3 hearing.

In deciding whether there is a need for an in-person hearing, I have considered two questions. First, I have assessed whether there are material facts pertaining to CORE's request for a hearing to contest HCFA's decision to award Brooke and Hancock counties to VOPA, which are not set forth completely in the parties' exhibits and which must be explicated by testimony. Second, I have assessed whether there exist material facts pertaining to HCFA's reconsideration of CORE's application for the former MSOPA service area which are not set forth completely in the parties' exhibits and which could be explicated by testimony. I conclude that there are no material facts at issue which are not set forth completely in the part of the parties' exhibits that I admit into evidence. Therefore, there is no need here for me to conduct an in-person hearing.

As I shall discuss in detail in Part VI of the Rationale, I find that CORE is not entitled to a hearing as to HCFA's determination to award Brooke and Hancock counties to LOOP. I base this conclusion on HCFA Exs. 1, 11, 12, 13, and 14,

and P. Exs. 2 and 4. Neither CORE nor HCFA has asserted that there exist material facts in other exhibits which are relevant to the issue of CORE's entitlement to a hearing as to Brooke and Hancock counties, and neither CORE nor HCFA has asserted that there is a need for testimony to elucidate any facts pertaining to the issue of CORE's entitlement to a hearing on this issue. I conclude that the exhibits I have cited here and relied on describe completely the facts which are relevant to resolving the issue of CORE's entitlement to a hearing as to Brooke and Hancock counties. In reaching that conclusion, I have reviewed also all of the other exhibits submitted by the parties and I find nothing in them that would affect or alter my conclusion.

CORE objected to HCFA Exs. 1 and 12 on the ground that these two exhibits contain unidentified, extraneous handwritten statements. I have resolved CORE's objections by not considering the handwritten statements in any respect in reaching my decision in this case. CORE objected also to HCFA Ex. 12 on the grounds that it is not signed, and that there is no proof that the exhibit (a letter dated December 5, 1991 from HCFA to CORE) was actually mailed to or received by CORE. However, in a letter from CORE to HCFA dated January 2, 1992 (HCFA Ex. 14) CORE admits that it received from HCFA a letter dated December 5, 1991 (the date on HCFA Ex. 12). Furthermore, contained in CORE's exhibits as P. Ex. 4 is a letter from CORE's files which is a duplicate of HCFA Ex. 12. In my judgment, the record establishes that CORE received a copy of HCFA's December 5, 1991 letter (HCFA Ex. 12) on or before January 2, 1992.

As I discuss in Part VII of this Rationale, HCFA failed to follow the regulatory requirements contained in 42 C.F.R. § 498.24 when it did not reconsider CORE's application for the service area vacated by MSOPA. I base my conclusion in that Part on my reading of the relevant regulations and on the facts as set forth in three documents: CORE's October 26, 1992 request for reconsideration (ALJ Ex. 1); the appendix to that request, consisting of 12 attachments, which CORE also submitted to HCFA (ALJ Ex. 2); and HCFA's August 31, 1993 reconsideration determination (HCFA Ex. 37). Neither party has objected to my consideration of these documents, and neither party has contended that there is a need for testimony to resolve the issue of whether HCFA conducted its reconsideration of CORE's application in accordance with the requirements of 42 C.F.R. § 498.24.

CORE has argued strenuously that there is a need for me to conduct an in-person hearing in this case with the admission of live testimony. However, none of the testimony which CORE seeks to present relates to the issues which I resolve in Parts VI and VII of this decision. CORE asserts that it

is entitled to an in-person de novo hearing to address the issue of whether it is the OPO that is best qualified to represent the entire service area vacated by MSOPA. CORE contends additionally, that my decision, based on the evidence of record, should supplant the initial and reconsideration determinations made by HCFA. For the reasons which I discuss below, I do not agree with CORE's arguments.[13]

Also, as I discuss in Part VII of the Rationale, I find that HCFA has not conducted a reconsideration, in accordance with the requirements of 42 C.F.R. § 498.24(b), of CORE's application for the nine West Virginia Counties that HCFA awarded to VOPA. This failure by HCFA constitutes a fundamental defect in the review process. I conclude that, inasmuch as the reconsideration determination is defective on its face, there exists no basis for me to consider the underlying merits of the parties' positions. I cannot review HCFA's determinations for propriety because HCFA has never completed the determinations it is obligated to perform.

IV. CORE is not entitled to an in-person de novo hearing in this case.

CORE argues that it is entitled to an in-person de novo hearing as to whether it is the OPO best qualified to provide services in the counties at issue. CORE contends that I must give no weight to HCFA's determination. In effect, CORE argues that the initial determination process and reconsideration are merely procedural hurdles it must clear on the way to a full evidentiary hearing before an administrative law judge, involving a de novo standard of review. That standard, according to CORE, comprises two elements. The first element is a de novo hearing, in which CORE would be permitted to offer all evidence that is relevant to its qualifications to serve the counties at issue, even if that evidence is generated at a point in time after HCFA's initial and reconsideration determinations. The second element is that CORE's qualifications should be evaluated by an administrative law judge without regard to

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[13] Additionally, CORE requested that it be permitted to conduct discovery, consisting of depositions of HCFA officials, in order to develop evidence. The Part 498 regulations do not provide for discovery in cases heard pursuant to Part 498, much less depositions. I am denying CORE's request to take depositions, because there is no need in this case for an in-person hearing. However, even if I were to conclude that there is a need for such a hearing, I would not grant CORE's request to take depositions.

the evaluation performed by HCFA. In other words, the evidence should be measured against only the tie-breaker criteria contained in 42 C.F.R. § 485.308(a)(1) - (6). In order to assure that the record is complete and that all affected parties be afforded due process, other affected OPOs (in this case, VOPA) should be joined as parties and afforded the same opportunities to present evidence as are afforded to CORE.

It is not necessary for me to decide here precisely what the standard of review is in administrative appeals from reconsideration determinations made pursuant to the Part 485 and 498 regulations. I do not need to reach that issue because I find that it would be premature in this case for me to consider the merits of HCFA's determinations, because HCFA's determinations are fundamentally flawed. However, I do not agree with CORE's formulation of the standard of review.

I conclude that the Secretary intended that review by administrative law judges of determinations made by HCFA pursuant to the Part 485 and 498 regulations be in some respects limited to a review of the propriety of HCFA's determinations, based on the record created before HCFA. In this case, HCFA failed to create the record which was required by the regulations. For that reason, I do not have a complete record to review and I must find HCFA's reconsideration determination to be defective. But that does not suggest that the Secretary intended that I supplant the initial determination and reconsideration process with a de novo hearing.

CORE asserts that the regulations contained in Part 498 contemplate de novo hearings, citing 42 C.F.R. § 498.60(b)(1). That section provides that, in a hearing, an administrative law judge inquires:

> fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

CORE asserts that this language expresses the Secretary's intent to provide de novo hearings in all cases heard by administrative law judges pursuant to the Part 498 regulations. CORE cites 42 C.F.R. § 498.56 as additional support for its contention that the proceedings in this case should be de novo. The regulations at 42 C.F.R. § 498.56 provide that administrative law judges may grant hearings on new issues which impinge on the rights of affected parties.

I disagree with CORE's analysis. My reading of the Part 498 regulations is that they do not necessarily provide for

hearings in which the standard of review is de novo. Rather, they provide for such hearings as may be appropriate, given the kind of case heard pursuant to those regulations. Neither the Act nor the Part 485 regulations provide for de novo hearings in cases involving HCFA's determinations to allocate service areas to OPOs. To the contrary, the implication of the Part 485 regulations is that appeals of HCFA's determinations pursuant to Parts 485 and 498 be evaluated using a standard of review which constitutes something less than a de novo review.

The language contained in 42 C.F.R. § 498.60(b)(1), on which CORE relies to support its assertion that it is entitled to a de novo hearing, requires administrative law judges to inquire fully into the matters that are at issue in particular cases. But it does not define what is meant by the term "matters that are at issue." It requires also that administrative law judges receive into evidence that which is relevant and material to a particular case. But it does not define what is meant by the term "relevant and material."

I read this language as constituting a directive to administrative law judges to conduct full hearings in cases brought pursuant to Part 498, consistent with whatever standard of review is applicable in such cases. But this language is neutral in terms of describing what may be a matter at issue or what may be relevant or material in a particular case. What is at issue in any case and what is relevant and material in deciding that issue depends on the nature of that case.

Furthermore, I do not find support for CORE's contention that I must afford it a hearing with a de novo review standard because of the language contained in 42 C.F.R. § 498.56. That regulation provides that, in a hearing conducted pursuant to the Part 498 regulations, an administrative law judge may, where appropriate, consider new issues that impinge on the rights of the affected party. It does not define the term "new issues." I read this language also as not embodying a standard of review. Rather, as with the language contained in 42 C.F.R. § 498.60(b)(1), it is neutral language which empowers an administrative law judge to consider a new issue where appropriate, without defining what a "new issue" constitutes. What is a "new issue" in any case depends on the standard of review employed to hear and decide that case.

The Part 498 regulations thus do not establish a standard of review for this case. They are generic hearing and appeals regulations which apply to a variety of cases. The standard

of review to be employed in any case heard and decided pursuant to the Part 498 regulations depends on what either Congress or the Secretary has directed that standard of review to be. That standard will be found either in the Act itself or in implementing regulations other than the Part 498 regulations.

The Part 498 regulations may be used to hear and decide cases where the standard of review is a de novo hearing. As I describe above, the Secretary has directed that they be used to hear and decide, among other things, cases brought pursuant to sections 1866(h)(1) and 1866(b)(1) of the Act. At one time, these regulations were used to hear and decide cases brought pursuant to sections 1128 and 1156 of the Act. All of these types of cases are cases in which the parties are entitled to de novo hearings. However, the reason that the parties to such cases receive de novo reviews by administrative law judges is that, in such cases, the parties have statutory rights to de novo hearings pursuant to section 205(b) of the Act. That section has been interpreted consistently to require that administrative hearings conducted pursuant to it constitute de novo reviews. Bernardo G. Bilang, M.D., DAB 1295 (1992); Eric Kranz, M.D., DAB 1286 (1991).[14]

This case is different from those in which parties have hearing rights pursuant to section 205(b) of the Act. In this case, CORE has no statutory right to a hearing. Section 1138(b) does not confer hearing rights on dissatisfied parties, either directly or by implication. CORE's hearing rights emanate solely from the Secretary's decision, in her discretion, to confer hearing rights on OPOs who are dissatisfied with HCFA's determinations.

Thus, in order for me to decide whether the standard of review in this case is a de novo review, I must look to what the Secretary has directed me to apply. Section 205(b) of the Act does not provide guidance here. The Secretary has neither stated nor implied that parties in cases involving determinations made pursuant to section 1138(b) of the Act should be given hearings using the standards of review contained in section 205(b). Nor do the Part 498 regulations provide guidance as to the standard of review that I should employ, because, as I find above, these regulations are generic hearing regulations which do not

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[14] Both Bilang and Kranz involved hearing requests brought pursuant to section 1128 of the Act. Section 1128 provides that parties entitled to hearings pursuant to that section have statutory hearing rights under section 205(b) of the Act. Social Security Act, section 1128(f).

establish review standards. I conclude that the source that I must look to for the standard of review in this case is the Part 485 regulations, which establish the criteria for HCFA to allocate designated service areas to OPOs, and which spell out the appeal rights for agencies dissatisfied with HCFA's determinations.

The regulations in Part 485 do not describe specifically a standard of review in administrative hearings involving determinations made pursuant to Part 485. The section which establishes the right to a hearing, 42 C.F.R. § 485.308(b), states only that:

> An organization that applies to HCFA to be the designated OPO for its service area and that is not designated may appeal its non-designation under part 498 of this chapter.

This section is essentially silent as to the scope of review which the Secretary intends to govern hearings before administrative law judges concerning determinations made pursuant to section 1138(b).

However, the review process described in the Part 485 regulations, when coupled with the reconsideration process described in the Part 498 regulations, suggests that the Secretary intended that hearings before administrative law judges in cases under section 1138(b) of the Act be limited to a review of the record generated by HCFA at the initial determination and on reconsideration (assuming that HCFA allows the parties to provide it with evidence in accord with the requirements of regulations). That falls short of the kind of de novo hearing which is advocated by CORE.[15]

It is helpful to consider the purpose of the Part 485 regulations. They were adopted by the Secretary to implement a statute which enfranchises OPOs to serve designated territories. Congress' intent in enacting section 1138(b) of the Act, and the Secretary's intent in publishing implementing regulations, was to assure that beneficiaries and recipients who were in need of transplanted organs had maximum opportunity to receive such organs in the most efficient way possible. Congress decided

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[15] HCFA asserts that, in such a hearing, the administrative law judge should confine the review to a finding that HCFA's initial and reconsideration determinations are or are not supported by substantial evidence. I make no finding here as to whether such a hearing should be based on a substantial evidence standard of review, or on some other standard.

that the way to achieve this objective was by designating specific territories to be allocated to OPOs and by directing that no more than one OPO be allocated a given territory.

One purpose of the Part 485 regulations was to establish a mechanism by which HCFA could decide which OPO was best qualified to provide transplant services to a designated service area. The regulations plainly envision competition among OPOs for service areas. They establish a complex and detailed set of criteria by which HCFA decides such competitions. 42 C.F.R. § 485.308(a)(1) - (6).

It is evident that OPOs who are allocated designated service areas by HCFA rely on such designations. VOPA has not awaited the outcome of this case to become active in the nine counties formerly allocated to MSOPA which HCFA allocated to it in July 1992. CORE has likewise devoted considerable energy and efforts to its designated service area. Relationships with hospitals have been established and organ donor networks have been created.

CORE's argument, essentially, is that the Secretary intends that I should ignore these realities now that the case is before me. It would have me begin the review process anew and receive evidence from all affected parties, including those OPOs who are satisfied with HCFA's determination and who did not request a hearing.

I do not read the Part 485 regulations as suggesting that CORE is entitled to a hearing which renders meaningless the determinations that HCFA is required to make under those same regulations. Additionally, I do not construe the Part 485 regulations as creating a process for CORE to contest HCFA's determinations and simultaneously contend that those same determinations are not entitled to at least some degree of deference.

Given that the regulations direct HCFA to conduct a review process that is both complex and wide-ranging in scope, and the likelihood that OPOs will rely on the results of that process even while appeals are pending, it makes little sense to conclude that the Secretary would, in effect, say that HCFA's determination was entitled to absolutely no deference once a case reached the level of the administrative law judge. Such a result would effectively render meaningless the HCFA review process and would suggest that parties rely on that process at their peril. It would encourage OPOs to hold back evidence from the HCFA review process if they thought they could get a more favorable hearing at the level of the administrative law judge. Such a result might deter an OPO who prevailed in a competition

for a service area to refrain from commencing operations in that area pending the outcome of the administrative hearing process. That in turn would frustrate the objectives of section 1138(b) of the Act, which include facilitating the procurement of organs for transplant for program beneficiaries and recipients. Ultimately, delays in implementing OPO activities in a service area resulting from the time delays inherent in the hearing process might affect adversely the welfare of beneficiaries and recipients.

For these reasons, I conclude that in an administrative hearing involving an OPO dissatisfied with a determination made pursuant to the Part 485 regulations, the evidence to be considered is limited to that which was provided to HCFA, in connection with the initial determination and the request for reconsideration. It would render meaningless the process of review which is established by the regulations if I were to accept evidence at the hearing that a party had the opportunity to present to HCFA, but which it did not present. Furthermore, the regulations plainly envision that the evidentiary record closes with the reconsideration decision.

My analysis here makes it all the more evident that HCFA must, in conducting its reconsideration review, allow a party full opportunity to present evidence to it consistent with the requirements of the regulations. As I discuss below, HCFA's failure to comply with the regulations in accepting and considering evidence renders its reconsideration determination defective on its face.

V. CORE withdrew its hearing request concerning Marshall, Mineral, and Ohio counties.

CORE concedes that the West Virginia counties of Ohio, Marshall, and Mineral should not be part of its appeal. Petitioner's Memorandum in Opposition to Respondent's Motion for Summary Disposition, at 3 - 4, n. 2. The regulations in 42 C.F.R. Part 498 provide that an administrative law judge may dismiss a request for a hearing if a party withdraws its request for a hearing or the affected party asks that the request be dismissed. 42 C.F.R. § 498.68(a). That regulation provides further that an affected party may request a dismissal by filing a written notice with the administrative law judge. 42 C.F.R. § 498.68(b). I construe CORE's concession as a written request to withdraw its request for a hearing as to the West Virginia counties of Ohio, Marshall, and Mineral. I dismiss the request for a hearing concerning these counties, pursuant to 42 C.F.R. § 498.68(a) and (b).

VI. CORE is not entitled to a hearing to contest HCFA's determination regarding Brooke and Hancock counties.

CORE contends that its hearing request properly includes the issue of whether HCFA should have awarded Brooke and Hancock counties to CORE. HCFA contends that CORE is not entitled to a hearing as to these two counties.

42 C.F.R. § 498.70(b) provides that an administrative law judge may dismiss a hearing request where a party has no right to a hearing. I conclude that CORE has no right to a hearing as to whether HCFA should have awarded Brooke and Hancock counties to CORE. I therefore dismiss that part of CORE's hearing request pertaining to Brooke and Hancock counties, pursuant to 42 C.F.R. § 498.70(b).

CORE's contention that it is entitled to a hearing as to HCFA's determinations concerning Brooke and Hancock counties raises two questions. The first question is whether Brooke and Hancock counties were formerly designated as part of MSOPA's service area. As to this question, I conclude that Brooke and Hancock counties were not part of the area for which HCFA solicited applications in December 1991. I conclude also that CORE did not apply for these counties in its final application for that area.
CORE is not entitled to a hearing as to HCFA's alleged failure to award it Brooke and Hancock counties as part of HCFA's determination concerning the former MSOPA service area, because Brooke and Hancock counties were not a subject of the determination. HCFA made it plain to interested OPOs in December 1991 that it was considering applications only for the service area vacated by MSOPA, which did not include Brooke and Hancock counties. In its initial determination, HCFA allocated only MSOPA's former service area, which did not include Brooke and Hancock counties.

Under the Part 498 regulations, a prospective supplier's entitlement to a hearing derives from the initial and reconsidered determinations made by HCFA. 42 C.F.R. § 498.5(d)(1). A prospective supplier is not entitled to a hearing as to matters which are not the subject of the initial or reconsidered determination.

In this case, the subject of HCFA's initial and reconsidered determinations was the West Virginia service area assigned previously to MSOPA. The service area assigned to MSOPA in West Virginia did not include Brooke and Hancock counties. HCFA had assigned those two counties previously to LOOP, when it awarded LOOP a territory which included the Steubenville-Weirton Ohio-West Virginia Metropolitan

Statistical Area (MSA). P. Ex. 2.[16] That MSA included Brooke and Hancock counties. HCFA Ex. 1.

HCFA made it plain in its December 20, 1991 announcement of the open service area in West Virginia that the service area for which it was soliciting applications comprised:

> all counties in West Virginia except Mineral, Hancock, Brooke, Ohio, Marshall, Cabell, Wayne and Wood.

HCFA Ex. 13 at 2 (emphasis added). CORE has not asserted that it was unaware of this announcement.

Because HCFA had allocated Brooke and Hancock counties to LOOP previously, they were not available for assignment as of January 31, 1992. HCFA did not consider that Brook and Hancock were part of the former MSOPA service area. Accordingly, HCFA did not consider Brooke and Hancock counties in its determination to allocate the former MSOPA service area. Brooke and Hancock counties were simply not counties that were the subject of that determination. Therefore, HCFA's determination and reconsidered determination as to the MSOPA service area does not give CORE the right to a hearing as to HCFA's failure to allocate Brooke and Hancock counties to CORE.

On October 18, 1991, CORE wrote to HCFA to tell it of its agreement with MSOPA to assume the service area which MSOPA had vacated. In that letter, CORE told HCFA that it would like to "apply for" counties in West Virginia served previously by MSOPA. The counties which CORE averred were included in the MSOPA service area included Brooke and Hancock counties. HCFA Ex. 11 at 2. If the October 18, 1991 letter were the only letter which CORE sent to HCFA concerning its intent to apply for the former MSOPA service area, then it could be construed as an application for all of West Virginia and not just for those counties vacated by MSOPA.

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[16] HCFA offered a version of its December 11, 1991 letter which it sent to CORE as HCFA Ex. 8. CORE objected to this exhibit on the ground that it contains some handwritten notations which appeared to have been added to the document, and on general authenticity grounds. However, CORE has produced as P. Ex. 2 the copy of the December 11, 1991 letter which it received. I am basing my findings concerning the December 11, 1991 letter and CORE's knowledge of the contents of that letter as it appears in P. Ex. 2, and not as it appears in HCFA Ex. 8.

But even if the October 18 application had been CORE's only communication with HCFA concerning its desire to be designated as a replacement for MSOPA in the service area formerly assigned to MSOPA, CORE would not be entitled to a hearing as to Brooke and Hancock counties. CORE is not entitled to a hearing merely because it applied to serve Brook and Hancock counties. In order to be considered to be the OPO to serve Brook and Hancock counties, those counties must have been part of the area vacated by MSOPA. The fact that CORE may have applied initially to be designated by HCFA to be the OPO in Brooke and Hancock counties under the mistaken notion that these two counties were part of the service area vacated by MSOPA does not give CORE a right to a hearing.

The record reflects unequivocally that the former MSOPA service area for which HCFA sought applications did not include Brooke and Hancock counties and that HCFA's initial determination did not allocate Brooke and Hancock counties. The fact is, however, that shortly after October 18, 1991, CORE learned that the former MSOPA service area did not include Brooke and Hancock counties and learned also that HCFA was not considering Brooke and Hancock counties as part of its determination to reallocate the MSOPA service area. CORE changed its application for the service area to reflect that knowledge. In January 1992, CORE explicitly changed its application for the service area vacated by MSOPA to include only those counties in West Virginia that had been vacated by MSOPA.

On December 5, 1991, HCFA responded to CORE's October 18, 1991 letter. It told CORE that the MSOPA service area did not include Brooke and Hancock counties. HCFA Ex. 12. On January 2, 1992, CORE responded to the December 5, 1991 letter from HCFA by stating that it:

> would like to change its application for the state of West Virginia. We would now like to apply for all counties currently not served by any other OPO. In essence we would like to apply for all counties previously served by . . . [MSOPA] . . .

HCFA Ex. 14; P. Ex. 4. Thus, not only did HCFA's determinations concerning the former MSOPA service area not include Brooke and Hancock counties, but CORE changed its application for the MSOPA service area to exclude Brooke and Hancock counties after being advised by HCFA that these counties were not part of the service area. The subject matter of the determination thus did not include Brooke and Hancock counties.

The second question is whether HCFA failed to notify CORE of a previous determination, in which it allocated Brooke and Hancock counties to LOOP, so that CORE was deprived of the opportunity to timely file a reconsideration request from this determination. I conclude that, on December 11, 1991, HCFA notified CORE of that previous determination. Furthermore, to the extent that the December 11, 1991 notice to CORE is arguably ambiguous, HCFA clarified that notice in its response to CORE's October 18, 1991 letter, which CORE received in early January, 1992. HCFA Ex. 14; P. Ex. 4. CORE did not request reconsideration timely, either from the December 11 notice, or from the other notice which CORE received in January, 1992. Therefore, CORE is not entitled to a hearing as to HCFA's determination to allocate to LOOP a service area which included Brooke and Hancock counties.

CORE asserts that it was unaware prior to July 21, 1992, when HCFA issued its initial determination to allocate the service area formerly allocated to MSOPA, that HCFA had assigned Brooke and Hancock counties to LOOP previously. CORE asserts that, because it was unaware that these counties had been allocated to LOOP, it was denied an opportunity to appeal that assignment. Therefore, according to CORE, the time period during which it could request reconsideration, either of HCFA's failure to allocate Brooke and Hancock counties as part of the MSOPA service area, or of HCFA's previous assignment of Brooke and Hancock counties to LOOP, should begin on July 21, 1992. The time period during which it could request a hearing as to those counties should begin to run with the date of the denial of the reconsideration request. Petitioner contends, therefore, that its request for reconsideration and a hearing as to the assignment of Brooke and Hancock counties is timely, given its first knowledge of that assignment. See P. Opp. at 3.

This argument is not persuasive. CORE cites no evidence to support its assertion that it was unaware prior to July 21, 1992 that HCFA considered Brooke and Hancock counties to be outside of the open service area. CORE's assertion is contradicted squarely by the December 5, 1991 and January 2, 1992 correspondence between CORE and HCFA which proves that, not only did CORE know that Brooke and Hancock counties were not part of the service area vacated by MSOPA, but that it changed its application for the service area to reflect that knowledge. HCFA Ex. 12, 14; P. Ex. 4. Furthermore, HCFA had advised CORE in another communication that it had determined to assign to LOOP a service area which included Brooke and Hancock counties. P. Ex. 2. CORE did not request reconsideration from this determination.

On December 11, 1991, HCFA advised CORE that the service area which included Brooke and Hancock counties had been

assigned to LOOP. P. Ex. 2. The service area had been advertised previously by HCFA as an open service area. In its correspondence with CORE, HCFA described that service area as comprising the Steubenville-Weirton Ohio-West Virginia MSA. CORE, LOOP, and MSOPA applied to be the designated OPO for that service area.

HCFA's December 11 letter does not state specifically that Brooke and Hancock counties are part of the Steubenville-Weirton Ohio-West Virginia MSA. However, the Census Bureau publication describing MSAs states that this MSA includes Brooke and Hancock counties. HCFA Ex. 1 at 7.[17] CORE had applied to serve this MSA. CORE could not possibly have made a credible application to serve the MSA without knowing that it comprised Brooke and Hancock counties. Therefore, CORE was on notice as of its receipt of HCFA's December 11, 1991 letter that HCFA had allocated Brooke and Hancock counties to LOOP.

Furthermore, even were I to assume that the December 11, 1991 notice is ambiguous, CORE was on notice no later than early January 1992, that HCFA would not accept applications for Brooke and Hancock counties, because they had been assigned previously to LOOP and were not part of the service area vacated by MSOPA. In its December 5, 1991 letter to CORE, HCFA informed CORE that Brooke and Hancock counties had been assigned previously to LOOP. Assuming for the sake of argument that CORE did not learn of the assignment of Brooke and Hancock counties to LOOP until January 1992, CORE made no effort to request reconsideration from that later notice within the 60 days required by the regulations. See 42 C.F.R. § 498.22(b)(3). Therefore, its October 26, 1992 request for reconsideration was untimely as to Brooke and Hancock counties.

From the foregoing, I conclude that: (1) CORE had no right to request reconsideration as to Brooke and Hancock counties from HCFA's determination to reallocate the MSOPA service area, because that service area did not include Brooke and Hancock counties; (2) CORE knew by no later than early January 1992 that HCFA had determined separately to assign Brooke and Hancock counties to LOOP; and (3) CORE did not request reconsideration timely from this determination.

VII. HCFA failed to follow the regulations governing reconsideration with regard to CORE's request for the nine West Virginia counties that HCFA assigned to VOPA.

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[17] Regulations which describe service areas for OPOs allude to MSAs, and not to counties. 42 C.F.R. § 485.302.

In reconsidering its determination to allocate the MSOPA service area, HCFA did not consider facts supplied to it by CORE concerning its activities and the activities of other West Virginia OPOs after January 31, 1992. This is inconsistent with the criteria for evaluating reconsideration requests established by 42 C.F.R. § 498.24(b). HCFA's reconsideration determination in this case is, therefore, defective.

In reconsidering an initial determination, HCFA is required to receive from a party relevant written evidence and statements which the party submits within a reasonable time after making the request for reconsideration. 42 C.F.R. § 498.24(a). HCFA is required to consider as relevant:

> the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other evidence submitted under paragraph (a) of this section, taking into account facts relating to the status of the prospective provider or supplier subsequent to the initial determination.

42 C.F.R. § 498.24(b) (emphasis added).

The regulation establishes that reconsideration is a process in which parties may submit new evidence which is relevant to the issues under consideration. Also, the regulation states unambiguously that the evidence which a party submits to HCFA in its request for reconsideration may relate to activities and events which transpire after the date of the initial determination. 42 C.F.R. § 498.24(a) and (b).

Here, the relevant issues in the reconsideration consisted of the comparative strengths and performance of the OPOs who were competing for the service area formerly assigned to MSOPA, as measured by the tie breaker criteria contained in 42 C.F.R. § 485.308(a)(1) - (6). The Part 498 regulations afforded CORE the opportunity to present HCFA with evidence concerning its performance in West Virginia after the date of the initial determination, as well as evidence concerning the performance of other OPOs in West Virginia after the date of the initial determination. 42 C.F.R. § 498.24. HCFA was obligated to consider that evidence in conducting reconsideration.

CORE supplied such additional information to HCFA. The reconsideration request which CORE filed on October 26, 1992 contained facts pertaining to CORE's performance in West Virginia after January 31, 1992. Finding 28; ALJ Exs. 1 and 2; Decision at 11 - 14. It contained comparisons between

CORE's performance and VOPA's performance in West Virginia after January 31, 1992. Id. However, HCFA did not consider this information in evaluating CORE's request for reconsideration. It refused to consider comparative cost information developed by CORE for the period after January 31, 1992 (although it rejected this information also as not being germane to the issue of comparative costs). HCFA Ex. 37 at 2. In refusing to consider this information, HCFA advised CORE that it did not consider information to be relevant if it pertained to a time period beginning after the January 31, 1992 deadline for filing applications for the service area formerly allocated to MSOPA. It refused to consider information supplied by CORE concerning its efforts to develop organ coordinator networks in West Virginia after January 31, 1992. Id. at 3. It failed to consider other information supplied by CORE in its reconsideration request concerning the period after January 31, 1992.

HCFA's refusal to consider information pertaining to the period after January 31, 1992 constitutes a failure to conduct a reconsideration in accordance with the criteria contained in 42 C.F.R. § 498.24(b). HCFA's reconsideration is therefore defective on its face and invalid.

HCFA argues that it was not required to consider the additional information supplied by CORE. It does not dispute that 42 C.F.R. § 498.24(b) requires that HCFA consider relevant information which relates to events which occur after the initial determination. However, HCFA contends that the Secretary did not intend that this regulation apply in cases where the tie-breaker criteria of 42 C.F.R. § 485.308 are used to determine the relative merits of competing applications from more than one OPO for a service area.

HCFA bases this contention on two arguments. First, it asserts that the Part 498 regulations were adopted by the Secretary in 1987 and the Part 485 regulations were adopted in 1988. From this, it argues that the provisions of the Part 485 regulations supersede the part 498 regulations. Second, HCFA argues that it would not make sense to require it to consider additional information here, where there was more than one OPO competing for a service area. HCFA asserts that, inasmuch as its initial determination involved resolving competing bids from three OPOs, it could not consider the additional information submitted by CORE with its reconsideration request without, in effect, reopening the entire application process to all three OPOs. HCFA contends that the Secretary did not contemplate "such a burdensome and inefficient reconsideration procedure" applying to reconsideration of competing bids among OPOs. HCFA MSD at 11.

I am not persuaded by HCFA's arguments. First, the Part 485 regulations specifically incorporate the appeals process contained in the Part 498 regulations, without qualifications or exceptions. 42 C.F.R. § 485.308(b). Thus, rather than supersede the Part 498 regulations with the Part 485 regulations, the Secretary chose explicitly to require that appeals from determinations made pursuant to Part 485 be conducted pursuant to Part 498. The reconsideration procedures contained at 42 C.F.R. § 498.24 were incorporated without exception or qualification.

Second, there is nothing in either the Part 485 regulations or the Part 498 regulations to suggest that the Secretary concluded that it would not make sense to utilize the reconsideration criteria of 42 C.F.R. § 498.24 in reconsidering applications from OPOs. I recognize that, in order to conduct a full reconsideration under 42 C.F.R. § 498.24, HCFA might have to reconsider the strengths and assets of competing OPOs under the tie-breaker criteria contained in 42 C.F.R. § 485.308(b). In the appropriate case -- that is, where an OPO that is dissatisfied with an initial determination brings new information relevant to the tie-breaker criteria to HCFA's attention -- HCFA might solicit additional information from other OPOs who did not seek reconsideration, in order to reconsider fully the issues raised. But that is exactly what is contemplated by the language contained in 42 C.F.R. § 498.24.

As is apparent from the language of 42 C.F.R. § 498.24, the reconsideration process is not an appellate review by HCFA of its initial determination, or even a revisiting of that determination to assure that it was made correctly. The regulation contemplates a new determination in which additional relevant evidence is submitted by the party and considered by HCFA. Thus, it may be that in conducting reconsideration, HCFA must afford all parties to the initial determination the opportunity to present new evidence as to issues raised by the party requesting reconsideration. HCFA may be required to reevaluate its conclusions based on the evidence it obtains in the reconsideration process.

HCFA's failure to consider the new information submitted to it by CORE is not just an "error" in its reconsideration. Rather, it constitutes a fundamental failure by HCFA to evaluate CORE's application consistent with the requirements of the regulation governing reconsideration. HCFA's review of CORE's application for the nine West Virginia counties is therefore defective because HCFA did not conduct a reconsideration in this case as is contemplated by 42 C.F.R. § 498.24.

VIII. Remand to HCFA is the appropriate remedy.

The question remains what remedy should be employed to address HCFA's failure to conduct reconsideration in accordance with the requirements of the regulation. CORE asserts that, even if it is not entitled to a de novo hearing under the regulations governing reconsideration, I should order that one be conducted as a remedy to rectify HCFA's failure to follow the applicable regulations. CORE contends that I should receive evidence concerning CORE's current status as an OPO in West Virginia. CORE argues that I should join VOPA as a party to this proceeding and afford it the opportunity to present evidence that is relevant concerning its current status. Then, according to CORE, I should apply the tie-breaker criteria in 42 C.F.R. § 485.308 to the evidence which CORE, VOPA, and HCFA offer and decide on the basis of the evidence and those criteria which OPO is better qualified to serve the nine West Virginia counties which HCFA allocated to VOPA. CORE urges that I should issue a decision superseding any determination made by HCFA, allocating the nine counties to the OPO best qualified under the tie-breaker criteria.

HCFA argues that, in this case, the appropriate remedy would be to remand the matter for a new reconsideration determination by HCFA. HCFA contends that any remand order I issue should direct HCFA to consider evidence concerning CORE and VOPA's relative merits in the nine counties up to August 31, 1993, the date of HCFA's reconsideration determination in this case.

Remand to HCFA for a new reconsideration determination is the appropriate remedy here. However, I disagree with HCFA that August 31, 1993 should be the cut-off date for the receipt of evidence relevant to CORE's allegedly superior qualifications for the nine counties. Rather, CORE is entitled to present evidence to HCFA concerning its status, or the relative strengths and weaknesses of VOPA, for a reasonable period of time after the date of this decision. For purposes of establishing a date certain, I construe that to be 60 days. HCFA may invite VOPA to present relevant evidence covering this time period as well.

Neither the part 485 regulations nor the Part 498 regulations spell out the remedies which may be imposed by administrative law judges, with the exception of remands, in cases involving appeals from allocations of designated service areas by HCFA. Remand is specifically recited as a remedy. A case may be remanded for consideration of a new issue. 42 C.F.R. § 498.56(d). A case may be remanded also where HCFA requests a remand, and "the affected party

concurs in writing or on the record . . . ." 42 C.F.R. § 498.78(a).

HCFA contends that this case is appropriate for remand. CORE asserts that a remand is not appropriate here. In any event, CORE does not concur, either in writing or on the record, to a remand. However, I do not read 42 C.F.R. §§ 498.56(d) and 498.78(a) as describing the only circumstances in which a case may be remanded. As I note above, the regulations do not set forth the general authority of administrative law judges to impose remedies. However, it is apparent from the context of the regulations relating to remand that administrative law judges' authority to impose remedies is far broader than just the limited remand authority described by the regulations. In the absence of a specific limitation on administrative law judges' authority to impose remedies, I read the remedial authority of the Part 498 regulations as being as broad as that which is vested in the Secretary. The remand regulations, in my judgment, are regulations which state merely that there are specific circumstances (identification of new issues or where requested by HCFA and concurred in by the affected party) where remand is authorized explicitly. However, they do not limit an administrative law judge's authority to order remands in other cases where such would be the appropriate remedy.

This conclusion follows logically, both from the regulations' silence as to the ambit of administrative law judges' remedial authority, and CORE's arguments concerning administrative law judges' authority. If, as CORE argues, my authority is so broad as to include substitution of my evaluation of the record for HCFA's evaluation, and ordering that HCFA's determination as to the best qualified OPO be superseded by my own, then it must include the authority to order less drastic relief.
I conclude that, in this case, remand to HCFA is the reasonable remedy. It is apparent from both the Part 485 and Part 498 regulations that the Secretary intended that HCFA conduct a complete review in order to determine which OPO is best qualified to serve the part of the service area formerly assigned to MSOPA which is the subject of this case. HCFA has not yet conducted a complete review because it has not considered information subsequent to its initial determination, as it is required to do under the regulations governing reconsideration. Therefore, the case should be remanded to HCFA so that it may conduct a complete review pursuant to the regulations governing reconsideration.

I am not suggesting here that I would order a remand to HCFA in every case where I found that HCFA failed to follow its regulations. There may be circumstances where the only

appropriate remedy would be something more directive than a remand. Moreover, I may not be able to order a remedy more directive than a remand without taking new evidence. But I do not conclude that this case is one in which a more directive remedy is appropriate. There is nothing here to show that HCFA is incapable of applying its regulations or that some other reason exists for me to conclude that HCFA will not conduct a full reconsideration on remand.

HCFA argues that review should consider relevant evidence concerning CORE and other OPOs' performance through August 31, 1993, the date of HCFA's remand determination. I disagree with this contention. HCFA never has conducted the reconsideration determination which the regulations mandate. The regulations require HCFA, in considering reconsideration requests, to receive evidence that is submitted within a "reasonable time after the request for reconsideration." 42 C.F.R. § 498.24(a). Inasmuch as HCFA has not yet conducted its reconsideration as required by the regulations, the August 31, 1993 date of HCFA's reconsideration determination should not be the date that the record closes. I conclude that CORE may provide HCFA with current data pertaining to its activities and to the activities of other OPOs as well. In order to impose some finality on the process, I direct that CORE should complete its submission to HCFA no later than 60 days from receipt of this decision. HCFA may invite other parties, including VOPA, to submit to it any evidence which they consider to be relevant.

HCFA has suggested that this case may be moot, because it may decide on its own to reopen the former MSOPA service area for new applications from agencies wishing to become OPOs for that service area. I do not conclude that this case is moot, in part because HCFA has not stated definitively that it is reopening the service area and because I have no definitive proof before me that such reopening will occur.

CONCLUSION

I conclude that CORE withdrew its request for a hearing concerning whether HCFA should have included the West Virginia counties of Ohio, Marshall, and Mineral within CORE's designated service area. I conclude that CORE does not have a right to a hearing concerning whether HCFA should have included the West Virginia counties of Brooke and Hancock within CORE's designated service area. I dismiss CORE's request for a hearing concerning Ohio, Marshall, Mineral, Brooke, and Hancock counties.

I conclude that HCFA did not reconsider its determination to assign the West Virginia counties of Morgan, Jefferson,

Fayette, Monroe, Mercer, Berkeley, Raleigh, Greenbrier, and Summers to VOPA, and not to CORE, in accordance with the requirements of 42 C.F.R. § 498.24(b). I remand this case to HCFA in order that it may conduct a reconsideration in accordance with the requirements of 42 C.F.R. § 498.24(b). CORE may submit relevant evidence to HCFA up to 60 days from receipt of this decision. Such evidence may include evidence which relates to the criteria contained in 42 C.F.R. § 485.308(a)(1) - (6) concerning CORE's performance, or the performance of other OPOs at any time up to the date the evidence is submitted by CORE to HCFA.

/s/

Steven T. Kessel
Administrative Law Judge