No. 98-1284

In the Supreme Court of the United States

OCTOBER TERM, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

GREGORIA GRIJALVA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 97-15877

GREGORIA GRIJALVA; CAROL KNOX; MARY LEA; BEATRICE BENNETT; AND MILDRED MORRELL, INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS-APPELLEES

v.

DONNA E. SHALALA, SECRETARY, HEALTH AND HUMAN SERVICES, DEFENDANT-APPELLANT

v.

JOSEPHINE BALISTRERI; FRED S. SCHERZ; KEVIN A. DRISCOLL; MINA AMES; EDMUNDO B. CARDENAS; ARLINE T. DONOHO; PATRICIA SLOAN; BETH ROBLEY; GOLDIE M. POWELL; RICHARD BAXTER, PLAINTIFFS-INTERVENORS

Appeal from the United States District Court for the District of Arizona

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[Argued and Submitted: Jan. 13, 1998
Decided: Aug. 12, 1998]

Before: CHOY, SCHROEDER, and WIGGINS, Circuit Judges.

WIGGINS, Circuit Judge:

Medicare beneficiaries enrolled in health maintenance organizations ("HMOs") in Arizona sued the Secretary of Health and Human Services ("Secretary"). Their suit alleged a failure to enforce due process requirements and a failure to monitor HMO denials of medical services to enrolled Medicare beneficiaries. The district court granted Plaintiffs summary judgment, holding that HMO denials of medical services to Medicare beneficiaries constitute state action and that the regulations issued by the Secretary fail to provide due process. The district court issued an injunction mandating certain procedural protections for Medicare beneficiaries enrolled in HMOs. The Secretary appeals. We affirm.

I. Background

Congress passed the Medicare Act, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, in 1965 to provide a federal health insurance program for the elderly and the disabled. Today, a Medicare beneficiary can receive Medicare services in two different ways. The first is to receive Medicare on a fee-for-service basis. Under this option, the beneficiary goes to a health care provider for the necessary covered services; either the provider or the beneficiary will be reimbursed by the government for the cost of the services. The second, newer option is to enroll in an

HMO or other eligible organization.[1] *See* 42 U.S.C. § 1395mm(b).

In 1982, Congress authorized the Secretary to enter into "risk-sharing" contracts with HMOs. *See* § 1395mm. Under these contracts, HMOs provide to enrolled Medicare beneficiaries all the Medicare services provided in the statute, *see* § 1395mm(c)(2)(A), in exchange for a monthly flat payment from the Secretary, *see* § 1395mm(a).

The Medicare statute establishes in § 1395mm(c) procedural protections for those beneficiaries that enroll in HMOs. Among these, the HMO must "provide meaningful procedures for hearing and resolving grievances between the organization . . . and members enrolled . . . ." § 1395mm(c)(5)(A). HMO members must also have certain appeal rights:

> A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in [42 U.S.C. § 405(b)], and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in [42 U.S.C. § 405(g)]. . . .

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[1] Here, "HMOs" refers to all eligible health services providers, including HMOs and other "competitive medical plans." 42 U.S.C. § 1395mm(b).

§ 1395mm(c)(5)(B).

The Secretary created additional appeal protections in subsequent regulations. *See* 42 C.F.R. §§ 417.600—417.638. Under § 417.604, each HMO must establish appeal procedures and ensure that beneficiaries receive written information about the appeal and grievance procedures. *See* § 417.604(a). If the HMO makes an "organization determination" (defined in § 417.606) adverse to the enrollee, "it must notify the enrollee of the determination within 60 days of receiving the enrollee's request for payment for services." § 417.608(a)(1). An example of an adverse organization determination is an HMO's decision that certain medical services are not covered by Medicare. The notice to the beneficiary must "[s]tate the specific reasons for the determination" and inform the enrollee of his or her "right to a reconsideration." § 417.608(b). Failure to provide timely notice is an adverse determination and may be appealed by the enrollee. *See* § 417.608(c).

If the enrollee is dissatisfied with an adverse determination, a request for reconsideration may be filed within 60 days from the date of the notice. *See* §§ 417.614 & 417.616(b). Within 60 days of the request, the HMO may make a decision fully favorable to the enrollee. *See* § 417.620(a). If it decides to make a decision that partially or completely affirms the adverse determination, it must explain its decision in writing and forward the case to the Health Care Financing Administration ("HCFA"). *See* § 417.620(b). If the enrollee is dissatisfied with the result of the reconsideration, and the amount remaining in controversy is $100 or more, the enrollee has a right to a hearing before an administrative law judge ("ALJ"). *See* § 417.630. The enrollee can appeal that hearing decision to the Appeals

Council and then to the district court. *See* §§ 417.634 & 417.636.

The Secretary possesses a number of sanctions to ensure HMO compliance with the Medicare statute and the Secretary's regulations. First, the Secretary "may not enter into a contract . . . with an [HMO] unless it meets the requirements of [§ 1395mm(c)] and [§ 1395mm(e)]." 42 U.S.C. § 1395mm(c)(1). The specified sections require the HMO, inter alia, to provide all Medicare services to eligible enrollees, to have particular open enrollment periods, to provide enrollees annually with information on their rights, including appeal rights, to provide covered services "with reasonable promptness," to provide the aforementioned procedural protections, and not to exceed certain limits on rates charged to beneficiaries and the Secretary. §§ 1395mm(c) & 1395mm(e).

Second, the Secretary may terminate any contract with an HMO if she determines that the HMO has not met the terms of the contract or has not satisfied the statutory or regulatory requirements. *See* § 1395mm(i)(1). If the Secretary determines that an HMO has failed to provide necessary covered services to an enrollee and that failure has adversely affected the individual, the Secretary may seek civil money penalties, suspend enrollment, or suspend payment to the HMO. *See* § 1395mm(i)(6).

In 1993, five Medicare beneficiaries enrolled in an Arizona HMO sued the Secretary. Among other claims, Plaintiffs alleged that the Secretary "has failed and refused to take effective action to implement beneficiaries' notice and appeal rights when they are denied health care services by their HMOs," and "has failed and refused to provide Medicare beneficiaries enrolled

in HMOs with a procedure of obtaining review of HMO denial decisions contemporaneously with the denial decisions." In a decision not on appeal, the district court certified a nationwide plaintiff class.

In October 1996, the district court granted partial summary judgment to Plaintiffs on the claims described above. *See Grijalva v. Shalala*, 946 F.Supp. 747 (D. Ariz. 1996). The court held that the "organization determinations" made by HMOs constitute state action, triggering constitutional due process requirements. *See id.* at 751-53. The court also held that the regulations promulgated by the Secretary regarding adverse determinations by HMOs fail to provide sufficient due process to enrollees under *Mathews v. Eldridge*, 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). *See Grijalva*, 946 F.Supp. at 756-60. In particular, the district court found that the notices issued by HMOs failed to provide adequate notice: they were often illegible, failed to specify the reason for the denial, and failed to inform the beneficiary that he or she had the right to present additional evidence to the HMO. *See id.* at 757-59. Therefore, "[s]ubsequent due process, available in the administrative review phase of the appeal, comes too late in many cases. . . ." *Id*. at 759. The district court also found that the language of § 1395mm(c)(1) ("The Secretary may not enter into a contract . . . with an eligible organization unless it meets the requirements of this subsection") was mandatory, requiring the Secretary to enforce her regulations by refusing to renew a contract with an HMO if the denial notices of that HMO fail to provide due process. *See id.* at 760.

The district court found that the Secretary violated § 1395mm(c)(1) by entering into a contract with any HMO that failed to provide timely notice for any and all

denials of service. The court held that the notice must be legible (at least 12-point type), state clearly the reason for the denial, inform the enrollee of all appeal rights, explain hearing rights and procedures, and provide "instruction on how to obtain supporting evidence, including medical records and supporting affidavits from the attending physician." *Id.* at 760-61. The district court also held that any hearing must be "informal, in-person communication with the decision-maker," available upon request for all service denials, and timely. *Id.* at 761. The district court also required expedited hearings for "acute care service denials." *Id.*

On March 3, 1997, the district court issued an injunction mandating the above requirements. *See Grijalva v. Shalala*, No. CIV 93-711 TUC ACM, 1997 WL 155392 (D. Ariz. Mar. 3, 1997).

The Secretary appealed the district court's decision in May 1997. The district court granted her a stay of its injunction pending this appeal.

II. Standards of Review

We review a grant of summary judgment de novo. *See Bagdadi v. Nazar*, 84 F.3d 1194, 1197 (9th Cir. 1996). We must determine, viewing the evidence in the light most favorable to the nonmoving party, whether there are any genuine issues of material fact and whether the district court applied correctly the relevant substantive law. *See id.* We may affirm on any ground supported by the record. *See Intel Corp. v. Hartford Accident & Indem. Co.*, 952 F.2d 1551, 1556 (9th Cir. 1991).

We review the scope of an injunction for an abuse of discretion or application of erroneous legal principles.

See SEC v. Interlink Data Network, 77 F.3d 1201, 1204 (9th Cir. 1996).

III. Discussion

A. *State Action Doctrine*

The Secretary appeals the district court's holding that HMO denials of medical services to enrolled Medicare beneficiaries constitute state action and therefore invoke constitutional due process protections.[2]

The actions of private parties are not subject to the requirements of constitutional due process unless they can fairly be considered government action. *See Shelley v. Kraemer*, 334 U.S. 1, 13, 68 S.Ct. 836, 92 L.Ed. 1161 (1948). We use the same standards to attribute the actions of private actors to the federal government under the Fifth Amendment as we do to attribute private actions to state governments under the Fourteenth Amendment. *See Kitchens v. Bowen*, 825 F.2d 1337, 1340 (9th Cir.1987).

The actions of private entities constitute state action under particular circumstances. In order to show that a private action is in fact state action, the plaintiff must show that "'there is a sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself.'" *Blum v. Yaretsky*, 457 U.S. 991, 1004, 102 S.Ct. 2777, 73 L.Ed.2d 534 (1982) (quoting *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 351, 95 S.Ct. 449, 42 L.Ed.2d 477 (1974)). The government's regulation of the private actor is insufficient

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[2] The district court held that such HMO denials constitute "state action." We interpret this as holding that such HMO actions constitute government action, specifically federal action.

alone to show federal action. *See Blum*, 457 U.S. at 1004, 102 S.Ct. 2777; *Jackson*, 419 U.S. at 350, 95 S.Ct. 449. Government action exists if there is a symbiotic relationship with a high degree of interdependence between the private and public parties such that they are "joint participant[s] in the challenged activity." *See Burton v. Wilmington Parking Auth.*, 365 U.S. 715, 725, 81 S.Ct. 856, 6 L.Ed.2d 45 (1961). Government action exists if the challenged private action occurs under government compulsion. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 170-71, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970). The government must do more, however, than merely acquiesce in the challenged action. *See Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 164, 98 S.Ct. 1729, 56 L.Ed.2d 185 (1978) (holding that government inaction is insufficient for state action). A detailed inquiry into the facts of the particular case may be necessary to determine whether there is state or federal action. *See Jackson*, 419 U.S. at 351, 95 S.Ct. 449.

In this case, the question is whether the challenged action—HMO denials of services to Medicare beneficiaries with inadequate notice—may fairly be treated as that of the federal government. We agree with the district court's cogent analysis and conclusion that, in the circumstances of the Secretary's regulation of and delegation of Medicare coverage decisions to HMOs, HMO denials of services to Medicare beneficiaries with inadequate notice constitute federal action.

We find that HMOs and the federal government are essentially engaged as joint participants to provide Medicare services such that the actions of HMOs in denying medical services to Medicare beneficiaries and in failing to provide adequate notice may fairly be

attributed to the federal government. The Secretary extensively regulates the provision of Medicare services by HMOs. HMOs are required, by the Medicare statute and their contracts with the Secretary, to comply with all federal laws and regulations. The Secretary is required to ensure, inter alia, that HMOs provide adequate notice and meaningful appeal procedures to beneficiaries. The Secretary pays HMOs for each enrolled Medicare beneficiary (regardless of the services provided). The federal government has created the legal framework—the standards and enforcement mechanisms—within which HMOs make adverse determinations, issue notices, and guarantee appeal rights. Medicare beneficiaries enrolled in HMOs may appeal an HMO's adverse determination to the Secretary, who has the power to overturn the HMO's decision. Each of these factors alone might not be sufficient to establish federal action. Together they show federal action. *See Catanzano v. Dowling*, 60 F.3d 113, 117-120 (2d Cir. 1995) (similar analysis in Medicaid context); *J.K. v. Dillenberg*, 836 F. Supp. 694, 697-99 (D. Ariz. 1993) (same).

The Secretary argues that the Supreme Court case of *Blum v. Yaretsky*, 457 U.S. 991, 102 S.Ct. 2777, 73 L.Ed.2d 534 (1982), mandates a finding that HMO adverse determinations are not state action. We disagree.

In *Blum*, the Supreme Court held that nursing home decisions made by doctors and administrators to transfer patients to other facilities, thereby terminating their Medicaid benefits, did not constitute state action. The Court held that the decisions at issue in the case turned "on medical judgment made by private parties according to professional standards that are not established by the State." 457 U.S. at 1008, 102 S.Ct.

2777. Because state officials did not have the power to approve or disapprove the nursing home decisions, but just altered the level of Medicaid benefits accordingly, the Court held that the decisions were not state action. *See id.* at 1010, 102 S.Ct. 2777.

Unlike the nursing home doctors and administrators in *Blum*, the HMOs in this case are not making decisions to which the government merely responds. HMOs are following congressional and regulatory orders and are making decisions as a governmental proxy—they are deciding that Medicare does not cover certain medical services. In *Blum*, by contrast, the nursing homes decided that certain medical services were no longer medically necessary. While such an inquiry may occur in HMO service denials, the decisions in the case at hand are more accurately described as coverage decisions—interpretations of the Medicare statute—rather than merely medical judgments (particularly when no reason for the denial is given other than that the service does not meet "Medicare guidelines . . . based upon [the HMO's] understanding and interpretation of Medicare . . . coverage policies and guidelines," to quote a typical notice provided by Plaintiffs).

The district court's reasoning and holding that HMO service denials are federal action therefore do not run counter to *Blum*. As noted by the district court, the government cannot avoid the due process requirements of the Constitution merely by delegating its duty to determine Medicare coverage to private entities. *See* 946 F. Supp. at 752; *see also Burton*, 365 U.S. at 725, 81 S.Ct. 856 ("But no State may effectively abdicate its responsibilities by either ignoring them or by merely

failing to discharge them whatever the motive may be.").

We hold, therefore, that, when denying medical services to enrolled Medicare beneficiaries, HMOs are federal actors.

B. *Due Process and Mathews v. Eldridge*

The parties agree that the balancing test used by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976), applies to determine the necessary procedural protections to ensure that due process is provided to Medicare beneficiaries enrolled in HMOs.

In *Mathews v. Eldridge*, the Supreme Court considered the sufficiency of the procedures by which Social Security disability benefits were terminated. *See* 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). The Supreme Court held that constitutional due process is flexible, demanding particular protections depending on the situation. *See id.* at 334, 96 S.Ct. 893. The requirements of due process in a particular situation depend on an analysis of three factors:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the functions involved and the fiscal and administrative burdens that the additional or substitute procedural requirements would entail.

Id. at 335, 96 S.Ct. 893. A court must balance these factors to determine whether the particular additional

procedural safeguards sought by a plaintiff are required in a given situation.[3] *See id.*

We agree with the district court's analysis of the *Eldridge* factors and its conclusion that due process requires additional protections for Medicare beneficiaries enrolled in HMOs.

1. *Private Interest at Stake*

The district court held that the private interest at stake from an HMO's initial denial of Medicare coverage is the potential that medical care will be precluded altogether. The court held that this interest is a substantial private interest in additional protections such as timely and effective notice of service denials. We agree.

In *Eldridge*, the Court held that the private interest at stake was the individual's interest in "uninterrupted receipt" of disability benefits. 424 U.S. at 340, 96 S.Ct. 893. The Court held that this interest was not based on financial need (unlike the situation of the welfare recipient in *Goldberg v. Kelly*, 397 U.S. 254, 90 S.Ct. 1011, 25 L.Ed.2d 287 (1970)), and does not implicate a high degree of potential deprivation. *See id.* at 340-41, 96 S.Ct. 893.

The district court was correct in holding that Plaintiffs' interest in Medicare benefits is greater than the interest of the plaintiff in *Eldridge*. As the district court noted, "[u]nlike *Eldridge*, the deprivation suffered from an HMO denial to provide care cannot so

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[3] The Secretary argues that, in general, the Secretary's views on the appropriate level of procedural protections should be accorded "great deference." There is nothing in *Mathews v. Eldridge* or subsequent cases to suggest that such is necessary or advisable.

easily be remedied by retroactive recoupment of benefits." 946 F.Supp. at 757. An HMO's denial of coverage is an initial refusal to provide any medical services. The mere fact that the enrollee may be able to go elsewhere and pay for the services herself is of little comfort to an elderly, poor patient—particularly one who is ill and whose skilled nursing care has been terminated without a specific reason or description of how to appeal.

The Secretary argues that the district court erred by "adjudicating a complex procedural scheme as falling short of basic standards of fairness, *without* conducting the sort of detailed inquiry needed." For example, the Secretary argues, the district court should have distinguished between different types of medical services and their urgency when considering this first *Eldridge* factor, the magnitude of the private interest at stake. The Secretary also argues that the district court's finding that the interests of Medicare HMO enrollees are "especially" great because they may not receive immediate medical care is erroneous because some beneficiaries can seek those services elsewhere (and then seek reimbursement from the HMO) or disenroll from the HMO. The Secretary's arguments fail. Although, in some cases, the effect of service denial may be remedied easily after the fact, the potential for irreparable damage is surely great when it comes to denial of medical services (particularly denial without notice of any reason for the denial), unlike the suspension of disability benefits pending review as in *Eldridge*. In many, if not most, cases, the denial of coverage may result in total failure to receive the services.

The Secretary argues that the district court failed to recognize that the Medicare program is not need-based,

a fact which the Secretary argues mandates holding against additional procedural protections. The Secretary cites to *Eldridge* for this proposition. The Court in *Eldridge*, however, discussed the fact that the disability benefits were not need-based in order to distinguish the case from that in *Goldberg v. Kelly*, 397 U.S. 254, 90 S.Ct. 1011, 25 L.Ed.2d 287 (1970), where the Court had held that a hearing was necessary prior to the suspension of welfare benefits. The Court did not hold that a program has to be need-based in order for this factor to weigh in favor of additional protections.

Other courts have found on similar facts that a significant private interest is at stake that weighs in favor of additional protections. *See*, *e.g.*, *Kraemer v. Heckler*, 737 F.2d 214, 222 (2d Cir. 1984) ("In applying the balancing test, the private interest at stake [in the termination of Medicare coverage] should be weighed more heavily than in *Eldridge* because of the astronomical nature of medical costs."); *Vorster v. Bowen*, 709 F. Supp. 934, 946 (C.D. Cal. 1989) ("The private interest, in this case, is the claimant's need to obtain reimbursement for medical bills that he or she has already paid. That interest is fairly great. Congress enacted the [Medicare] program because of the special coincidence of medical needs and financial problems of the elderly."). The interest of the HMO enrollees in medical services weighs in favor of additional procedural protections beyond that offered by the Secretary's original regulations.

2. *Risk of Erroneous Deprivation*

The district court also held that factor two weighed in favor of greater procedural protections for Medicare beneficiaries enrolled in HMOs. The court reviewed Plaintiffs' analysis of notice failures and conducted its

own review of the notices provided to Plaintiffs. The court held that the notices failed to provide adequate explanation for the denials. *See* 946 F.Supp. at 757-58. We agree. This failure creates a high risk of erroneous deprivation of medical care to Medicare beneficiaries. The appeal rights and other procedural protections available to Medicare beneficiaries are meaningless if the beneficiaries are unaware of the reason for service denial and therefore cannot argue against the denial. "Due process requires notice that gives an agency's reason for its action in sufficient detail that the affected party can prepare a responsive defense." *Barnes v. Healy*, 980 F.2d 572, 579 (9th Cir. 1992). Therefore, inadequate notice creates the risk of erroneous deprivation by undermining the appeal process.

The Secretary attacks the district court's analysis of this factor by arguing that the court simply identified an "arguable problem" faced by enrollees— inadequate notice—rather than address whether that problem actually results in deprivations. The Secretary argues that the district court "simply *assumed* that the perceived failures of notice resulted in fewer appeals, and that more appeals would diminish erroneous deprivations." The Secretary fails to recognize the real problem: Inadequate notice renders the existence of an appeal process meaningless. Moreover, the question established by *Eldridge* is not whether the inadequate notices actually resulted in erroneous deprivations, but whether the inadequate notices created an unjustifiably high risk of erroneous deprivation. Because due process has at its foundation the notion of adequate notice, the risk of erroneous deprivation caused by ineffective notices points towards the need for added procedural

protections for Medicare beneficiaries enrolled in HMOs.

3. *The Government's Interest*

The Secretary argues that the district court paid only cursory attention to this factor, dismissing the government's concerns. The Secretary argues that the procedures sought by plaintiffs would impose a large burden on HMOs, which would accordingly affect the benefits received by enrollees.

The district court did not engage in as detailed an analysis of this third factor as of the other two. A shorter analysis, however, does not mean the analysis is cursory or dismissive. The Secretary has failed to show that the added procedural protections sought by Plaintiffs would result in significant additional costs to the government. Unlike the plaintiff in *Eldridge*, Plaintiffs do not seek a hearing prior to every denial, which would greatly increase costs. Adequate notices do not impose a burden on HMOs that outweighs the beneficiaries' need for them. "[A] weighing of the *Mathews [v. Eldridge]* factors suggests that the administrative burden of providing an explanation for denying a [certain benefit] is minimal in light of the added potential for spotting erroneously withheld [benefits]." *Barnes v. Healy*, 980 F.2d 572, 579 (9th Cir. 1992). The Secretary fails to advance any convincing argument that an additional burden on the government outweighs the effects of the other factors such that additional procedural safeguards are not necessary.

Taken together, the *Eldridge* factors point to a need for additional procedural protections for Medicare beneficiaries enrolled in HMOs, in particular for adequate notice of service denials, including the specific reason

for the denial and an explanation of appeal rights, and expedited review for critical care denials. We therefore affirm the district court's holdings on *Eldridge*.

C. *The Scope of the Injunction*

The Secretary challenges the scope of the injunction issued by the district court.[4] The scope of an injunction is reviewed for an abuse of discretion or application of erroneous legal principles. *See SEC v. Interlink Data Network*, 77 F.3d 1201, 1204 (9th Cir. 1996). "When

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[4] In addition, the Secretary argues that the district court should not have issued any injunction, because the proper course, if the existing regulations were insufficient to provide due process, was to remand the case to the Secretary for her to produce new regulations comporting with due process. The cases cited by the Secretary, however, do not support this argument in the present case.

For example, in *Thompson v. United States Dep't of Labor*, 885 F.2d 551 (9th Cir.1989), this court remanded the case to the Secretary on very particular facts. The Secretary had entered into a settlement agreement with a whistleblower who had sued the Department. Despite prior discussions on the question, the agreement was silent on the question of whether the Secretary could dismiss the complaints with prejudice. The Secretary then dismissed the complaints with prejudice. This court held that the Secretary could not dismiss the complaints with prejudice and remanded the case for the Secretary to decide if it still wanted to enter into the settlement agreement. *See* 885 F.2d at 558.

This case is not analogous. The Secretary never had adjudicative jurisdiction over this case. The Secretary does not provide any case that states that this court must remand to her on the facts of this case. The issuance of an injunction was within the district court's equitable powers. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13, 102 S.Ct. 1798, 72 L.Ed.2d 91 (1982) (holding that a district court possesses the equity jurisdiction to issue an injunction, provided that it has subject matter jurisdiction and that Congress has not mandated otherwise).

injunctive relief is sought against a state agency or official, such relief 'must be no broader than necessary to remedy the constitutional violation.'" *Barnes v. Healy*, 980 F.2d 572, 576 (9th Cir. 1992) (quoting *Toussaint v. McCarthy*, 801 F.2d 1080, 1086 (9th Cir. 1986)).

The Secretary argues vociferously that the injunction issued by the district court was widely and irrationally broad in scope. For example, the Secretary repeatedly ridicules the district court's requirement of 12-point type for all notices of service denials. The scope of the district court's injunction, however, is not either an abuse of discretion or the result of application of erroneous legal principles.

The district court required legible (which requires 12-point type for senior citizens) and clear notices that adequately explain to beneficiaries the reasons for the denial of services and inform them of their appeal rights. The court required any hearings to be informal and in-person. An abuse of discretion is not apparent in these requirements. Moreover, many of them are already required by the Medicare statute or the Secretary's regulations (which might make them redundant, but does not make them an abuse of discretion). The court also required the Secretary to monitor the behavior of HMOs. This requirement is not an abuse of discretion given that Congress implicitly required such in the Medicare statute by forbidding the Secretary from entering into contracts with HMOs that did not comply with the statute or the regulations and by providing the Secretary with the power to sanction the HMOs.

The Secretary argues that the district court abused its discretion by prohibiting the Secretary from entering into new contracts with HMOs that fail to provide

the procedural protections mandated by the court. The Secretary argues that Congress provided the Secretary with a wide range of enforcement mechanisms, and that the district court could not require the Secretary to use the harshest mechanism. This argument fails. The Medicare Act mandated that the Secretary "may not enter into a contract . . . with an [HMO] unless it meets the requirements of [§ 1395mm(c)] and [§ 1395mm(e)]." 42 U.S.C. § 1395mm(c)(1). Under its clear meaning, this provision is not permissive; to the contrary, it is mandatory. The district court did not err or abuse its discretion.

The Secretary notes that, since the district court's summary judgment and injunction in favor of Plaintiffs, she has promulgated new regulations providing additional procedural protections for Medicare beneficiaries enrolled in HMOs. She asks us to review and modify the district court's injunction accordingly. Finding it unnecessary to do so, we decline her invitation. The district court has continuing jurisdiction over the modification of the injunction. *See Transgo, Inc. v. Ajac Transmission Parts Corp.*, 768 F.2d 1001, 1030 (9th Cir. 1985) (declining to remand to district court with directions to modify injunction, noting that the party "may apply directly" to the district court for modification in light of post-trial events). The Secretary may move in the district court for a modification of its injunction.

IV. Conclusion

For the foregoing reasons, we AFFIRM the district court's summary judgment and injunction in favor of Plaintiffs.

AFFIRMED.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 97-15877
D.C. No. CV-93-00711-ACM

GREGORIA GRIJALVA; CAROL KNOX; MARY LEA; BEATRICE BENNETT; AND MILDRED MORRELL, INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS-APPELLEES

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AMERICAN ASSOCIATION OF RETIRED PERSONS, ET AL., AMICUS

[Filed: Nov. 12, 1998]

ORDER

Before: WIGGINS, Circuit Judge:

The panel votes to deny the petition for rehearing. Judge Schroeder votes to reject the suggestion for rehearing en banc and Judges Choy and Wiggins so recommend.

The full court has been advised of the suggestion for rehearing en banc and no active judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing is denied and the suggestion for rehearing en banc is rejected.

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Civ. No. 93-711 TUC ACM

GREGORIA GRIJALVA, CAROL KNOX; MAY LEA, BEATRICE BENNETT, AND MILDRED MORRELL, AS INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS

JOSEPHINE BALISTRERI, FRED S. SCHERZ, KEVIN A. DRISCOLL, MINA AMES; EDMUNDO B. CARDENAS, ARLINE T. DONOHO, PATRICIA SLOAN, BETH ROBLEY, GOLDIE M. POWELL AND RICHARD BAXTER, PLAINTIFFS-INTERVENERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: Oct. 17, 1996]

ORDER

MARQUEZ, Senior District Judge.

This action involves the Medicare program and its coverage of medical care dispensed by Health Main-

tenance Organizations (HMOs).[1] Plaintiffs seek declaratory and injunctive relief against the Secretary for abdicating her responsibility to monitor HMOs and to ensure that HMOs provide Medicare covered benefits. Plaintiffs ask that the Court order Defendant Shalala, Secretary of Health and Human Services, to implement and enforce effective notice, hearing, and appeals procedures for HMO service denials. Plaintiffs and Defendant simultaneously move for summary judgment.

Defendant alleges that HMOs are privately owned entities and their actions cannot be imputed to the federal government. Defendant contends that this Court has no jurisdiction to review the Health Care Finance Administration's (HCFA's) supervision of HMOs. Defendant asserts that neither the Administrative Procedure Act (APA), Constitution, or the Medicare statutes provide for judicial oversight of the Secretary.[2] Defendant repeats her previous argument that, here, there can be no judicial review because

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[1] These plans include Competitive Medical Plans (CMPs) which provide more limited services than an HMO. Either type of plan can be a public or private entity. Both are risk-based, e.g. paid on a flat rate basis, rather than fee-for-service. Risk based organizations receive a predetermined per capita monthly prospective payment to cover Medicare beneficiaries. The organization is responsible for any difference between the prepaid capitated amount and the actual costs incurred to furnish medical services to its Medicare enrollees, hence the term "at risk."

[2] Defendants charge that Plaintiffs fail to specify the legal basis for their claims. The Court resolved this issue on December 15, 1994, when it denied Defendants' Motion to Dismiss. This Court waived the requirement of exhaustion under 42 U.S.C. § 405(g) and held that jurisdiction exists over this case pursuant to 42 U.S.C. § 1395mm. *See* Order filed December 15, 1994.

Plaintiffs failed to exhaust their administrative remedies.

Plaintiffs seek summary judgment for Defendant's failure to enforce service requirements on HMOs in violation of statutory mandates and the Due Process Clause of the Constitution. Plaintiffs complain HMOs either fail to provide any notice or provide inadequate notice when medical services are denied. Plaintiffs contend that the Constitution requires an expedited hearing before an HMO can deny services and that HMOs carry the burden of proof for Medicare denials.

A. Jurisdiction Revisited: 42 U.S.C. § 405(g)

Section 405(g) of the Social Security Act applies to service denials by HMOs because 42 U.S.C. § 1395mm provides:

> (B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 405(b) of this title, and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1000 or more, the individual or eligible organization shall, upon notifying the other party, *be entitled to judicial review of the Secretary's final decision as provided in section 405(g) of this title*, and both the individual and the eligible

> organization shall be entitled to be parties to that judicial review. (emphasis added).

42 U.S.C. § 405(b) requires that the Secretary make findings of fact, and decide the rights of any individual applying for a payment under this subchapter. Any decision by the Secretary which is in whole or in part unfavorable to a claimant "shall contain a statement of the case, in understandable language, setting forth a discussion of the evidence, and stating the Secretary's determination and the reason or reasons upon which it is based." 42 U.S.C. § 405(b). Further:

> Upon request . . . and showing in writing that rights may be prejudiced by any decision the Secretary has rendered, [the Secretary] . . . shall give . . . reasonable notice and opportunity for hearing. If a hearing is held, [the Secretary] shall, on the basis of evidence adduced at the hearing, affirm, modify, or reverse his findings of fact and such decision. Any such request . . . must be filed within sixty days after notice of such decision is received. . . .

Id.

42 U.S.C. § 405(g) provides for judicial review of a final decision by the Secretary. "A final judgment in the context of § 405(g) and § 1395mm(c)(5)(B) consists of two elements: (1) the presentment of a claim to the Secretary; and 2) exhaustion of administrative remedies. *Johnson v. Shalala*, 2 F.3d 918, 921 (9th Cir. 1993)." (Order filed December 5, 1994 at 4.) The presentment requirement, the non-waiveable criteria for jurisdiction, is not an issue here, *Id.* at 5; all Plaintiffs in

the instant case filed claims for Medicare covered services and protested HMO denials. (Plaintiffs' Supplement to Plaintiffs' Memorandum in Support of Motion for Certification of Class Action filed June 26, 1995.) This Court waived the exhaustion requirement by its Order of December 15, 1994, (*See* Order at 5-8); this Court previously held, and again affirms, that jurisdiction exists under § 405(g).

Abundant case law supports such jurisdiction under § 405(g) for challenges involving various Social Security entitlement Programs. *See e.g.*: *Johnson v. Shalala*, 2 F.3d 918 (9th Cir.1993) (exhaustion waived: Social Security Income (SSI) recipient challenged Social Security Administration policy of counting all in-kind loans as income); *Briggs v. Sullivan*, 886 F.2d 1132 (9th Cir. 1989) (exhaustion waived: challenge to Secretary's policy of withholding SSI beneficiaries' representative payments during time beneficiary was without representation; declaratory and injunctive action against Secretary for improper policy and procedure); *Schoolcraft v. Sullivan*, 971 F.2d 81 (8th Cir.1992) (exhaustion waived: Social Security disability beneficiaries challenged Secretary's failure to ensure that uniform standards were applied at all levels of review, specifically initial determination conducted by state agency), *cert. denied*, 510 U.S. 1081, 114 S. Ct. 902, 127 L.Ed.2d 93 (1994); *Himmler v. Califano*, 611 F.2d 137 (6th Cir. 1979) (exhaustion waived: applicants for Medicare benefits alleged due process violations when benefits were terminated by fiscal intermediary without notice and hearing); *Kraemer v. Heckler*, 737 F.2d 214 (2nd Cir. 1984) (exhaustion waived: due process challenge to Secretary's policy of allowing Utilization Review Committee (URC) to terminate Medicare without notice or

hearing); *Goodnight v. Shalala*, 837 F. Supp. 1564 (Utah 1993) (exhaustion waived: claim against state agency for procedural irregularities violating Medicare regulations and against Secretary for failure to enforce); *Vorster v. Bowen*, 709 F. Supp. 934 (C.D. Cal. 1989) (exhaustion waived: due process challenge to initial determination of coverage by private carrier providing Part B, Medicare supplemental insurance); *Fox v. Bowen*, 656 F. Supp. 1236 (D.Conn.1987) (exhaustion waived: fiscal intermediaries' routine denials of Medicare coverage, based on improper presumptions, for certain categories of physical therapy violated due process).

Assuming this Court correctly waived the exhaustion requirement for jurisdiction under § 405(g), there is nothing unique about 42 U.S.C. § 1395mm and its provisions for judicial review via § 405(g) of the Social Security Act which affects jurisdiction over claims against the Secretary just because dispensation of medical care is via an HMO.

B. State Action: HMO Service Denials

Defendant makes much of the fact that HMOs are private, non-governmental entities because it is a fundamental rule of law that due process under the Fourteenth Amendment attaches only to actions which may fairly be said to be those of the state. *Shelley v. Kraemer*, 334 U.S. 1, 13, 68 S. Ct. 836, 842, 92 L.Ed. 1161 (1948). Therefore, Plaintiffs' claim hinges on whether HMO denials of service constitute state action.

Defendant argues that HMOs are merely private providers who contract with the government to provide medical care to Medicare beneficiaries. Defendant's

scenario fits within the protected confines of *Blum v. Yaretsky*, 457 U.S. 991, 102 S. Ct. 2777, 73 L.Ed.2d 534 (1982). In *Blum*, the Supreme Court found nursing home decisions to transfer patients to lower care facilities did not constitute state action even though the transfer decision resulted in a corresponding termination of benefits. The transfer decisions, made by attending physicians and home administrators,[3] were made by private parties according to professional standards. *Id.* at 1008, 102 S. Ct. at 2787-88. Since there was no evidence that the State had exercised coercive power or provided significant encouragement, overt or covert, there could be no finding in law of state action. *Id.* at 1004, 102 S. Ct. at 2785-86.

Defendant, the State of Arizona, made this same argument in *J.K. v. Dillenberg*, 836 F. Supp. 694 (Ariz. 1993): "REBHAs [regional behavioral health authorities] are responsible for the decision making that Plaintiffs seek to enjoin, but [ ] they function as private entities whose actions cannot be attributed to the state." *Dillenberg*, 836 F. Supp. at 697. Judge John M. Roll distinguished the nursing homes in *Blum* as private providers which did not execute state responsibilities for a state created service, *Id.* at 698, from those in *Dillenberg*, where the state had delegated the entire responsibility for its mandated behavioral health care duties to REBAHs. The state action factors in *Dillenberg* were: 1) the private entities, REBHAs, were subject to extensive state involvement; and 2) the

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[3] URC transfers were not at issue in *Blum*, the issue having been settled prior to the Supreme Court's review of the case. *Blum* left open the issue of whether URC transfers constituted state action. *Kraemer v. Heckler*, 737 F.2d at 220.

contract required REBHAs to "'comply with all Federal, State, and local laws, rules, regulations, standards and executive orders, governing performance of duties . . . and shall comply with provisions of federal laws and regulations governing the Title XIX Program. . . ." *Id.* at 698-99.[4]

Similarly, the Second Circuit recently found that decisions made by certified home health agencies (CCHAs), non-governmental private entities, to deny or reduce the amount of home health care prescribed for Medicaid recipients are "state actions" that trigger due process rights to a fair hearing. *Catanzano v. Dowling*, 60 F.3d 113 (2nd Cir.1995). The Second Circuit found that the state defendants exercised significant control over the CCHAs: 1) the government paid for covered services; and 2) the government regulated CCHAs activities, issued directives which could not be ignored and created the legal framework which gov-

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[4] Following *Dillenberg*, Judge Richard M. Bilby ruled in *Perry v. Chen*, CIV 95-140 TUC RMB, 1996 WL 159808, that there was state action when HMO, AHCCCS health plans terminated authorization for previously covered Medicaid services. Judge Bilby reasoned the Due Process Clause of the Constitution requires notice and an opportunity for a face-to-face hearing because: 1) the HMOs are paid by AHCCCS for covered services; 2) the HMOs' activities are regulated by AHCCCS; 3) AHCCCS issues directives which plans must follow and creates through rules, contracts and policies the framework under which the plans act to dispense medical care to AHCCCS beneficiaries; 4) the challenged HMO decisions are based on medical judgment and cost effectiveness; and 5) appeal of HMO decisions are made to AHCCCS which has the ultimate power to correct erroneous denials. Judge Bilby concluded that the HMOs assumed obligations of the state to provide Arizona's version of Medicaid (AHCCCS) benefits to the needy.

erned the grievous activities. The Circuit found Judge Roll's reasoning in *Dillenberg* persuasive:

> "It is patently unreasonable to presume that Congress would permit a state to disclaim federal responsibilities by contracting away its obligations to a private entity."

Id. at 118 (quoting *Dillenberg*, 836 F. Supp. at 699).

It seems equally unreasonable that Congress would permit the Secretary to disclaim her responsibility to "determine whether individual is entitled to benefits under part A or part B of [Medicare], and [to determine] the amount of benefits under part A or part B of [Medicare]." 42 U.S.C. § 1395ff; *see also*, 42 U.S.C. § 405(b) (Secretary shall make findings of fact, and decide the rights of any individual applying for a payment under Medicare).

Other criteria of *Dillenberg* and *Catanzano* for finding state action apply as well: 1) the government pays for covered services; 2) the government regulates HMOs' activities as they apply to Medicare beneficiaries, especially benefit coverage determinations; 3) the Secretary issues regulations and directives which cannot be ignored; the Secretary creates the legal framework which governs the activities complained of by Plaintiffs;[5] and 4) Medicare beneficiaries appeal

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[5] The Secretary has the power to inspect and audit the HMOs to determine quality of service and financial stability. 42 U.S.C. § 1395mm(i)(3). The Secretary can terminate HMO contracts, 42 U.S.C. § 1395mm(i)(3), or impose civil fines for noncompliance, 42 U.S.C. § 1395mm(i)(6)(B). *See also*: Section C of this Order setting out the regulatory provisions under which HMOs are required to

HMO service denials directly to the Secretary, who has the power to overturn the HMO decision.

Defendant's argument that HMOs are *Blum*-type private providers ignores the Medicare scheme.[6] In risk-based, managed care, the HMO performs two functions: direct provider of medical care and insurer. In the fee-for-service system, separate entities perform these functions: medical providers, i.e., doctors, and insurance companies, e.g. Blue Cross Blue Shield. This case questions the performance of the latter function by private provider HMOs.

There is really nothing new about a private, non-governmental entity being involved in the administrative arena of Medicare.

> The determination and review procedures for claims arising under the two parts of the Act [Parts A and B] are similar. *Both are administered primarily through non-governmental organizations*,[7] *usually insurance companies, pursuant to contracts with*

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operate, specifically the notice and appeal procedures which apply to Medicare service denials.

[6] Congress created the Medicare program in 1965 by enacting Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.* In 1972, Congress expanded Medicare to cover the permanently disabled and authorized the program to reimburse HMOs for services to Medicare beneficiaries. The Tax Equity and Fiscal Responsibility Act of 1982, § 114(a), weakened participation standards for HMOs and prompted widespread use of risk-based HMOs by Medicare.

[7] Under Part A of Medicare, the organizations are called "intermediaries." Under Part B, the organizations are called "carriers."

> *the Department.* (footnote omitted). Claims for payment or reimbursement are submitted to the carrier, which makes an initial determination as to the claim and sends a notice of its action together with any payment to the claimant. If the claimant is dissatisfied, a request for review may be made, (footnote omitted).

Gray Panthers v. Schweiker, 652 F.2d 146, 149 (D. C. Cir. 1980) (emphasis added). These fiscal intermediaries act as agents for the Secretary. *Kraemer v. Heckler*, 737 F.2d at 215 (citing 42 U.S.C. § 1395h); *Fox v. Bowen*, 656 F. Supp. at 1249 (Conn.1987); *see also*: *Himmler v. Califano*, 611 F.2d at 140 (fiscal intermediary is alter ego of Secretary for day-to-day administration of Medicare program); *Vorster v. Bowen*, 709 F. Supp. at 946-47 (denials issued by carrier treated like official action; court found due process required detailed notice of reasons for denial by carrier).

There is nothing unique about the performance of these same duties by HMOs which warrants a contrary finding here. Even if HMOs' performance of administrative duties is somehow distinguishable from those authorized by 42 U.S.C. § 1395h, the Court finds that HMO denials of Medicare services are properly held state action under the analysis set forth in *Dillenberg* and *Catanzano*.

C. *Procedural Due Process and HMO Determinations That There is No Medicare Coverage for a Requested Service*

Defendant has not referred this Court to, and this Court has not found, any provision in the Medicare

statutes or regulations pertaining to HMOs, to suggest that beneficiaries of Medicare who are denied services by HMOs are entitled to any less procedural due process than beneficiaries who are denied fee-for-service coverage. There is nothing in the Congressional record which suggests that Congress intended any less than full benefits and rights to apply when it embraced HMOs as Medicare providers.[8]

The Medicare statute, 42 U.S.C. § 1395mm(c)(2)(A), requires HMOs to provide the same range of services to plan enrollees as provided for Medicare beneficiaries generally.[9] HMOs are further required to:

> (A) make the services described in paragraph (2) (and such other health services as such individu-

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[8] Defendants argue that Medicare enrollees in HMOs exchanged Medicare appeal rights for expanded medical care. The Court rejects this notion. As well, the Court does not consider the ability to disenroll from the HMO and reenroll with a fee-for-service provider appropriate relief for disputed HMO service denials. Such freedom of choice might serve to resolve disputes between treating physicians, but it would be poor public policy to offer such relief for service denials based on Medicare coverage determinations. As Plaintiffs point out, this would allow HMOs to shift their risk back to Medicare. Essentially, Medicare (the tax payer) would pay twice: once as a flat rate to the HMO ostensibly to cover the service and again as a fee-for-service, after the beneficiary disenrolled from the HMO and obtained the service.

[9] Part A of Medicare provides: inpatient hospital services up to 150 days; post hospital extended care services up to 100 days. 42 U.S.C. § 1395d(a). Part B provides: home health care services; medical and other health services, such as physicians' services; outpatient physical therapy; certain health clinic services; outpatient rehabilitation facility services; and facility services furnished in connection with certain surgical procedures. 42 U.S.C. § 1395k(a)(2), (s), (x) (1992).

> als have contracted for) (i) available and accessible to each such individual within the area served by the organization, with reasonable promptness and in a manner which assures continuity, and (ii) when medically necessary, available and accessible twenty-four hours a day and seven days a week, and
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> (B) provide for reimbursement with respect to services which are described in subparagraph (A) and which are provided to such an individual other than through the organization, if (i) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition and (ii) it was not reasonable given the circumstances to obtain the services through the organization.

42 U.S.C. § 1395mm(c)(4). HMOs "must provide meaningful procedures for hearing and resolving grievances between the organization . . . and members enrolled with the organization under [the Medicare program]." 42 U.S.C. § 1395mm(c)(5)(A).

The regulatory scheme adopted by the Secretary to implement the statutory mandates of 42 U.S.C. § 1395mm[10] is very similar to that set out for initial fee-

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[10] An HMO must establish grievance and appeals procedures, 42 C.F.R. § 417.600(a)(2)(i), for Medicare enrollees dissatisfied because they do not receive health care services to which they believe they are entitled, at no greater cost than they believe they are required to pay. 42 C.F.R. § 417.600(a)(2)(ii). These enrollees have the right to an ALJ hearing if the amount in controversy is $100 or more, 42 C.F.R. § 417.600(a)(2)(ii)(A), or have the right to judicial review, if the amount exceeds $1000, 42 C.F.R. § 417.600(a)(2)(ii)(B). "For any claimant whose disagreement with

for-service coverage denials rendered by fiscal intermediaries or carriers. Reconsideration and appeal procedures for intermediary decisions on Part A claims are covered by 42 C.F.R. §§ 405.701-730; reconsideration and appeal for Part B claims are covered by 42 C.F.R. §§ 405.801-812. The two are essentially the same. *Gray Panthers*, 652 F.2d at 149, n. 6. Reconsideration procedures for HMO denials are set out in 42 C.F.R. §§ 417.600-694.

An HMO must establish and maintain appeal procedures for issues that involve organization determinations, 42 C.F.R. § 417.604(a)(1)(i):[11] 1) payment for emergency or urgently needed services; 2) any other health service furnished by a provider other than the HMO that the enrollee believes is covered under Medicare and should have been furnished by the HMO; and 3) HMO's refusal to provide services that the enrollee believes should be furnished by the HMO and enrollee has not received them outside the HMO. 42 C.F.R. § 417.606(a).[12] "Within 60 days of receiving the enrollee's request for payment for services,"[13] an HMO

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the [HMO] at this stage does not amount to more than $100, that is the end of the process, according to the Secretary's procedures. There is no further review, and there is at no time an opportunity to present one's case personally to the decisionmaker." *Gray Panthers*, 652 F.2d at 149 (assessing identical provisions pertaining to initial coverage denials rendered by Medicare carriers (42 C.F.R. §§ 405.720, 405.730, 405.815)).

[11] *Compare* 42 C.F.R. § 405.801.

[12] *Compare* 42 C.F.R. §§ 405.704, 405.803.

[13] Unlike the fee-for-service system which determines coverage after services are rendered, the HMO system generally entertains the question based on an enrollee's request for medical services, prior to rendering care. Emergency, urgent care, and

must give notice to an enrollee of any adverse organizational determination. 42 C.F.R. § 417.608(a).[14] The notice must state the specific reasons for the determination and inform the enrollee of his or her right to reconsideration. 42 C.F.R. § 417.608(b).[15] Failure to provide timely notice constitutes an adverse organizational determination and may be appealed. 42 C.F.R. § 417.608(c).

The organizational determination is final and binding unless reconsidered. 42 C.F.R. § 417.612.[16] An enrollee who is dissatisfied with an organization determination may file a written request for reconsideration within 60 days of the determination.[17] 42 C.F.R. § 417.614; 42 C.F.R. § 417.616(c).[18] "The HMO [ ] must provide the parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing." 42 C.F.R. § 417.618.[19]

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out-of-area services are provided by the HMO upfront and the initial determination for these services comes after the fact like fee-for-service denials. Therefore, HCFA's HMO Manual requires that the initial determination notice issue when a member requests payment or services. (Joint Statement of Facts at p. 20, HMO Manual 2403.2)

[14] *Compare* 42 C.F.R. §§ 405.702, 405.803.

[15] *Compare* 42 C.F.R. §§ 405.702, 405.804.

[16] *Compare* 42 C.F.R. §§ 405.708, 405.804.

[17] The request for reconsideration may be filed with the HMO, any local SSA office; or railroad retirement beneficiaries may file with the RRB. 42 C.F.R. § 417.616(a).

[18] *Compare* 42 C.F.R. §§ 405.710, 405.711, 405.807 (Part B reconsideration has a 6 month filing limitation).

[19] *Compare* 42 C.F.R. §§ 405.715 (HCFA performs Part A reconsideration; there is no right to in person participation by the

"If the HMO [ ] can make a reconsidered determination that is completely favorable to the enrollee, the HMO issues the reconsideration determination." 42 C.F.R. § 417.620(a). The HMO must issue its favorable decision within "60 calendar days from the date of receipt of the request for reconsideration" or submit the file to HCFA. 42 C.F.R. § 417.620(c)-(f). If on reconsideration, the HMO partially or wholly affirms its denial, the HMO must prepare a written explanation and send the entire case to HCFA. HCFA makes the reconsidered determination. 42 C.F.R. § 417.620(b).[20] HCFA contracts with Network Design Group (NDG) to make the reconsidered determination within 30 days. (Joint Statement of Facts ¶ 13.)

Notice of the reconsideration determination must be mailed to the enrollee, and if issued by the HMO, a copy of the determination must be sent to HCFA. 42 C.F.R. § 417.624. The notice must state the reasons for the reconsidered determination and inform the party that if the claim is for $100 or more, he or she has a right to a hearing before an Administrative Law Judge (ALJ).[21] *Id.*[22] The notice must describe the procedures for obtaining a hearing. *Id.*[23] A reconsidered deter-

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beneficiary), 405.809 (carrier performs reconsideration, there is no right to in person participation).

[20] *See* n. 19.

[21] For Medicare Part A claims, under circumstances involving constitutional challenges, there is an expedited appeal process which bypasses ALJ and Appeal Council review. 42 C.F.R. § 405.718.

[22] *Compare* 42 C.F.R. §§ 405.716, 405.811 (Part B claims for $100 are entitled to a carrier hearing; thereafter, claims of $500 or more can be appealed to an ALJ).

[23] *Compare* 42 C.F.R. § 405.811.

mination is final and binding, 42 C.F.R. § 417.630,[24] unless a written request for a hearing is filed within 60 days of the date of notice of the reconsidered determination, 42 C.F.R. § 417.632.[25]

Any party to the ALJ hearing may request the Appeals Council to review the case. 42 C.F.R. § 417.634.[26] Judicial review of the Appeals Council decision may be had if the amount in controversy is $1,000 or more. 42 C.F.R. § 417.636.[27]

The Court finds that the Medicare statute,[28] the Secretary's regulations,[29] and the Due Process Clause of the Constitution, unequivocally provide that a Medicare beneficiary is entitled to notice and hearing when an HMO denies services based on coverage determinations.

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[24] *Compare* 42 C.F.R. §§ 405.717, 405.812.

[25] *Compare* 42 C.F.R. §§ 405.717, 405.722.

[26] *Compare* 42 C.F.R. §§ 405.724, 405.815.

[27] *Compare* 42 C.F.R. §§ 405.730, 405.815.

[28] HMOs "must provide meaningful procedures for hearing and resolving grievances between the organization . . . and members enrolled with the organization under [Medicare]." 42 U.S.C. § 1395mm(c)(5)(A).

[29] "Within 60 days of receiving a request for payment for services, an HMO must give notice to an enrollee of any adverse organization determination." 42 C.F.R. § 417.608(a). The notice must state the specific reasons for the determination and inform the enrollee of his or her right to reconsideration. 42 C.F.R. § 417.608(b). When reconsidering a claim, the HMO must provide the beneficiary a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. 42 C.F.R. § 417.618.

In *Gray Panthers*, the appellate court for the District of Columbia Circuit found that due process applies even to Medicare denials for claims of $100 or less and requires a "genuine opportunity" to be heard, even though the "full fair hearing" described in *Goldberg v. Kelly*, 397 U.S. 254, 90 S. Ct. 1011, 25 L.Ed.2d 287 (1970), was not necessary. *Gray Panthers*, 652 F.2d at 152 n. 15, 158-59. The court defined "hearing" as "any confrontation, oral or otherwise,[30] between an affected individual and an agency decisionmaker sufficient to allow the individual to present his case in a meaningful manner." *Id.* at 148 n. 3. The exact form of the hearing does not upset the core requirements of due process "—adequate notice of why the benefit is being denied and a genuine opportunity to explain why it should not be." *Id.* at 165.

In *Gray Panthers*, the court found oral hearings were required in part because of deficiencies in the notice provided to beneficiaries. The court reasoned that, at the oral hearings, beneficiaries could obtain clarification about the basis for denial and have a meaningful opportunity to respond. The court limited its opinion to the facts of the case and conjectured that alternative procedures such as better notice might alleviate some, perhaps all, due process deficiencies. *Id.* at 148 n. 4, 166.

Exactly what process is owed the Medicare beneficiary by the HMO is determined by a balancing test,

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[30] "Paper hearings" can, depending on the total context of the entire notice and hearing process, provide an adequate opportunity to explain one's case. *Gray Panthers*, 652 F.2d at 165 (citing *Basciano v. Herkimer*, 605 F.2d 605 (2nd Cir.1978), *cert. denied*, 442 U.S. 929, 99 S. Ct. 2858, 61 L.Ed.2d 296 (1979)).

first established in *Mathews v. Eldridge*, 424 U.S. 319, 334-35, 96 S. Ct. 893, 902-03, 47 L.Ed.2d 18 (1976): the private interest at stake; the risk of an erroneous deprivation; the probable value of additional or substitute procedural safeguards, and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

D. The Mathews v. Eldridge Balancing Test

1. The Private Interest

In *Mathews v. Eldridge*, the Supreme Court held that an evidentiary hearing, as provided for in *Goldberg v. Kelly*,[31] was not required prior to an initial termination of disability benefits. *Eldridge*, 424 U.S. at 340-50, 96 S. Ct. at 905-10. The *Eldridge* Court distinguished the welfare benefits at stake in Goldberg, as an interest "'not present in the case of . . . virtually anyone else whose governmental entitlements are ended—[that is,] that termination of aid pending resolution of a controversy over eligibility may deprive an eligible recipient of the very means by which to live while he waits.'" *Eldridge*, 424 U.S. at 340, 96 S. Ct. at 905 (quoting *Goldberg*, 397 U.S. at 264, 90 S. Ct. at 1018). The *Eldridge* Court concluded, "Eligibility for disability

[31] The pretermination due process rights of *Goldberg*, rejected by the Court in *Eldridge*, are: 1) timely and adequate notice of the reasons for termination; 2) an effective opportunity to defend a claim by confronting adverse witnesses and by presenting the case, including evidence, orally; 3) retained counsel, if desired; 4) an impartial decisionmaker; 5) a decision based on the law and evidence adduced at the hearing; and 6) a statement of reasons for the decision and the evidence relied on. *Goldberg*, 397 U.S. at 266-71, 90 S. Ct. at 1019-22.

benefits, in contrast, is not based upon financial need." *Id.*

The Court, nonetheless, recognized that the degree of distinction could be easily overstated because a disability recipient is by definition, "unable to engage in substantial gainful activity" and correspondingly will usually be in a precarious economic position. *Id.* at 342, 96 S. Ct. at 588-89. The Court, however, found that there was less reason than in *Goldberg* to require a full blown hearing because any temporary loss in disability benefits could possibly be offset by access to private financial resources or if not, other governmental, such as state, welfare subsidy programs could temporarily replace the lost disability benefit. *Id.*

Finally, the Court considered the "possible length of wrongful deprivation of benefits" as an important factor in assessing the impact on the private interest at stake. *Id.* at 341-42, 96 S. Ct. at 905-06. In *Eldridge*, the time between an initial determination of ineligibility for disability benefits and a final determination exceeded one year. *Id.* But then, wrongfully withheld benefits could be retroactively recovered. *See Eldridge*, 424 U.S. at 340, 96 S. Ct. at 905 (full retroactive relief confines the claimant's interest to the uninterrupted receipt of benefits).

The private interest at stake from an initial denial of Medicare coverage "should be weighed more heavily than in *Eldridge* because of the astronomical nature of medical costs." *Kraemer v. Heckler*, 737 F.2d 214, 222 (2nd Cir.1984). The Second Circuit assessed the time between an adverse Utilization Review Committee (URC) decision which triggered termination of benefits

and the agency's affirmation of the termination which triggered appeal rights and concluded that the approximately three-week period could financially cripple all but the very wealthy. The court held that because the potential for personal liability for medical costs would most likely cause a patient to discontinue receiving medical care, due process attaches to URC denial decisions. *Id.*

The *Kraemer* court distinguished the procedures available to the recipient facing termination of Medicare benefits by the URC and those available in *Eldridge*. In *Eldridge*, the plaintiff asked for an evidentiary hearing or oral presentation prior to the initial termination of disability benefits. The Secretary had already provided: notification of the tentative assessment and reasons for the denial, including a summary of the evidence; the beneficiary had access to all the information being considered by the agency and had an opportunity to make written submissions, with the assistance of a treating physician to rebut the agency's information and tentative conclusion. In *Kraemer*, no procedural process was afforded the beneficiary prior to URC termination of benefits. *See also*: *Vorster v. Bowen*, 709 F. Supp. at 946 (disproportionate number of Medicare recipients live near the poverty level; in combination with the astronomical cost of medical care, there is a substantial interest in obtaining reimbursement for medical bills already paid); *Fox v. Bowen*, 656 F. Supp. at 1249-50 (private interest in receiving Medicare coverage for physical therapy; due process attaches to coverage denials which terminate receipt of physical therapy). *But see Himmler v. Califano*, 611 F.2d at 146 (post-denial notice and hearing via administrative appeal sufficient due process because no sub-

stantial deprivation; medical services are already received so the only issue is ultimate financial liability).

Here, the Court finds that Plaintiffs have a greater interest in Medicare benefits than the disability benefits assessed in *Eldridge*, especially because they are HMO enrollees. The HMO's initial adverse coverage determination in many cases prevents receipt of medical care. Unlike *Eldridge*, the deprivation suffered from an HMO denial to provide care cannot so easily be remedied by retroactive recoupment of benefits. When Medicare services are denied, they are often foregone and, depending on the medical condition, final adjudication may come too late to rectify the situation, especially if the deprivation contributed to or resulted in unnecessary pain and suffering or death. (*See* Volume I Plaintiffs' Declarations: Exhibit A in Support of Motion for Summary Judgment.)[32]

The Court is aware that many HMO denials involve emergency or urgent care services which occur after delivery of service and address only whether the patient is the financially liable party. This was the issue in *Gray Panthers* and *Vorster v. Bowen.* The Court finds the reasoning in *Gray Panthers* and *Vorster* persuasive and finds that in all instances, Medicare beneficiaries have a substantial interest in receiving timely services or timely payment for care already received.

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[32] The Court shall not repeat the sad case histories of the Plaintiffs, but this exclusion in no way makes their stories any less heart breaking. The Court finds that in each Plaintiffs' case the denial of Medicare services worked a substantial and painful deprivation upon the beneficiary.

2. The Risk of an Erroneous Deprivation through the Procedures Used

In 1993 and 1994, the rate of appeals from fee-for-service denials were respectively, 27 and 31 times higher than appeals from HMO denials. (Joint Statement of Facts at ¶ 15.)[33] Defendant argues that this evinces the great job being performed by HMOs. The Court concludes otherwise.

Plaintiffs reviewed 570 HMO adverse notices and report:

1. *Readability*: 52% of the notices reviewed were illegible, based primarily on criteria of 12-point type as the recognized minimum print size for readability by elderly persons.
2. *Reason for Denial*: 74% of the notices provided vague, ambiguous, nonspecific reasons for denial.
3. *Personal Liability*: only 41% contained an explanation of personal liability resulting from care incurred subsequent to denial.

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[33] For purposes of Plaintiffs' Motion for Summary Judgment, the Court assumes timeliness at all stages of the appeal process. The record reflects rampant timeliness problems, but Defendants submit any time problems have been recently resolved and that HMOs and NDG are now complying with regulatory deadlines. (Joint Statement of Facts at ¶ 16.) The Court believes strict compliance is mandatory, especially in light of the severe hardship which can be worked by a Medicare service denial and the fact that there is no expedited appeal mechanism for acute medical care decisions. Hospital discharges are the only services subject to immediate appeal by Peer Review Organizations (PROs). 42 C.F.R. § 417.605.

4. *Appeal Rights*: vast majority of the notices provided information on appeal rights. Ninety-six percent of the notices included the time frame for appeal; 91% directed claimants on where or with whom to file the appeal; 73% explained that additional evidence could be provided; only 10% provided information about Peer Review Organization (PRO)[34] review.

(Volume III Plaintiffs' Exhibit C in Support of Motion for Summary Judgment at 2.)

The Court additionally reviewed the denial notices it found sprinkled throughout the 44 declarations of party Plaintiffs. (See Volume I Plaintiffs' Declarations Exhibit A in Support of Motion for Summary Judgment at 2, 9, 10, 13, 20, 23, 30, 33, 38, and 42.)[35] Of these ten examples, six were issued in 1995, two in 1994, one in 1993, and one in 1992. The Court found the notices failed to provide adequate reasons for the denials. Not one notice provided the specific basis for coverage denial; the notices only included explanations like, "beneficiary no longer receiving "skilled nursing care" and therefore, based on the HMO's "understanding of Medicare coverage policies," the HMO would not continue to provide the care after some date

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[34] PROs are independent organizations of health care professionals which by law HCFA must contract with to review the quality of care given to Medicare beneficiaries. (Joint Statement of Facts at ¶ 35); 42 U.S.C. § 1395mm(i)(1). Congress mandated funding for PRO review activities. 42 U.S.C. § 1395mm(i)(7)(B) and (C).

[35] The Court finds that these are not isolated cases. *See* same Exhibit at 11, 19, 27, 29, 35, 37, and 41 (supporting affidavits of various client advocacy groups).

certain—usually two days from the day the letter was written. This does not inform the beneficiary of the factual basis for the denial, nor enlighten him or her as to what specific service is not covered and why. Without proper notice, the claimant must guess at what evidence to submit for reconsideration of the claim. *Gray Panthers*, 652 F.2d at 168.

The notice format used by the HMOs hides the ball. For example, the notices reviewed by the Court were primarily denials for Skilled Nursing Facility (SNF) care and they all failed to include important coverage information:

> Coverage for care provided in a skilled nursing facility exists, if one of three criteria are met: 1) the patient requires skilled nursing services or skilled rehabilitation services, i.e., the care is being furnished by or under the supervision of professional or technical personnel; 2) the patient requires these skilled services on a daily basis; and 3) as a practical matter, considering economy and efficiency, the daily skilled services can be provided only on an inpatient basis in a Skilled Nursing Facility (SNF). The services must also be furnished pursuant to a physician's orders and be medically necessary.

Health Care Financing Administration Manual at § 3132.

A denial of coverage because a SNF is providing custodial, nonskilled, nursing care should identify which noncoverage factor(s) applies. Custodial care criteria is set forth in another section of the Health Care Financing Administration Manual, § 3159. Reference to

this section would also assist claimants in forming appeal arguments.

Without this type of notice, a claimant cannot begin to fathom what additional evidence to present to rebut the denial. *Gray Panthers*, 652 F.2d at 168; *Vorster v. Bowen*, 709 F. Supp. at 946-47. "Congress, in enacting and amending Medicare, has repeatedly recognized that the elderly, as a group, are less able than the general populace to deal effectively with legal notices and written registration requirements—. . . 'due to inattention or inability to manage their affairs.'" *Gray Panthers*, 652 F.2d at 169 (quoting S. Rep. No. 1230, 92d Cong., 2d Sess. 38 (1972)). "To countenance granting them less than adequate notice of the reasons for denial of medical benefits would be inconsistent with the Congressional intent, to say the least." *Id.* at 169.

In 25% of the notices reviewed by Plaintiffs, or in eight of the ten reviewed by the Court, the HMO failed to inform the claimant that he or she had a right to present additional evidence to the HMO for reconsideration. This omission violates 42 C.F.R. § 417.618. All the notices fail to direct claimants to their attending physicians as a primary means for obtaining substantiating evidence of medical necessity to rebut a denial. HMOs ignore that the managed care system has made strange bed-fellows of provider doctors who in the fee-for-service system provided patient advocacy for many claim denials. *See Kraemer*, 737 F.2d at 222 (URC only notifies physician to appear in advocacy of patient and there are "built-in" incentives for them not to). At best, HMO policies and procedures ignore the void; at worst, policies and procedures, such as "gag rule" contract provisions, eliminate this key evidentiary source.

Defendant argues that the HMO considers the claimant's medical records on reconsideration, but without additional evidence from the treating physician regarding medical necessity, HMO reconsideration approximates a "rubber stamp" of the initial denial. This has grave consequences because an HMO denial may mean the enrollee will go without medically necessary service. Given the length of time it takes for further appeal of the HMO denial, deprivations will certainly have significant impacts on quality of life and some may even be life threatening.

Due process requires a meaningful opportunity to present one's case at a meaningful time. *Gray Panthers*, 652 F.2d at 164. The statute and regulations reflect this standard. 42 U.S.C. § 1395mm(c)(4) requires that an "HMO must provide meaningful procedures for hearing and resolving grievances. . . ." 42 C.F.R. § 417.618 requires that an "HMO must provide parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing." Some HMOs enact these provisions by allowing the request for reconsideration to be filed with the HMO in person. Even where the HMO informs a claimant that evidence can be provided in person, the notices fail to describe any procedures for securing an in-person communication with the HMO person reconsidering the claim. *See Gray Panthers*, 652 F.2d at 157 (a phone number on the notice doesn't mean the claimant has an opportunity to speak directly to the decisionmaker; value of informal hearing is the ability to talk directly to the decisionmaker). The Court is not aware of any HMO providing any type of in-person communications, such as informal hearings.

The statutes and regulations also provide for direct appeal of quality of service complaints to PROs. 42 U.S.C. § 1395mm(i)(7). The HMO must have an outreach program designed to apprise enrollees of the peer review system, its purpose, and the method for securing PRO review. 42 U.S.C. § 1320c-3(a)(4)(B). Quality of service includes under-utilization and continuity of care issues. *Id.* Both could arise within the context of a service denial. For this reason, notices should, but routinely do not, include any reference to the PRO appeal process.

The Court finds that existing reconsideration procedures followed by HMOs fail to secure minimum due process for Medicare beneficiaries. Notice and informal hearing requirements set forth by statute and regulations are all but ignored. The existing system fails to provide "a meaningful opportunity" to present the claim "at a meaningful time." Subsequent due process, available in the administrative review phase of the appeal, comes too late in many cases: assuming no delay by claimant, the HMO has 60 days to make the reconsideration decision; HCFA/NDG has 30 days to decide reconsiderations not granted by the HMO;[36] if the claim is for less than $100 there is no further due process; if the claim is for $100 or more, the matter can be appealed to an ALJ. In 1994, ALJ review took approximately 250 days. (Joint Statement of Facts at ¶ 17.) This Court, as did the court in *Gray Panthers*, concludes:

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[36] Settlement agreement in class action law suit, *Levy v. Sullivan*, No. 88-3271, 1989 WL 265476 (C.D.Cal. March 14, 1989); (Medicare & Medicaid Guide ¶ 37,809 at 19,748).

> Current procedures allotted to the elderly Medicare claimant, probably disadvantaged by disability and poverty, resemble playing against a stacked deck— . . . [and result] in a significant possibility of deprivation.

Gray Panthers, 652 F.2d at 172.

3. The Government's Interest, Including the Fiscal and Administrative Burdens that the Additional or Substitute Procedural Requirements Would Entail

The alternative procedural safeguards discussed by this Court entail no greater fiscal and administrative burdens for Defendant than that contemplated by Congress and provided for by applicable law and regulation.[37] A more meaningful appeal process by the HMO may actually reduce fiscal burdens on the federal government because improper denials by HMOs cause Medicare beneficiaries to return to fee-for-service providers at greater expense to the government. In conclusion, the burden of proper notice and an opportunity to be heard on reconsideration by the HMO does not outweigh the substantial interest at stake and the risk of erroneous deprivation posed by the existing procedures.

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[37] The Court finds no statutory basis for Plaintiffs' proposal that appellate review place the burden of proof on the HMO and the HMO carries the burden on reconsideration before the NDG. (Joint Statement of Facts at ¶ 14.) Congress placed the burden on the claimant to establish eligibility, *Ward v. Schweiker*, 686 F.2d 762, 765 (9th Cir.1982), and this Court is not inclined to disrupt this chosen balance.

E. Relief: Judicial Authority to Order the Secretary of Health and Human Services to Enforce Regulatory and Statutory Provisions of 42 U.S.C. § 1395mm

1. Enforcement Decisions are Generally Committed to Agency Discretion

Defendant argues that there can be no judicial review of the Secretary's enforcement activities, or lack thereof.

> Review is not to be had if the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion . . . —if no judicially manageable standards are available for judging how and when an agency should exercise its discretion, then it is impossible to evaluate agency action for "abuse of discretion."

Heckler v. Chaney, 470 U.S. 821, 830, 105 S. Ct. 1649, 1655, 84 L.Ed.2d 714 (1985). Under *Heckler v. Chaney*, refusal to take enforcement action by an administrative agency is presumptively nonreviewable. *Id.* (citing Administrative Procedure Act (APA); 5 U.S.C. § 701(a)(1) and (a)(2)). The presumption, however, can be overcome where the statute provides guidelines for the agency to follow for then there is law to apply. *Id.*

The statute discussed in *Chaney* was a general provision: "the Secretary is authorized to conduct examinations and investigations. . . ." *Id.* at 835, 105 S. Ct. at 1657. The Court described this language as permissive compared to language it had identified in *Dunlop v.*

Bachowski, 421 U.S. 560, 95 S. Ct. 1851, 44 L.Ed.2d 377 (1975), as mandatory: "the Secretary shall investigate such complaint and, if he finds probable cause to believe that a violation . . . has occurred . . . he shall . . . bring a civil action. . . ." *Id.* at 833, 105 S. Ct. at 1657. In the latter, there is law to apply; in the former, a refusal to institute proceedings is a decision "committed to agency discretion by law." *Id.* at 834-35, 105 S. Ct. at 1657. (quoting APA § 701(a)(2)).

The statutory provisions at issue in this case are contained in 42 U.S.C. § 1395mm(c) which provides:

> (1) The Secretary *may not* enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection . . .

Subsections 4-6 address service and continuity of care standards, notice and hearing procedures, and appeal rights held by Medicare recipients. The Court finds that Congress expressly prohibits the Secretary from entering into arrangements with HMOs which fail to meet these requirements. *Cf. Barron v. Reich*, 13 F.3d 1370, 1375 (9th Cir.1994) ("shall" or "shall not" reflect mandatory duties; "may" describes a permissive function). As evident from the Court's analysis in the prior sections of this Order, the provisions and requirements of 42 U.S.C. § 1395mm(c) provide an ample basis in law to apply to the facts of this case.

The Court finds that the Secretary violates 42 U.S.C. § 1395mm(c)(1) by entering into a contract with any HMO that fails to meet the following notice requirements:

> Notice:

1. Shall always be given for any and all denials of service;

2. Shall be timely;

3. Shall be readable: at least 12-point type;

4. Shall state the reason for denial clearly and in such terms as to enable the enrollee to argue his or her case;

5. Shall inform the enrollee of all appeal rights, including PRO review;

6. Shall inform the enrollee of the right to a hearing on reconsideration and that additional evidence may be presented, in person, and shall explain the procedure for securing an informal hearing, and

7. Shall provide instruction on how to obtain supporting evidence, including medical records and supporting affidavits from the attending physician. The HMO must abolish any policy or procedure which would impede such advocacy.

The Court finds that the Secretary violates 42 U.S.C. § 1395mm(c)(1) by entering into a contract with any HMO that fails to meet the following hearing requirements:

Hearing:

1. Shall be informal, in-person communication with the decisionmaker;

2. Shall be available upon request for all service denials, and

3. Shall be timely according to the seriousness of the medical condition implicated by the denied service:

Immediate hearing shall be available for acute care service denials, specifically where delivery of the service is prevented by the denial. (Assuming the HMO's reconsideration decision will be correspondingly expeditious, the appeal to NDG will be expedited for these cases). All other hearings can be within the normal course of the HMO's 60-day time frame for reconsideration, especially for more routine, nonacute medical care decisions or when care has been rendered and financial liability remains as the only issue.

2. Abuse of Discretion

An example of the Secretary's discretionary enforcement power appears in 42 U.S.C. § 1395mm(i)(1) which provides that she may terminate a contract prior to its expiration, upon finding that the HMO substantially fails to meet certain conditions, including those at issue here. Additionally, if she determines there is substantial noncompliance, she may impose civil monetary fines, suspend enrollment, or prevent an HMO from expanding its service area. 42 U.S.C. § 1395mm(i)(6).

Here, the Court reviews for abuse of discretion. *Heckler v. Chaney*, 470 U.S. at 833 n. 4, 105 S. Ct. at 1656 n. 4 (consciously and expressly adopted policy that is so extreme as to be an abdication of statutory responsibility is an abuse of discretion). Has the Secretary wholly abdicated her enforcement responsibilities? Is her policy of "continual improvement," so extreme as to undermine the fundamental statutory scheme that the Secretary be empowered to ensure that HMOs provide an effective and efficient medical delivery system to Medicare beneficiaries?

Plaintiffs urge the affirmative and proffer evidence that the Secretary fails to collect service utilization data; has a policy of encouraging voluntary improvement rather than penalizing HMOs; fails to use PROs to effectively review underservicing, and fails to implement a beneficiary complaint system. The Secretary admits to problems with the HMO delivery system, but counters that under her tutelage, the HMOs have continually improved and many of Plaintiffs' complaints have been corrected. The Court finds that there are material facts in dispute as to the effectiveness of the Secretary's monitoring and her enforcement choices. Summary judgment is not appropriate to determine whether she has abused her discretion.

Accordingly,

IT IS ORDERED that Defendant's Motion for Summary Judgment is DENIED.

IT IS FURTHER ORDERED that Plaintiffs' Motion for Summary Judgment is GRANTED in part and DENIED in part.

IT IS FURTHER ORDERED that within 20 days of the filing date of this Order the Plaintiff shall file a proposed form of judgment in accordance with the findings of this Court; Defendant shall respond.

IT IS FURTHER ORDERED that if the procedural changes resulting from this Order do not rectify delivery of care and quality of service issues, the Court retains jurisdiction over this case to reconsider the issue of the Secretary's discretionary enforcement duties and to refer the matter to a special master pursuant to Federal Rule of Civil Procedure 53.

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

No. CIV 93-711 TUC ACM

GREGORIA GRIJALVA; CAROL KNOX; MARY LEA; BEATRICE BENNETT; AND MILDRED MORRELL, AS INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS

JOSEPHINE BALISTRERI; FRED S. SCHERZ; KEVIN A. DRISCOLL; MINA AMES; EDMUNDO B. CARDENAS; ARLINE T. DONOHO; PATRICIA SLOAN; BETH ROBLEY; GOLDIE M. POWELL AND; RICHARD BAXTER, PLAINTIFFS-INTERVENERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: March 3, 1997]

JUDGMENT

On October 17, 1996, the Court entered an Order in this case, which denied the Defendant's Motion for Summary Judgment and granted in part and denied in part, Plaintiffs' Motion for Summary Judgment. In accordance with the findings and conclusions set out in that Order, the Court hereby issues judgment as follows:

IT IS ORDERED that Defendant Shalala require her Medicare contracting health maintenance organizations (HMOs)[1] to give their enrollees written notice whenever a coverage determination results in a service or referral requested by a health care provider, enrollee, or person acting on his or her behalf, being denied, or an ongoing course of treatment being reduced or terminated.

Denial notices shall meet the following minimal requirements:

(a) Notice shall be given promptly, but no more than five working days after written or oral request for a service or referral by a health care provider, enrollee, or person acting on his or her behalf, and at least one working day before reduction or termination of a course of treatment.[2]

(b) It may be delayed in exceptional circumstances for up to 60 days, if an HMO needs additional information to make a responsibly considered medical determination. To obtain an extension of the five-day notice requirement, the HMO must notify the enrollee that it needs additional information, specifically: what additional information it needs, the steps necessary to acquire the information, and the time estimated for completing the investigation.

(c) It shall be on a clear, readable form designed by the Defendant, in at least 12-point type, and include the following information:

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[1] All references in this document to HMOs shall include CMPs (comprehensive medical plans as defined in 42 U.S.C. § 1395(b)).

[2] Failure to provide timely notice constitutes an adverse determination and may be reconsidered. *See e.g.*, 42 C.F.R. § 417.608(c).

(i) an explanation in lay language of the coverage rule upon which the adverse decision was based, sufficiently detailed to allow the enrollee to understand the decision and argue his or her case;

(ii) a description of the regular and expedited appeal processes, and an explanation of the Peer Review Organization (PRO) complaint and quality review process;

(iii) a description of the additional evidence that would support the enrollee's position; instructions on how to obtain doctor's letters and medical records in support of the enrollee's position—which shall be freely provided by the HMO;[3] and how and when the enrollee may submit such evidence (in-person, if desired);

(iv) the procedures for securing an informal hearing before the decision-maker for reconsideration.

IT IS FURTHER ORDERED that the Secretary shall monitor and investigate the compliance of HMOs with the foregoing notice requirements. If the Secretary determines that a contracting HMO has failed to substantially comply with these notice requirements, the Secretary is prohibited from renewing or entering into a subsequent Medicare contract with the HMO.

IT IS FURTHER ORDERED that the Secretary shall provide Medicare HMO enrollees with an administrative reconsideration process for all adverse service decisions meets the following minimal requirements:

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[3] This does not mean that doctors are required to submit supporting letters if they believe the health service at issue is not warranted.

(a) First level reconsideration by the HMO shall include informal, in-person communication with the reconsideration decision-maker;[4]

(b) An expedited reconsideration process shall be made available when services are urgently needed, such as where acute care services are being denied or terminated: certain types of nursing facility care, certain types of home health and therapy services, and denials of certain types of non-cosmetic surgery.

An enrollee can establish that services are urgently needed by providing a written explanation of urgency from his or her doctor. Plan doctors shall be free to give supporting documentation without fear of retaliation or reprisal from the HMO.

A doctor's statement is not required to trigger expedited reconsideration. Under certain circumstances, especially where acute care services are being denied or terminated, lay testimony may suffice to establish that the care is urgently needed.

(c) An expedited decision by the HMO must be issued within three working days of the request for expedited reconsideration. Either the HMO or the enrollee may request up to ten additional working days to obtain evidence;

(d) Upon denial of an expedited reconsideration by the HMO, the independent HCFA review agency (currently NDG) shall complete review, as

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[4] The due process requirement of informal in-person hearings provides a great degree of flexibility and allows for creative approaches to address Defendant's logistic concerns. For example, informal hearings might be conducted telephonically, and beneficiaries in ill health could be represented by close friends or family members.

provided by law, within ten working days of the request for HCFA review;

(e) When acute care services are denied, so as to trigger the expedited reconsideration process, services must continue until a final reconsideration decision has been issued;[5]

(f) Any HMO policy or procedure that impedes an enrollee from obtaining supporting evidence, including medical records and letters from health care providers, is prohibited.

IT IS FURTHER ORDERED that the Secretary shall monitor and investigate the compliance of HMOs with the foregoing hearing requirements. If the Secretary establishes that a contracting HMO has failed to substantially comply with these hearing requirements, the Secretary is prohibited from renewing or entering into a subsequent Medicare contract with the HMO.

IT IS FURTHER ORDERED that the Secretary shall monitor and investigate the compliance of HMOs with the foregoing requirement that plan doctors be free to give supporting documentation without fear of retaliation or reprisal from the HMO. If the Secretary establishes that an HMO has retaliated in any way or manner against any doctor, the Secretary is prohibited from renewing or entering into a subsequent Medicare contract with the HMO.

IT IS FURTHER ORDERED that the Defendant shall implement the foregoing changes in the HMO notice

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[5] This does not prevent services from being terminated if the attending physician determines that continued treatment may be harmful to the enrollee.

and hearing procedures within 120 days of entry of Judgment.

IT IS FURTHER ORDERED that Count IV of Plaintiffs' Complaint is DISMISSED.

THE COURT FINDS that there are material issues of fact concerning the Defendant Secretary's compliance with the enforcement sections of the Medicare HMO statute that prevent the Court from entering summary judgment on Count I of the Complaint. These material issues of fact are set out in the parties' Joint Statement of Facts, at pages 11 to 25.

IT IS FURTHER ORDERED that the Court shall retain jurisdiction over this case for a period of three years from the date of implementation by Defendant to determine whether the procedural changes ordered above will rectify Count I delivery of care and quality of service issues. If the Plaintiffs believe that these issues have not been resolved, they may return to the Court at any time within the three-year period and request relief.

DATED this 3rd day of March, 1997.

/s/ ALFREDO C. MARQUEZ
ALFREDO C. MARQUEZ
Senior U. S. District Judge

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

No. CIV 93-711-TUC-ACM

GREGORIA GRIJALVA; CAROL KNOX; MARY LEA; BEATRICE BENNETT; AND MILDRED MORRELL, AS INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS

JOSEPHINE BALISTRERI; FRED S. SCHERZ; KEVIN A. DRISCOLL; MINA ARLINE T. DONOHO; PATRICIA SLOAN; BETH ROBLEY; GOLDIE M. POWELL; AND RICHARD BAXTER, INTERVENERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: June 11, 1997]

ORDER

On March 3, 1997, this Court ordered Defendant to implement certain notice and hearing procedures within 120 days. Defendant filed her Notice of Appeal on May 2, 1997. On May 12, 1997, Defendant filed a motion with this Court asking for a stay of the March 3, 1997 Order. Defendant contends that many of the required changes identified by this Court are currently being addressed by a proposed rule change to establish a new expedited

appeals process for Medicare beneficiaries enrolled in HMOs. "The April 30 regulations provide Medicare beneficiaries (including the Plaintiff class) with many of the procedural rights ordered by the Court, and, in some cases, actually hold HMOs to a more stringent standard than is required by the Court's Judgment." (Defendant's Motion for a Stay at 3.) The Court is also aware of other efforts on the part of state and federal legislatures which are addressing the same issues addressed by this Court in its March 3, 1997 Order. It is sincere hope of this Court that on appeal much of the March 3, 1997 Order might be moot because of these efforts.

The Court, however, finds fault with the Defendant's complaint that "several of the provisions of the Judgment are particularly problematic." (Defendant's Motion for Stay at 3.) Again, Defendant refers to: "such requirements in the Judgment as issuance of written notice of *all* (not just urgent) denials of care within five working days, provision of notice for all oral as well as written requests and the continuation of all 'acute care services' (vaguely defined) during reconsideration, would, if implemented on even a temporary basis, cause harm to HCFA, HMOs, and most importantly, the Medicare beneficiaries.'" (Defendant's Motion to Stay at 3-4 (citing 2d Fried Decl. ¶¶ 12-13.) Defendant made this same argument during the briefing on the form of Judgment. The Court presumed to clarify for Defendant the breadth of its ruling by emphasizing on page one of the Judgment that notice and hearing requirements apply "whenever a coverage determination results in a service or referral . . . being denied, or an ongoing course of treatment being reduced or terminated." (Judgment filed on March 3, 1997 at 1.) Plain-

tiffs never argued, nor has this Court ever suggested, that the notice and hearing rights identified by the Court attach during the doctor patient visit.[1] The notice and hearing requirements identified by this Court have always been discussed within the context of the HMO denying a service because it determines the service to be not covered by Medicare, not denials of service by doctors when they determine such care not to be medically necessary.

The Court made every attempt to confine its Judgment to what it deemed Constitutional parameters, and to resist mandating details which in this Court's opinion are better left to the Secretary and the medical profession. For example, the Court restrained its Judgment from defining "acute care services" when it ordered that "when acute care services are denied, so as to trigger the expedited reconsideration process, services must continue until a final reconsideration decision has been issued." (Judgment at 5, ¶ (e).) It would seem to the Court that within the medical profession there must be some general consensus regarding what types of

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[1] *See* Defendant's Motion for Stay at 10 ("The requirement that written notice be given within five working days of any 'oral request' for services is also problematic. (2d Fried Decl. ¶ 8.) The practice of medicine routinely involves give-and-take discussions between doctors and patients about treatment options, and it may be difficult at times to determine whether an enrollee is merely asking questions about the availability of alternative treatments, or is making an 'oral request' to which a detailed written notice must be provided within five days. At the very least, HCFA feels that further consideration is necessary before imposition of such a requirement, which would greatly increase the amount of physician time spent on documenting each and every treatment choice—time that could otherwise be spent providing patient care. *Id.* ¶¶ 8, 12.")

conditions are considered "acute," and that the parties should be able to develop a workable definition for purposes of implementing the Judgment. Ultimately, the Court could make this determination, but only after hearing testimony from medical experts on the subject.

This Court finds that many of the Secretary's problematic objections to the Judgment are self inflicted. The Secretary chooses to construe the Judgment in such a fashion so as to create unnecessary problems. This Court drafted the Judgment to allow for flexibility in its implementation. (Judgment filed May 3, 1997 at 3 n.4).

The standard for granting a stay pending appeal is similar to the standard for granting a preliminary injunction in this Circuit. *Nevada Airlines, Inc. v. Bond*, 622 F.2d 1017, 1018 n.3 (9th Cir. 1980). To obtain a stay, "the moving party must demonstrate either a combination of probable success on the merits and the possibility of irreparable injury or that serious questions are raised and the balance of hardships tips sharply in the moving party's favor." *Beltran v. Meyers*, 677 F.2d 1317, 1320 (9th Cir. 1982). These tests are merely the extremes of a continuum so that as one factor increases in weight the other decreases. *Brenda v. Grand Lodge of International Ass'n. of Machinists*, 584 F.2d 308, 314 (9th Cir. 1978).

The Court finds that the hardships faced by the Plaintiffs outweigh those of the Defendant, but that the entire case may become largely moot if the Secretary's attestations regarding rule changes are true and are implemented without delay.

Accordingly,

IT IS ORDERED that Defendant's Motion for Stay Pending Appeal, filed May 12, 1997, is GRANTED.

DATED this 10th day of June, 1997.

/s/ ALFREDO C. MARQUEZ
ALFREDO C. MARQUEZ
Senior U. S. District Judge

APPENDIX F

The Balanced Budget Act of 1997, Public Law No. 105-33, Sections 4001-4002, 111 Stat. 275-330, provides in relevant part as follows:

SEC. 4001. ESTABLISHMENT OF MEDICARE+CHOICE PROGRAM.

"SEC. 1851. (a) CHOICE OF MEDICARE BENEFITS THROUGH MEDICARE+CHOICE PLANS—

"(1) IN GENERAL.—Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits under this title—

"(A) through the original medicare fee-for-service program under parts A and B, or

"(B) through enrollment in a Medicare+Choice plan under this part.

"(2) TYPES OF MEDICARE+CHOICE PLANS THAT MAY BE AVAILABLE.—A Medicare+Choice plan may be any of the following types of plans of health insurance:

"(A) COORDINATED CARE PLANS.—Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by provider-sponsored organizations (as defined in section 1855(d)), and preferred provider organization plans.

"(B) COMBINATION OF MSA PLAN AND CONTRIBUTIONS TO MEDICARE+CHOICE MSA.—An MSA plan, as defined in section 1859(b)(3), and a contribution into a Medicare+Choice medical savings account (MSA).

"(C) PRIVATE FEE-FOR-SERVICE PLANS.—A Medicare+Choice private fee-for-service plan, as defined in section 1859(b)(2).

"(3) MEDICARE+CHOICE ELIGIBLE INDIVIDUAL.—

"(A) IN GENERAL.—In this title, subject to subparagraph (B), the term 'Medicare+Choice eligible individual' means an individual who is entitled to benefits under part A and enrolled under part B.

"(B) SPECIAL RULE FOR END-STAGE RENAL DISEASE.—Such term shall not include an individual medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan.

* * * * *

"(d) PROVIDING INFORMATION TO PROMOTE INFORMED CHOICE.—

"(1) IN GENERAL.—The Secretary shall provide for activities under this subsection to broadly disseminate information to medicare beneficiaries (and prospective medicare beneficiaries) on the coverage options pro-

vided under this section in order to promote an active, informed selection among such options.

"(2) PROVISION OF NOTICE.—

"(A) OPEN SEASON NOTIFICATION.—At least 15 days before the beginning of each annual, coordinated election period (as defined in sub section (e)(3)(B)), the Secretary shall mail to each Medicare+Choice eligible individual residing in an area the following:

"(i) GENERAL INFORMATION.—The general information described in paragraph (3).

"(ii) LIST OF PLANS AND COMPARISON OF PLAN OPTIONS.—A list identifying the Medicare+Choice plans that are (or will be) available to residents of the area and information described in paragraph (4) concerning such plans. Such information shall be presented in a comparative form.

"(iii) ADDITIONAL INFORMATION.—Any other information that the Secretary determines will assist the individual in making the election under this section.

The mailing of such information shall be coordinated, to the extent practicable, with the mailing of any annual notice under section 1804.

"(B) NOTIFICATION TO NEWLY ELIGIBLE MEDICARE+CHOICE ELIGIBLE INDIVIDUALS.—To the extent practicable, the Secretary shall, not later than 30 days before the beginning of the initial Medicare+Choice enrollment period for an individ-

ual described in subsection (e)(1), mail to the individual the information described in subparagraph (A).

"(C) FORM.—The information disseminated under this paragraph shall be written and formatted using language that is easily understandable by medicare beneficiaries.

"(D) PERIODIC UPDATING.—The information described in subparagraph (A) shall be updated on at least an annual basis to reflect changes in the availability of Medicare+Choice plans and the benefits and Medicare+Choice monthly basic and supplemental beneficiary premiums for such plans.

"(3) GENERAL INFORMATION.—General information under this paragraph, with respect to coverage under this part during a year, shall include the following:

"(A) BENEFITS UNDER ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—A general description of the benefits covered under the original medicare fee-for-service program under parts A and B, including—

"(i) covered items and services,

"(ii) beneficiary cost sharing, such as deductibles, coinsurance, and copayment amounts, and

"(iii) any beneficiary liability for balance billing.

"(B) ELECTION PROCEDURES.—Information and instructions on how to exercise election options under this section.

"(C) RIGHTS.—A general description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program and the Medicare+Choice program and the right to be protected against discrimination based on health status-related factors under section 1852(b).

"(D) INFORMATION ON MEDIGAP AND MEDICARE SELECT.—A general description of the benefits, enrollment rights, and other requirements applicable to medicare supplemental policies under section 1882 and provisions relating to medicare select policies described in section 1882(t).

"(E) POTENTIAL FOR CONTRACT TERMINATION.—The fact that a Medicare+Choice organization may terminate its contract, refuse to renew its contract, or reduce the service area included in its contract, under this part, and the effect of such a termination, nonrenewal, or service area reduction may have on individuals enrolled with the Medicare+Choice plan under this part.

"(4) INFORMATION COMPARING PLAN OPTIONS.—Information under this paragraph, with respect to a Medicare+Choice plan for a year, shall include the following:

"(A) BENEFITS.—The benefits covered under the plan, including the following:

"(i) Covered items and services beyond those provided under the original medicare fee-for-service program.

"(ii) Any beneficiary cost sharing.

"(iii) Any maximum limitations on out-of-pocket expenses.

"(iv) In the case of an MSA plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.

"(v) In the case of a Medicare+Choice private fee-for-service plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.

"(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

"(vii) The extent to which an enrollee may select among in-network providers and the types of providers participating in the plan's network.

"(viii) The organization's coverage of emergency and urgently needed care.

"(B) PREMIUMS.—The Medicare+Choice monthly basic beneficiary premium and Medicare+Choice monthly supplemental beneficiary premium, if any, for the plan or, in the case of an MSA plan, the Medicare+Choice monthly MSA premium.

"(C) SERVICE AREA.—The service area of the plan.

"(D) QUALITY AND PERFORMANCE.—To the extent available, plan quality and performance indicators for the benefits under the plan (and how they compare to such indicators under the original medicare fee-for-service program under parts A and B in the area involved), including—

"(i) disenrollment rates for medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan's service area),

"(ii) information on medicare enrollee satisfaction,

"(iii) information on health outcomes, and

"(iv) the recent record regarding compliance of the plan with requirements of this part (as determined by the Secretary).

"(E) SUPPLEMENT BENEFITS.—Whether the organization offering the plan includes mandatory supplemental benefits in its base benefit package or offers optional supplemental benefits and the terms and conditions (including premiums) for such coverage.

"(5) MAINTAINING A TOLL-FREE NUMBER AND INTERNET SITE.—The Secretary shall maintain a toll-free number for inquiries regarding Medicare+Choice options and the operation of this part in all areas

in which Medicare+Choice plans are offered and an Internet site through which individuals may electronically obtain information on such options and Medicare+Choice plans.

"(6) USE OF NON-FEDERAL ENTITIES.—The Secretary may enter into contracts with non-Federal entities to carry out activities under this subsection.

"(7) PROVISION OF INFORMATION.—A Medicare+Choice organization shall provide the Secretary with such information on the organization and each Medicare+Choice plan it offers as may be required for the preparation of the information referred to in paragraph (2)(A).

"(e) COVERAGE ELECTION PERIODS.—

"(1) INITIAL CHOICE UPON ELIGIBILITY TO MAKE ELECTION IF MEDICARE+CHOICE PLANS AVAILABLE TO INDIVIDUAL.—If, at the time an individual first becomes entitled to benefits under part A and enrolled under part B, there is one or more Medicare+Choice plans offered in the area in which the individual resides, the individual shall make the election under this section during a period specified by the Secretary such that if the individual elects a Medicare+Choice plan during the period, coverage under the plan becomes effective as of the first date on which the individual may receive such coverage.

"(2) OPEN ENROLLMENT AND DISENROLLMENT OPPORTUNITIES.—Subject to paragraph (5)—

"(A) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT THROUGH 2001.—At any time during 1998, 1999, 2000, and 2001, a Medicare+Choice eligile individual may change the election under subsection (a)(1).

* * * * *

"(f)" EFFECTIVENESS OF ELECTIONS AND CHANGES OF ELECTIONS.—

"(1) DURING INITIAL COVERAGE ELECTION PERIOD.—An election of coverage made during the initial coverage election period under subsection (e)(1)(A) shall take effect upon the date the individual becomes entitled to benefits under part A and enrolled under part B, except as the Secretary may provide (consistent with section 1838) in order to prevent retroactive coverage.

"(2) DURING CONTINUOUS OPEN ENROLLMENT PERIODS.—An election or change of coverage made under subsection (e)(2) shall take effect with the first day of the first calendar month following the date on which the election is made.

* * * * *

"BENEFITS AND BENEFICIARY PROTECTIONS"

"SEC. 1852. (a) BASIC BENEFITS.—

"(1) IN GENERAL.—Except as provided in section 1859(b)(3) for MSA plans, each Medicare+Choice plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this title and part A of title XI—

"(A) those items and services (other than hospice care) for which benefits are available under parts A and B to individuals residing in the area served by the plan, and

"(B) additional benefits required under section 1854(f)(1)(A).

"(2) SATISFACTION OF REQUIREMENT.—

"(A) IN GENERAL.—A Medicare+Choice plan (other than an MSA plan) offered by a Medicare+Choice organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that—

"(i) the sum of such payment amount and any cost sharing provided for under the plan, is equal to at least

"(ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and B (including any balance billing permitted under such parts).

"(B) REFERENCE TO RELATED PROVISIONS.—For provision relating to—

"(i) limitations on balance billing against Medicare+Choice organizations for non-contract providers, see sections 1852(k) and 1866(a)(1)(O), and

"(ii) limiting actuarial value of enrollee liability for covered benefits, see section 1854(e).

"(3) SUPPLEMENT BENEFITS.—

"(A) BENEFITS INCLUDED SUBJECT TO SECRETARY'S APPROVAL.—Each Medicare+Choice organization may provide to individuals enrolled under this part, other than under an MSA plan, (without affording those individuals an option to decline the coverage) supplemental health care benefits that the Secretary may approve. The Secretary shall approve any such supplemental benefits unless the Secretary determines that including such supplemental benefits would substantially discourage enrollment by Medicare+Choice eligible individuals with the organization.

"(B) AT ENROLLEES' OPTION.—

"(i) IN GENERAL.—Subject to clause (ii), a Medicare+Choice organization may provide to individuals enrolled under this part supplemental health care benefits that the individuals may elect, at their option, to have covered.

"(ii) SPECIAL RULE FOR MSA PLANS.—A Medicare+Choice organization may not provide, under an MSA plan, supplemental health care benefits that cover the deductible described in

section 1859(b)(2)(B). In applying the previous sentence, health benefits described in section 1882(u)(2)(B) shall not be treated as covering such deductible.

"(C) APPLICATION TO MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—Nothing in this paragraph shall be construed as preventing a Medicare+Choice private fee-for-service plan from offering supplemental benefits that include payment for some or all of the balance billing amounts permitted consistent with section 1852(k) and coverage of additional services that the plan finds to be medically necessary.

"(4) ORGANIZATION AS SECONDARY PAYER.—Notwithstanding any other provision of law, a Medicare+Choice organization may (in the case of the provision of items and services to an individual under a Medicare+Choice plan under circumstances in which payment under this title is made secondary pursuant to section 1862(b)(2)) charge or authorize the provider of such services to charge, in accordance with the charges allowed under a law, plan, or policy described in such section—

"(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

"(B) such individual to the extent that the individual has been paid under such law, plan, or policy for such services.

"(5) NATIONAL COVERAGE DETERMINATIONS.—If there is a national coverage determination made in the period beginning on the date of an announcement under section 1853(b) and ending on the date of the next

announcement under such section and the Secretary projects that the determination will result in a significant change in the costs to a Medicare+Choice organization of providing the benefits that are the subject of such national coverage determination and that such change in costs was not incorporated in the determination of the annual Medicare+Choice capitation rate under section 1853 included in the announcement made at the beginning of such period, then, unless otherwise required by law—

"(A) such determination shall not apply to contracts under this part until the first contract year that begins after the end of such period, and

"(B) if such coverage determination provides for coverage of additional benefits or coverage under additional circumstances, section 1851(i)(1) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period.

"(b) ANTIDISCRIMINATION.—

"(1) BENEFICIARIES.—

"(A) IN GENERAL.—A Medicare+Choice organization may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

"(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as requiring a Medicare+Choice organization to enroll individuals who are

determined to have end-stage renal disease, except as provided under section 1851(a)(3)(B).

"(2) PROVIDERS.—A Medicare+Choice organization shall not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This paragraph shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

"(c) DISCLOSURE REQUIREMENTS.—

"(1) DETAILED DESCRIPTION OF PLAN PROVISIONS.—A Medicare+Choice organization shall disclose, in clear, accurate, and standardized form to each enrollee with a Medicare+Choice plan offered by the organization under this part at the time of enrollment and at least annually thereafter, the following information regarding such plan:

"(A) SERVICE AREA.—The plan's service area.

"(B) BENEFITS.—Benefits offered under the plan, including information described in section 1851(d)(3)(A) and exclusions from coverage and, if it is an MSA plan, a comparison of benefits under such a plan with benefits under other Medicare+Choice plans.

"(C) ACCESS.—The number, mix, and distribution of plan providers, out-of-network coverage (if any) provided by the plan, and any point-of-service option (including the supplemental premium for such option).

"(D) OUT OF AREA COVERAGE.—Out-of-area coverage provided by the plan.

"(E) EMERGENCY COVERAGE.—Coverage of emergency services, including—

"(i) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

"(ii) the process and procedures of the plan for obtaining emergency services; and

"(iii) the locations of (I) emergency departments, and (II) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

"(F) SUPPLEMENTAL BENEFITS.—Supplemental benefits available from the organization offering the plan, including—

"(i) whether the supplemental benefits are optional,

"(ii) the supplemental benefits covered, and

"(iii) the Medicare+Choice monthly supplemental beneficiary premium for the supplemental benefits.

"(G) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in nonpayment.

"(H) PLAN GRIEVANCE AND APPEALS PROCEDURES.—All plan appeal or grievance rights and procedures.

"(I) QUALITY ASSURANCE PROGRAM.—A description of the organization's quality assurance program under subsection (e).

"(2) DISCLOSURE UPON REQUEST.—Upon request of a Medicare+Choice eligible individual, a Medicare+Choice organization must provide the following information to such individual:

"(A) The general coverage information and general comparative plan information made available under clauses (i) and (ii) of section 1851(d)(2)(A).

"(B) Information on procedures used by the organization to control utilization of services and expenditures.

"(C) Information on the number of grievances, redeterminations, and appeals and on the disposition in the aggregate of such matters.

"(D) An overall summary description as to the method of compensation of participating physicians.

"(d) ACCESS TO SERVICES.—

"(1) IN GENERAL.—A Medicare+Choice organization offering a Medicare+Choice plan may select the providers from whom the benefits under the plan are provided so long as—

"(A) the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;

"(B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;

"(C) the plan provides for reimbursement with respect to services which are covered under subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—

"(i) the services were not emergency services (as defined in paragraph (3)), but (I) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition, and (II) it was not reasonable given the circumstances to obtain the services through the organization,

"(ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan's service area, or

"(iii) the services are maintenance care or post-stabilization care covered

under the guidelines established under paragraph (2);

"(D) the organization provides access to appropriate providers, including credentialed specialists, for medically necessary treatment and services; and

"(E) coverage is provided for emergency services (as defined in paragraph (3)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization.

"(2) GUIDELINES RESPECTING COORDINATION OF POST-STABILIZATION CARE.—A Medicare+Choice plan shall comply with such guidelines as the Secretary may prescribe relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after the enrollee has been determined to be stable under section 1867.

"(3) DEFINITION OF EMERGENCY SERVICES.—In this subsection—

"(A) IN GENERAL.—The term 'emergency services' means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that—

"(i) are furnished by a provider that is qualified to furnish such services under this title, and

"(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (B)).

"(B) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

"(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

"(ii) serious impairment to bodily functions, or

"(iii) serious dysfunction of any bodily organ or part.

"(4) ASSURING ACCESS TO SERVICES IN MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—In addition to any other requirements under this part, in the case of a Medicare+Choice private fee-for-service plan, the organization offering the plan must demonstrate to the Secretary that the organization has sufficient number and range of health care professionals and providers willing to provide services under the terms of the plan. The Secretary shall find that an organization has met such requirement with respect to any category of health care professional or provider if, with respect to that category of provider—

"(A) the plan has established payment rates for covered services furnished by that category of provider that are not less than the payment rates provided for under part A, part B, or both, for such services, or

"(B) the plan has contracts or agreements with a sufficient number and range of providers within such category to provide covered services under the terms of the plan,

or a combination of both. The previous sentence shall not be construed as restricting the persons from whom enrollees under such a plan may obtain covered benefits.

"(e) QUALITY ASSURANCE PROGRAM.—

"(1) IN GENERAL.—Each Medicare+Choice organization must have arrangements, consistent with any regulation, for an ongoing quality assurance program for health care services it provides to individuals enrolled with Medicare+Choice plans of the organization.

"(2) ELEMENTS OF PROGRAM.—

"(A) IN GENERAL.—The quality assurance program of an organization with respect to a Medicare+Choice plan (other than a Medicare+Choice private fee-for-service plan or a non-network MSA plan) it offers shall—

"(i) stress health outcomes and provide for the collection, analysis, and reporting of data (in accordance with a quality measurement system that the

Secretary recognizes) that will permit measurement of outcomes and other indices of the quality of Medicare+Choice plans and organizations;

"(ii) monitor and evaluate high volume and high risk services and the care of acute and chronic conditions;

"(iii) evaluate the continuity and coordination of care that enrollees receive;

"(iv) be evaluated on an ongoing basis as to its effectiveness;

"(v) include measures of consumer satisfaction;

"(vi) provide the Secretary with such access to information collected as may be appropriate to monitor and ensure the quality of care provided under this part;

"(vii) provide review by physicians and other health care professionals of the process followed in the provision of such health care services;

"(viii) provide for the establishment of written protocols for utilization review, based on current standards of medical practice;

"(ix) have mechanisms to detect both underutilization and overutilization of services;

"(x) after identifying areas for improvement, establish or alter practice parameters;

"(xi) take action to improve quality and assesses the effectiveness of such action through systematic followup; and

"(xii) make available information on quality and outcomes measures to facilitate beneficiary comparison and choice of health coverage options (in such form and on such quality and outcomes measures as the Secretary determines to be appropriate).

"(B) ELEMENTS OF PROGRAM FOR ORGANIZATIONS OFFERING MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS AND NON-NETWORK MSA PLANS.—The quality assurance program of an organization with respect to a Medicare+Choice private fee-for-service plan or a non-network MSA plan it offers shall—

"(i) meet the requirements of clauses (i) through (vi) of subparagraph (A);

"(ii) insofar as it provides for the establishment of written protocols for utilization review, base such protocols on current standards of medical practice; and

"(iii) have mechanisms to evaluate utilization of services and inform providers and enrollees of the results of such evaluation.

"(C) DEFINITION OF NON-NETWORK MSA PLAN.—In this subsection, the term 'non-network MSA plan' means an MSA plan offered by a Medicare+Choice organization that does not provide

benefits required to be provided by this part, in whole or in part, through a defined set of providers under contract, or under another arrangement, with the organization.

"(3) EXTERNAL REVIEW.—

"(A) IN GENERAL.—Each Medicare+Choice organization shall, for each Medicare+Choice plan it operates, have an agreement with an independent quality review and improvement organization approved by the Secretary to perform functions of the type described in sections 1154(a)(4)(B) and 1154(a)(14) with respect to services furnished by Medicare+Choice plans for which payment is made under this title. The previous sentence shall not apply to a Medicare+Choice private fee-for-service plan or a non-network MSA plan that does not employ utilization review.

"(B) NONDUPLICATION OF ACCREDITATION. —Except in the case of the review of quality complaints, and consistent with subparagraph (C), the Secretary shall ensure that the external review activities conducted under subparagraph (A) are not duplicative of review activities conducted as part of the accreditation process.

"(C) WAIVER AUTHORITY.—The Secretary may waive the requirement described in subparagraph (A) in the case of an organization if the Secretary determines that the organization has consistently maintained an excellent record of quality assurance and compliance with other requirements under this part.

"(4) TREATMENT OF ACCREDITATION.—The Secretary shall provide that a Medicare+Choice organization

is deemed to meet requirements of paragraphs (1) and (2) of this subsection and subsection (h) (relating to confidentiality and accuracy of enrollee records) if the organization is accredited (and periodically re-accredited) by a private organization under a process that the Secretary has determined assures that the organization, as a condition of accreditation, applies and enforces standards with respect to the requirements involved that are no less stringent than the standards established under section 1856 to carry out the respective requirements.

"(f) GRIEVANCE MECHANISM.—Each Medicare+Choice organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrollees with Medicare+Choice plans of the organization under this part.

"(g) COVERAGE DETERMINATIONS, RECONSIDERATIONS, AND APPEALS.—

"(1) DETERMINATIONS BY ORGANIZATION.—

"(A) IN GENERAL.—A Medicare+Choice organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. Subject to paragraph (3), such procedures shall provide for such determination to be made on a timely basis.

"(B) EXPLANATION OF DETERMINATION.—Such a determination that denies coverage, in whole in part, shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

"(2) RECONSIDERATIONS.—

"(A) IN GENERAL.—The organization shall provide for reconsideration of a determination described in paragraph (1)(B) upon request by the enrollee involved. The reconsideration shall be within a time period specified by the Secretary, but shall be made, subject to paragraph (3), not later than 60 days after the date of the receipt of the request for reconsideration.

"(B) PHYSICIAN DECISION ON CERTAIN RECONSIDERATIONS.—A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treatment who is other than a physician involved in the initial determination.

"(3) EXPEDITED DETERMINATIONS AND RECONSIDERATIONS.—

"(A) RECEIPT OF REQUESTS.—

"(i) ENROLLEE REQUESTS.—An enrollee in a Medicare+Choice plan may request, either in writing or orally, an expedited determination under paragraph (1) or an expedited reconsideration under paragraph (2) by the Medicare+Choice organization.

"(ii) PHYSICIAN REQUESTS.—A physician, regardless whether the physician is affiliated with the organization or not, may request, either in writing or orally, such an expedited determination or reconsideration.

"(B) ORGANIZATION PROCEDURES.—

"(i) IN GENERAL.—The Medicare+Choice organization shall maintain procedures for expediting organization determinations and reconsiderations when, upon request of an enrollee, the organization determines that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

"(ii) EXPEDITION REQUIRED FOR PHYSICIAN REQUESTS.—In the case of a request for an expedited determination or reconsideration made under subparagraph (A)(ii), the organization shall expedite the determination or reconsideration if the request indicates that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

"(iii) TIMELY RESPONSE.—In cases described in clauses (i) and (ii), the organi-

zation shall notify the enrollee (and the physician involved, as appropriate) of the determination or reconsideration under time limitations established by the Secretary, but not later than 72 hours of the time of receipt of the request for the determination or reconsideration (or receipt of the information necessary to make the determination or reconsideration), or such longer period as the Secretary may permit in specified cases.

"(4) INDEPENDENT REVIEW OF CERTAIN COVERAGE DENIALS—The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part.

"(5) APPEALS.—An enrollee with a Medicare+ Choice plan of a Medicare+Choice organization under this part who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 205(b), and in any such hearing the Secretary shall make the organization a party. If the amount in controversy is $1,000 or more, the individual or organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g), and both the individual and the organization shall be entitled to be parties to that judicial

review. In applying subsections (b) and (g) of section 205 as provided in this paragraph, and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

"(h) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—Insofar as a Medicare+Choice organization maintains medical records or other health information regarding enrollees under this part, the Medicare+Choice organization shall establish procedures—

"(1) to safeguard the privacy of any individually identifiable enrollee information;

"(2) to maintain such records and information in a manner that is accurate and timely, and

"(3) to assure timely access of enrollees to such records and information.

"(i) INFORMATION ON ADVANCE DIRECTIVES.—Each Medicare+Choice organization shall meet the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

"(j) RULES REGARDING PROVIDER PARTICIPATION.—

"(1) PROCEDURES.—Insofar as a Medicare+Choice organization offers benefits under a Medicare+Choice plan through agreements with physicians, the organization shall establish reasonable procedures relating to the participation

(under an agreement between a physician and the organization) of physicians under such a plan. Such procedures shall include—

"(A) providing notice of the rules regarding participation,

"(B) providing written notice of participation decisions that are adverse to physicians, and

"(C) providing a process within the organization for appealing such adverse decisions, including the presentation of information and views of the physician regarding such decision.

"(2) CONSULTATION IN MEDICAL POLICIES.—A Medicare+Choice organization shall consult with physicians who have entered into participation agreements with the organization regarding the organization's medical policy, quality, and medical management procedures.

"(3) PROHIBITING INTERFERENCE WITH PROVIDER ADVICE TO ENROLLEES.—

"(A) IN GENERAL.—Subject to subparagraphs (B) and (C), a Medicare+Choice organization (in relation to an individual enrolled under a Medicare+Choice plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional

about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

"(B) CONSCIENCE PROTECTION.—Subparagraph (A) shall not be construed as requiring a Medicare+Choice plan to provide, reimburse for, or provide coverage of a counseling or referral service if the Medicare +Choice organization offering the plan—

> "(i) objects to the provision of such service on moral or religious grounds; and
>
> "(ii) in the manner and through the written instrumentalities such Medicare+Choice organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

"(C) CONSTRUCTION.—Nothing in subparagraph (B) shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

* * * * *

SEC. 4002. TRANSITIONAL RULES FOR CURRENT MEDICARE HMO PROGRAM.

* * * * *

(b) TRANSITION.—

(1) RISK-SHARING CONTRACTS.—Section 1876 (42 U.S.C. 1395mm) is amended by adding at the end the following new subsections:

"(k)(1) Except as provided in paragraph (2)—

"(A) on or after the date standards for Medicare+Choice organizations and plans are first established under section 1856(b)(1), the Secretary shall not enter into any risk-sharing contract under this section with an eligible organization; and

"(B) for any contract year beginning on or after January 1, 1999, the Secretary shall not renew any such contract.

"(2) An individual who is enrolled in part B only and is enrolled in an eligible organization with a risk-sharing contract under this section on December 31, 1998, may continue enrollment in such organization in accordance with regulations described in section 1856(b)(1).

"(3) Notwithstanding subsection (a), the Secretary shall provide that payment amounts under risk-sharing contracts under this section for months in a year (beginning with January 1998) shall be computed—

"(A) with respect to individuals entitled to benefits under both parts A and B, by substituting payment rates under section 1853(a) for the payment rates otherwise established under section 1876(a), and

"(B) with respect to individuals only entitled to benefits under part B, by substituting an appropriate proportion of such rates (reflecting the relative proportion of payments under this title attributable to such part) for the payment rates otherwise established under subsection (a).

APPENDIX G

Section 1395mm of Title 42, superseded in relevant part by Sections 4001-4002 of the Balanced Budget Act of 1997, Public Law No. 105-33, 111 Stat. 275-330, provides in pertinent part:

§ 1395mm. Payments to health maintenance organizations and competitive medical plans

* * * * *

(c) Enrollment in plan; duties of organization to enrollees

(1) The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) of this section with respect to members enrolled under this section.

(2)(A) The organization must provide to members enrolled under this section, through providers and other persons that meet the applicable requirements of this subchapter and part A of subchapter XI of this chapter—

(i) only those services covered under parts A and B of this subchapter, for those members entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, or

(ii) only those services covered under part B of this subchapter, for those members enrolled only under such part,

which are available to individuals residing in the geographic area served by the organization, except that (I) the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered, and (II) in the case of an organization with a risk-sharing contract, the organization may provide such members with such additional health care services as the Secretary may approve. The Secretary shall approve any such additional health care services which the organization proposes to offer to such members, unless the Secretary determines that including such additional services will substantially discourage enrollment by covered individuals with the organization.

* * * * *

(3)(A)(1) Each eligible organization must have an open enrollment period, for the enrollment of individuals under this section, of at least 30 days duration every year . . . .

* * * * *

(B) An individual may enroll under this section with an eligible organization in such manner as may be prescribed in regulations and may terminate his enrollment with the eligible organization as of the beginning of the first calendar month following the date on which the request is made for such termination (or, in the case of financial insolvency of the organization, as may be

prescribed by regulations) or, in the case of such an organization with a reasonable cost reimbursement contract, as may be prescribed by regulations. In the case of an individual's termination of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this subchapter other than through the organization.

* * * * *

(5)(A) The organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and members enrolled with the organization under this section.

(B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 405(b) of this title, and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 405(g) of this title, and both the individual and the eligible organization

shall be entitled to be parties to that judicial review. In applying sections 405(b) and 405(g) of this title as provided in this subparagraph, and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals, which program (A) stresses health outcomes and (B) provides review by physicians and other health care professionals of the process followed in the provision of such health care services.

(7) A risk-sharing contract under this section shall provide that in the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) as of the effective date of the individual's—

(A) enrollment with an eligible organization under this section—

(i) payment for such services until the date of the individual's discharge shall be made under this subchapter as if the individual were not enrolled with the organization,

(ii) the organization shall not be financially responsible for payment for such services until the date after the date of the individual's discharge, and

(iii) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this section; or

(B) termination of enrollment with an eligible organization under this section—

(i) the organization shall be financially responsible for payment for such services after such date and until the date of the individual's discharge,

(ii) payment for such services during the stay shall not be made under section 1395ww(d) of this title, and

(iii) the organization shall not receive any payment with respect to the individual under this section during the period the individual is not enrolled.

(8) A contract under this section shall provide that the eligible organization shall meet the requirement of section 1395cc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(d) Right to enroll with contracting organization in geographic area

Subject to the provisions of subsection (c)(3) of this section, every individual entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter or enrolled under part B of this subchapter only (other than an individual medically determined to have end-stage renal disease) shall be eligible to enroll under this section with any eligible organization with which the Secretary has entered into a

contract under this section and which serves the geographic area in which the individual resides.

* * * * *

(g) Risk-sharing contract

(1) The Secretary may enter a risk-sharing contract with any eligible organization, as defined in subsection (b) of this section, which has at least 5,000 members, except that the Secretary may enter into such a contract with an eligible organization that has fewer members if the organization primarily serves members residing outside of urbanized areas.

(2) Each risk-sharing contract shall provide that—

(A) if the adjusted community rate, as defined in subsection (e)(3) of this section, for services under parts A and B of this subchapter (as reduced for the actuarial value of the coinsurance and deductibles under those parts) for members enrolled under this section with the organization and entitled to benefits under part A of this subchapter and enrolled in part B of this subchapter, or

(B) if the adjusted community rate for services under part B of this subchapter (as reduced for the actuarial value of the coinsurance and deductibles under that part) for members enrolled under this section with the organization and entitled to benefits under part B of this subchapter only

is less than the average of the per capita rates of payment to be made under subsection (a)(1) of this sec-

tion at the beginning of an annual contract period for members enrolled under this section with the organization and entitled to benefits under part A of this subchapter and enrolled in part B of this subchapter, or enrolled in part B of this subchapter only, respectively, the eligible organization shall provide to members enrolled under a risk-sharing contract under this section with the organization and entitled to benefits under part A of this subchapter and enrolled in part B of this subchapter, or enrolled in part B of this subchapter only, respectively, the additional benefits described in paragraph (3) which are selected by the eligible organization and which the Secretary finds are at least equal in value to the difference between that average per capita payment and the adjusted community rate (as so reduced); except that this paragraph shall not apply with respect to any organization which elects to receive a lesser payment to the extent that there is no longer a difference between the average per capita payment and adjusted community rate (as so reduced) and except that an organization (with the approval of the Secretary) may provide that a part of the value of such additional benefits be withheld and reserved by the Secretary as provided in paragraph (5). If the Secretary finds that there is insufficient enrollment experience to determine an average of the per capita rates of payment to be made under subsection (a)(1) of this section at the beginning of a contract period, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this section.

* * * * *

(h) Reasonable cost reimbursement contract; requirements

(1) If—

(A) the Secretary is not satisfied that an eligible organization has the capacity to bear the risk of potential losses under a risk-sharing contract under this section, or

(B) the eligible organization so elects or has an insufficient number of members to be eligible to enter into a risk-sharing contract under subsection (g)(1) of this section.

the Secretary may, if he is otherwise satisfied that the eligible organization is able to perform its contractual obligations effectively and efficiently, enter into a contract with such organization pursuant to which such organization is reimbursed on the basis of its reasonable cost (as defined in section 1395x(v) of this title) in the manner prescribed in paragraph (3).

* * * * *

APPENDIX H

63 Fed. Reg. 34,968 (1998) (adding 42 C.F.R. 422.562-422.662), provides in relevant part as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 403, 410, 411, 417, and 422

[HCFA-1030-IFC]

RIN 0938-A129

Medicare Program; Establishment of the Medicare+ Choice Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

* * * * *

42 CFR Chapter IV is amended as set forth below.

* * * * *

22. Subparts M through O are added to read as follows:

Subpart M—Grievances, Organization Determinations and Appeals

Sec.

* * * * *

Subpart M—Grievances, Organization Determinations and Appeals

* * * * *

§ 422.562 General provisions.

(a) *Responsibilities of the M+C organization.* (1) An M+C organization, with respect to each M+C plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 422.564 for addressing issues that do not involve organization determinations;

(ii) A procedure for making timely organization determinations; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(2) An M+C organization must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the M+C organization; and

(ii) Complaint process available to the enrollee under the PRO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the M+C organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of M+C enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the M+C organization heard and resolved, as described in § 422.564.

(2) The right to a timely organization determination, as provided under § 422.566.

(3) The right to request an expedited organization determination, as provided under § 422.570.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the M+C organization, as provided under § 422.578.

(ii) The right to request an expedited reconsideration, as provided under § 422.584.

(iii) If, as a result of a reconsideration, an M+C organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by HCFA, as provided in § 422.592.

(iv) The right to an ALJ hearing if the amount in controversy is $100 or more, as provided in § 422.600.

(v) The right to request DAB review of the ALJ hearing decision, as provided in § 422.608.

(vi) The right to judicial review of the hearing decision if the amount in controversy is $1000 or more, as provided in § 422.612.

(c) *Limits on when this subpart applies.* (1) If an enrollee receives immediate PRO review (as provided

in § 422.622) of a determination of noncoverage of inpatient hospital care—

(i) The enrollee is not entitled to review of that issue by the M+C organization; and

(ii) The PRO review decision is subject only to the appeal procedures set forth in part 473 of this chapter.

(2) If an enrollee has no further liability to pay for services that were furnished by an M+C organization, a determination regarding these services is not subject to appeal.

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in 20 CFR, part 404, subparts J and R (covering, respectively, the administrative review and hearing process and representation of parties under title II of the Act), apply under this subpart to the extent they are appropriate.

§ 422.564 Grievance procedures.

(a) *General rules.* (1) Each M+C organization must provide meaningful procedures for timely hearing and resolution of grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any M+C plan it offers.

(2) Grievance procedures must meet any guidelines established by HCFA.

(b) *Distinguished from organization determinations and appeals.* Grievance procedures are separate and distinct from organization determinations and appeal procedures, which address organization determinations.

(c) *Distinguished from the PRO complaint process.* Under section 1154(a)(14) of the Act, the PRO must

review beneficiaries' written complaints about the quality of services they have received under the Medicare program; this process is separate and distinct from the grievance procedures of the M+C organization.

§ 422.566 Organization determinations.

(a) *Responsibilities of the M+C organization.* Each M+C organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an M+C plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The M+C organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572.

(b) *Actions that are organization determinations.* An organization determination is any determination made by an M+C organization with respect to any of the following:

(1) Payment for emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the M+C organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the M+C organization.

(3) The M+C organization's refusal to provide services that the enrollee believes should be furnished or arranged for by the M+C organization when the enrollee has not received the services outside the M+C organization.

(4) Discontinuation of a service, if the enrollee disagrees with the determination that the service is no longer medically necessary.

(c) *Who can request an organization determination.* Any of the parties listed in § 422.574 can request an organization determination, with the exception that only the parties listed in § 422.570(a) can request an expedited determination.

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the

enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* The M+C organization must process requests for payment according to the "prompt payment" provisions set forth in § 422.520.

(c) *Written notification for denials.* If an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

(d) *Content of the notice.* The notice of any denial under paragraph (c) of this section must—

(1) State the specific reasons for the denial in understandable language;

(2) Inform the enrollee of his or her right to a reconsideration;

(3) Describe both the standard and expedited reconsideration processes, including the enrollee's right to and conditions for obtaining an expedited reconsideration for service requests, and the rest of the appeal process; and

(4) Comply with any other requirements specified by HCFA.

(e) *Effect of failure to provide timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the M+C organization) may request that an M+C organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the determination, as directed by the M+C organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the M+C organization must process requests.* The M+C organization must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The M+C organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the M+C organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize

the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the M+C organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an M+C organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in § 422.568 for a standard determination. The 14-day period begins with the day the M+C organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter that—

(i) Explains that the M+C organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision not to expedite; and

(iii) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an M+C organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

(f) *Prohibition of punitive action.* An M+C organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited determination.

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframe.* Except as provided in paragraph (b) of this section, an M+C organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 2 working days of the oral notification.

(d) *How information from noncontract providers affects timeframes for expedited determinations.* If an M+C organization must receive medical information

from noncontract providers, the 72-hour period begins when the organization receives that information. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information in order to receive timely payment.

(e) *Content of the notice of expedited determination.* (1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a reconsideration;

(ii) Describe both the standard and expedited reconsideration processes, including the enrollee's right to request, and conditions for obtaining, an expedited reconsideration, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by HCFA.

(f) *Effect of failure to provide a timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

§ 422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her authorized representative);

(b) An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the

enrollee and formally agrees to waive any right to payment from the enrollee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other provider or entity (other than the M+C organization) determined to have an appealable interest in the proceeding.

§ 422.576 Effect of an organization determination.

The organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.

§ 422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in § 422.616) may request that the determination be reconsidered under the procedures described in § 422.582, which address requests for a standard reconsideration. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

§ 422.580 Reconsideration defined.

A reconsideration consists of a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the M+C organization or HCFA obtains.

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by filing a written request with—

(1) The M+C organization that made the organization determination;

(2) An SSA office; or

(3) In the case of a qualified railroad retirement beneficiary, an RRB office.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for a reconsideration within 60 calendar days from the date of the notice of the organization determination. If the SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The timeframe within which the organization must conduct its review begins when it receives the request.

(c) *Extending the time for filing a request.*

(1) *General rule.* If a party shows good cause, the M+C organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a reconsideration has expired, a party to the organization determination may file a request for reconsideration with the M+C organization, SSA, or an RRB office. If SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in § 422.574, and any other provider or entity (other than the M+C organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the M+C organization) may request that an M+C organization expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment.) A physician that requests an expedited reconsideration must be acting on behalf of the enrollee as an authorized representative.

(b) *How to make a request.* (1) To ask for an expedited reconsideration, an enrollee or a physician acting on behalf of an enrollee must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the M+C organization.

(2) A physician may provide oral or written support for a request for an expedited reconsideration.

(c) *How the M+C organization must process requests.* The M+C organization must establish and main-

tain the following procedures for processing requests for expedited reconsiderations:

(1) *Handling of requests.* The M+C organization must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* Promptly decide on whether to expedite the reconsideration or follow the timeframe for standard reconsideration based on the following requirements:

(i) For a request made by an enrollee, the M+C organization must provide an expedited reconsideration if it determines that applying the standard timeframe for reconsidering a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the M+C organization must provide an expedited reconsideration if the physician indicates that applying the standard timeframe for conducting a reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an M+C organization denies a request for expedited reconsideration, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 422.590(a). The 30-day period begins the day the M+C organization receives the request for expedited reconsideration.

(2) Give the enrollee prompt oral notice, and follow up, within 2 working days, with a written letter that—

(i) Explains that the M+C organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite; and

(iii) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If an M+C organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590(d).

(f) *Prohibition of punitive action.* An M+C organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited reconsideration.

§ 422.586 Opportunity to submit evidence.

The M+C organization must provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the M+C organization must inform the parties of the conditions for submitting the evidence.

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.*

(1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). For extensions, the M+C organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) If the M+C organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by HCFA as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gather-

ing and forwarding information to the independent entity.

(b) *Standard reconsideration: Request for payment.* (1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the M+C organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by HCFA no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Effect of failure to meet timeframe for standard reconsideration.* If the M+C organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, this failure constitutes an affirmation of its adverse organization determination, and the M+C organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

(d) *Expedited reconsideration—(1) Timeframe.* Except as provided in paragraph (d)(2) of this section, an M+C organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as

appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee orally of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 2 working days.

(4) *How information from noncontract providers affects timeframes for expedited reconsiderations.* If the M+C organization must receive medical information from noncontract providers, the 72-hour period begins when the organization receives the information. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information in order to receive timely payment.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the M+C organization affirms, in whole or in part, its adverse expedited organization determination, the M+C organization must submit a written explanation and the case file to the independent entity contracted by HCFA as expeditiously as the enrollee's health

condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(e) *Notification of enrollee.* If the M+C organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

(f) *Failure to meet timeframe for expedited reconsideration.* If the M+C organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the M+C organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

(g) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the M+C organization's denial of coverage based on a lack of medical necessity, the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue.

§ 422.592 Reconsideration by an independent entity.

(a) When the M+C organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with HCFA.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same parties listed in § 422.582(d) who qualified during the M+C organization's reconsideration, with the addition of the M+C organization.

§ 422.594 Notice of reconsidered determination by the independent entity.

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to HCFA.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the M+C organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy is $100 or more;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by HCFA.

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy is $100 or more, any party to the reconsideration (except the M+C organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ. The M+C organization does not have the right to request a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with § 405.740 of this chapter for Part A services and § 405.817 of this chapter for Part B services.

(c) If the basis for the appeal is the M+C organization's refusal to provide services, HCFA uses the projected value of those services to compute the amount remaining in controversy.

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request.* A party must file a written request for a hearing at one of the places listed in § 422.582(a) or with the independent, outside entity. The organizations listed in § 422.582(a) forward the request to the independent, outside entity, which is

responsible for transferring the case to the appropriate ALJ hearing office.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in 20 CFR 404.933(c), a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the M+C organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *When the amount in controversy is less than $100.* (1) If a request for a hearing clearly shows that the amount in controversy is less than $100, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than $100, he or she discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 422.608 Departmental Appeals Board (DAB) review.

Any party to the hearing, including the M+C organization, who is dissatisfied with the ALJ hearing decision, may request that the DAB review the ALJ's decision or dismissal. Regulations located at 20 CFR 404.967 through 404.984 regarding SSA Appeals Council Review apply to DAB review for matters addressed by this subpart.

§ 422.612 Judicial review.

(a) *Review of ALJ's decision.* Any party, including the M+C organization, may request judicial review

(upon notifying the other parties) of an ALJ's decision if—

(1) The DAB denied the party's request for review; and

(2) The amount in controversy is $1,000 or more.

(b) *Review of DAB decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of the DAB decision if—

(1) It is the final decision of HCFA; and

(2) The amount in controversy is $1,000 or more.

(c) *How to request judicial review.* A party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of the procedures to follow in requesting judicial review).

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an M+C organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the DAB that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in § 405.750 of this chapter.

(b) Reopening may be at the instigation of any party.

(c) The filing of a request for reopening does not relieve the M+C organization of its obligation to make payment or provide services as specified in § 422.618.

(d) Once an entity issues a revised determination or decision, any party may file an appeal.

§ 422.618 How an M+C organization must effectuate reconsidered determinations or decisions.

(a) *Reversals by the M+C organization*—(1) *Requests for service.* If, on reconsideration of a request for service, the M+C organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the M+C organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the M+C organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the M+C organization receives the request for reconsideration.

(b) *Reversals other than by the M+C organization.* If the M+C organization's organization determination is reversed in whole or in part by the independent outside entity or at a higher level of appeal, the M+C organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the organization determination. The M+C organization must also inform the independent, outside entity that the organization has effectuated the decision.

§ 422.620 How M+C organizations must notify enrollees of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* Where an M+C organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the enrollee remains entitled to inpatient hospital care until he or she receives notice of noncoverage of that care.

(b) *Physician concurrence required.* Before the M+C organization gives notice of noncoverage as described in paragraph (c) of this section, the physician who is responsible for the enrollee's hospital care must concur.

(c) *Notice to the enrollee.* The M+C organization must give the enrollee written notice that includes the following:

(1) The reason why inpatient hospital care is no longer needed.

(2) The effective date of the enrollee's liability for continued inpatient care.

(3) The enrollee's appeal rights.

(4) Comply with any other requirements specified by HCFA.

(d) *Physician concurrence when a hospital determines if care is necessary.* If the M+C organization allows the hospital to determine whether inpatient care is necessary, the hospital obtains the concurrence of the contracting physician responsible for the enrollee's hospital care or of another physician as authorized by the M+C organization, and notifies the enrollee, follow-

ing the procedures set forth in § 412.42(c)(3) of this chapter.

§ 422.622 Requesting immediate PRO review of noncoverage of inpatient hospital care.

(a) *Enrollee's right to review or reconsideration.* (1) An enrollee who wishes to appeal a determination by an M+C organization or hospital that inpatient care is no longer necessary must request immediate PRO review of the determination in accordance with paragraph (b) of this section. An enrollee who requests immediate PRO review may remain in the hospital with no additional financial liability as specified in paragraph (c) of this section.

(2) An enrollee who fails to request immediate PRO review in accordance with the procedures in paragraph (b) of this section may request expedited reconsideration by the M+C organization as described in § 422.584, but the financial liability rules of paragraph (c) of this section do not apply.

(b) *Procedures enrollee must follow.* For the immediate PRO review process, the following rules apply:

(1) The enrollee must submit the request for immediate review—

(i) To the PRO that has an agreement with the hospital under § 466.78 of this chapter;

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the M+C organization or hospital has determined that the hospital stay is no longer necessary.

(2) On the date it receives the enrollee's request, the PRO must notify the M+C organization that the enrollee has filed a request for immediate review.

(3) The M+C organization must supply any information that the PRO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day immediately following the day the enrollee submits the request for review.

(4) In response to a request from the M+C organization, the hospital must submit medical records and other pertinent information to the PRO by close of business of the first full working day immediately following the day the organization makes its request.

(5) The PRO must solicit the views of the enrollee who requested the immediate PRO review.

(6) The PRO must make a determination and notify the enrollee, the hospital, and the M+C organization by close of business of the first working day after it receives all necessary information from the hospital, or the organization, or both.

(c) *Liability for hospital costs*—(1) *When the M+C organization determines that hospital services are not, or are no longer, covered.* (i) Except as provided in paragraph (c)(1)(ii) of this section, if the M+C organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the organization continues to be financially responsible for the costs of the hospital stay when a timely appeal is filed under paragraph (a)(1) of this section until noon of the calendar day following the day the PRO notifies the enrollee of its

review determination. If coverage of the hospital admission was never approved by the M+C organization (or the admission does not constitute emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the M+C organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the M+C plan.

(ii) The hospital may not charge the M+C organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate PRO review; and

(B) The PRO upholds the noncoverage determination made by the M+C organization.

(2) *When the hospital determines that hospital services are no longer required.* If the hospital determines that inpatient hospital services are no longer necessary, and the enrollee could not reasonably be expected to know that the services would not be covered, the hospital may not charge the enrollee for inpatient services received before noon of the calendar day following the day the PRO notifies the enrollee of its review determination.

APPENDIX I

42 C.F.R. 417.608-417.634 (1996), superseded by 63 Fed. Reg. 34,968 (1998), provided as follows:

§ 417.608 Notice of adverse organization determinations.

(a) if an HMO or CMP makes an organization determination that is partially or fully adverse to the enrollee, it must notify the enrollee of the determination within 60 days of receiving the enrollee's request for payment for services.

(b) The notice must—

(1) State the specific reasons for the determination; and

(2) Inform the enrollee of his or her right to reconsideration.

(c) The failure to provide the enrollee with timely notification of an adverse organization determination constitutes an adverse organization determination and may be appealed.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59942, Nov. 21, 1994]

§ 417.610 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee;

(b) An assignee of the enrollee (that is, a physician or other supplier who has provided a service to the enrollee and formally agrees to waive any right to payment from the enrolee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other entity determined to have an appealable interest in the proceeding.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59942, Nov. 21, 1994]

§ 417.612 Effect of organization determination.

The organization determination is final and binding on all parties unless it is reconsidered in accordance with §§ 417.614 through 417.626, or revised in accordance with § 417.638.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59941, Nov. 21, 1994]

§ 417.614 Right to reconsideration

Any party who is dissatisfied with an organization determination or with one that has been reopened and revised may request reconsideration of the determination in accordance with the procedures of § 417.616.

[59 FR 59942, Nov. 21, 1994]

§ 417.616 Request for reconsideration

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with—(1) The HMO or CMP that made the organization determination;

(2) An SSA office; or

(3) In the case of a qualified railroad retirement beneficiary, an RRB office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, the request for reconsideration must be filed within 60 days from the date of the notice of the organization determination.

(c) *Extension of time to file a request.* (1) *Rule.* If good cause is shown, the HMO or CMP that made the organization determination may extend the time for filing the request for reconsideration.

(2) *Method of requesting an extension.* If the time limit in paragraph (b) of this section has expired, a party to the organization determination may file a request for reconsideration with the HMO or CMP, HCFA, SSA, or, in the case of qualified railroad retirement beneficiary, the RRB office. The request to extend the time limit must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed timely.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the initial determination as described in 417.610, and any other person or entity whose rights with respect to the initial determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawal of request.* A request for reconsideration may be withdrawn by the party who filed the request. The request for withdrawal must be filed at one of the places specified in paragraph (c)(2) of this section.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 59 FR 59942, Nov. 21, 1994]

§ 417.618 Opportunity to submit evidence.

The HMO or CMP must provide the parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 59 FR 59942, Nov. 21, 1994]

§ 417.620 Responsibility for reconsiderations; time limits.

(a) If the HMO or CMP can make a reconsidered determination that is completely favorable to the enrollee, the HMO or CMP issues the reconsideration determination.

(b) If the HMO or CMP recommends partial or complete affirmation of its adverse determination, the HMO or CMP must prepare a written explanation and send the entire case to HFCA. HCFA makes the reconsidered datermination.

(c) The HMO or CMP must issue the reconsidered determinations to the enrollee, or submit the explanation and file to HCFA, within 60 calendar days from the date of receipt of the request for reconsideration.

(d) For good cause shown, HCFA may allow expeditions to the time limit set forth in paragraph (c) of this section.

(e) Failure by the HMO or CMP to provide the enrollee with a reconsidered determination within the 60-day limit described in paragraph (c) of this section or to obtain a good cause extension described in paragraph (d) of this section constitutes an adverse determination, and the HMO or CMP must submit the file to HCFA.

(f) If the HMO or CMP refers the matter to HCFA, it must concurrently notify the beneficiary of that action.

[59 FR 59942, Nov. 21, 1994]

§ 417.622 Reconsidered determination

A reconsidered determination is a new determination that—

(a) Is based on a review of the organization determination, the evidence and findings upon which it was based, and any other evidence submitted by the parties or obtained by HCFA or the HMO or CMP; and

(b) Is made by a person or persons who were not involved in making the organization determination.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59941, 59942, Nov. 21, 1994]

§ 417.624 Notice of reconsidered determination.

(a) *Responsibility for notice.* The entity that makes the reconsidered determination is responsible for mailing notice to the parties and, if that entity is not HCFA, for sending a copy to HCFA.

(b) *Content of notice.* The notice must—

(1) State the specific reasons for the reconsidered determination;

(2) Inform the party of his or her right to a hearing if the amount in controversy is $100 or more; and

(3) Describe the procedures that the party must follow to obtain a hearing.

[50 FR 1346, Jan. 10, 1985]

§ 417.630 Right to a hearing.

If the amount remaining in controversy is $100 or more, any party to the reconsideration who is dissatisfied with the reconsidered determination has a right to a hearing. (The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with § 405.740 of this chapter for Part A services and § 405.820(b) of this chapter for Part B services. If the basis for the appeal is the refusal of services, the projected value of those services is used in computing the amount remaining in controversy.)

[59 FR 59942, Nov. 21, 1994]

§ 417.632 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed at one of the places specified in § 417.616(a).

(b) *Time for filing a request.* Except when the time is extended by a presiding officer as provided in 20 CFR 404.933(c), a request for a hearing must be filed within 60 days of the date of the notice of reconsidered determination.

(c) *Parties to a hearing.* (1) The parties to a hearing must be the parties to the reconsideration and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(2) The HMO or CMP must be made a party to the hearing but does not have a right to request a hearing.

(d) *ALJ action when the amount in controversy is less than $100.* (1) If the request plainly shows that the amount in controversy is less than $100, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than $100, he or she discontinues the hearing and does not rule on the substantive issues raised in the appeal.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.623 Departmental Appeals Board review.

Any party to the hearing, including the HMO or CMP, who is dissatisfied with the hearing decision, may request the Departmental Appeals Board to review the ALJ's decision or dismissal. Provisions regarding Departmental Appeals Board review are contained in 20 CFR 404.967 through 404.983.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; 58 FR 38083, July 15, 1993, as amended at 61 FR 32348, June 24, 1996]

§ 417.636 Court review.

(a) *Review of ALJ's decision.* A party or the HMO or CMP may request judicial review of an ALJ's decision if—

(1) The Departmental Appeals Board denied the party's or the HMO's or CMP's request for review; and

(2) The amount in controversy is $1,000 or more.

(b) *Review of Departmental Appeals Board decision.* A party or the HMO or CMP may request judicial review of the Departmental Appeals Board decision if—

(1) It is the final decision of HCFA; and

(2) The amount in controversy is $1,000 or more.

(c) *Request for review.* The civil action must be filed in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of the procedures to follow in requesting judicial review).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 61 FR 32348, June 24, 1996]

§ 417.638 Reopening determinations and decisions

An organization, reconsidered, or revised determination made by an HMO, CMP, or HCFA, or a decision or revised decision of an ALJ or the Depart-

mental Appeals Board, may be reopened in accordance with the provisions of § 405.750 of this chapter.

[59 FR 59942, Nov. 21, 1994, as amended at 61 FR 32348, June 24, 1996]