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*

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

Before 42 U.S.C. 1395mm(g) was superseded, it authorized the Secretary of Health and Human Services to enter into contracts with private health maintenance organizations (HMOs) under which they received a fixed, per-person monthly fee for each Medicare beneficiary who chose to enroll in an HMO in place of traditional fee-for-services Medicare coverage. The HMO, in turn, was required to provide enrolled beneficiaries with all medical services covered by Medicare. Disputes between the HMO and the beneficiary regarding services were resolved by the Secretary or her agents.

The questions presented by this case are:

1. Whether the decision by a Section 1395mm(g) HMO to deny an enrolled Medicare beneficiary's request for health services constitutes government action subject to the requirements of the Due Process Clause of the Fifth Amendment.

2. Whether, in this nationwide class action, the district court properly issued an injunction, on due process grounds, imposing new procedural requirements that all HMOs that enroll Medicare beneficiaries under Section 1395mm(g) must follow and that the Secretary must enforce through Section 1395mm(g) contracts.

3. Whether, in light of Congress's enactment of new Medicare Part C, which eliminates the Secretary's authority to contract under Section 1395mm(g) and establishes a new "Medicare+Choice" program that provides greatly enhanced procedural protections for Medicare beneficiaries enrolled in HMOs, the judgments below should be vacated and the case remanded to the district court for further proceedings.

## PARTIES TO THE PROCEEDINGS

The petitioner is Donna E. Shalala, Secretary, Health and Human Services. The respondents are plaintiffs Gregoria Grijalva, Carol Knox, Mary Lea, Beatrice Bennett, and Mildred Morrell, individuals and representatives of a class of persons similarly situated, and plaintiffs-intervenors 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.

TABLE OF CONTENTS



TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page



Constitution, statutes and regulations:

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The Solicitor General, on behalf of Donna E. Shalala, Secretary of Health and Human Services, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

## OPINIONS BELOW

The opinion of the court of appeals (App. 1a-21a) is reported at 152 F.3d 1115. The opinion of the district court (App. 24a-58a) is reported at 946 F. Supp. 747.

## JURISDICTION

The judgment of the court of appeals was entered on August 12, 1998. A petition for rehearing was denied on November 12, 1998. App. 22a-23a. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATUTORY AND REGULATORY PROVISIONS INVOLVED

Relevant portions of the Medicare Act, as it existed when the district court ruled, 42 U.S.C. 1395mm, are reproduced in the Appendix to this petition, see App. 102a-109a, as are relevant provisions of the Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275-330, see App. 70a-101a. Relevant portions of the Secretary's regulations implementing 42 U.S.C. 1395mm(g), as they existed at the time the district court ruled, 42 C.F.R. 417.608-417.638 (1996), are likewise set out in the Appendix, see App. 140a-149a, as are relevant provisions of the Secretary's current regulations, 63 Fed. Reg. 34,968 (1998), see App. 110a-139a.

## STATEMENT

1. The Medicare program, established under Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*, pays for covered medical care for eligible aged and disabled persons. Originally, Medicare operated exclusively in a manner similar to fee-for-service medical insurance. Under such arrangements, the beneficiary first obtains needed medical care. The beneficiary or his healthcare provider then submits a claim for reimbursement to the Medicare program. Claims are then reviewed by processing agents known as "fiscal intermediaries" or "carriers"—private companies that act under contract as the Secretary's fiscal agent to evaluate claims and determine whether payment is authorized by the Medicare statute. Where the fiscal intermediary or carrier approves the claim, it is paid by the federal government out of the Medicare Trust Funds in the Treasury. See generally *Regions Hosp.* v. *Shalala*, 118 S. Ct. 909, 912 (1998); *Schweiker* v. *McClure*, 456 U.S. 188 (1982).

In 1982, Congress added a provision to the Medicare Act to permit beneficiaries to obtain covered services in a fundamentally different way—by enrolling in private healthcare plans like health maintenance organizations (HMOs).

See Pub. L. No. 97-248, § 114(a), 96 Stat. 341, codified at 42 U.S.C. 1395mm. (Section 1395mm has now been superseded by new Medicare Part C, as discussed in greater detail below.) Because HMOs often operate efficiently and can obtain discounts for medical services from participating providers, they frequently can offer their enrollees a more comprehensive package of services—including extras like dental care—at the same or lower cost than the fee-for-service model.

To give Medicare beneficiaries the option of enrolling in HMOs at government expense, Section 1395mm authorized the Secretary to enter into two types of contracts with qualified HMOs. First, the Secretary could enter into a cost-based contract, under which Medicare reimbursed the HMO's reasonable costs (based on submitted reports) for services actually rendered to any Medicare beneficiary enrolled with the HMO. See 42 U.S.C. 1395mm(h); 42 C.F.R. 417.530-417.576 (1996). Second, the Secretary could enter into "risk-sharing" contracts, under which the HMO was paid a fixed monthly payment for each Medicare beneficiary who chose to enroll with the HMO; in return, the HMO was required to provide each enrollee with the full range of services covered by Medicare. 42 U.S.C. 1395mm(g). Under such risk-sharing contracts, the HMO bore the risks of increased patient needs, as Medicare did not adjust its monthly payments based on services actually used. Thus, such contracts were similar to HMO coverage purchased by individuals or by employers for their employees, as the HMO (and not the purchaser of the coverage) bore all costs associated with providing appropriate medical care. This case concerns only patients enrolled in risk-sharing HMOs, *i.e.*, HMOs that entered into contracts pursuant to 42 U.S.C. 1395mm(g).

Under 42 U.S.C. 1395mm, HMOs were required to provide "meaningful procedures for hearing and resolving grievances" between themselves and enrolled members.

42 U.S.C. 1395mm(c)(5)(A). Under the HHS regulations implementing Section 1395mm(c)(5)(A) that were before the district court, HMOs denying requests for medical services were required to notify beneficiaries of such decisions, give the reasons for denial, and notify beneficiaries of the right to ask the HMO to reconsider the decision. 42 C.F.R. 417.608 (1996). HMOs, however, had 60 days in which to issue such decisions, *ibid.*, as well 60 days in which to resolve reconsideration requests, *id.* § 417.620. Neither the statute nor the regulations provided an expedited decision mechanism for cases involving urgent medical needs. And neither the statute nor the regulations addressed the qualifications of HMO decisionmakers. HMO enrollees dissatisfied with adverse HMO decisions, however, could obtain reconsideration review by the HMO and the Secretary or her agents, *id.* §§ 417.614-417.626 (1996), and, subject to certain amount-in-controversy requirements, a hearing before an administrative law judge (ALJ) in the Department of Health and Human Services (HHS), followed by appeal to the Departmental Appeals Board (DAB) and judicial review. See 42 U.S.C. 1395mm(c)(5)(B); 42 C.F.R. 417.630-417.636 (1996). The HMO was required to be made a party to any hearing before an ALJ, and the HMO, if aggrieved by the ALJ's decision, also could seek review by the DAB and judicial review. 42 C.F.R. 417.632(c)(2), 417.634, 417.636 (1996).

2. Respondents have been certified as the named representatives of a nationwide class of Medicare-eligible individuals who enrolled in risk-based HMOs under Section 1395mm(g). See Order of July 18, 1995, C.A. E.R. 36; App. 25a n.1. They alleged that the HMOs were not providing adequate notice and appeal rights with respect to decisions to reduce or deny services. More effective procedures, they asserted, were required by Section 1395mm(c)(5)(A). They further claimed that initial HMO decisions constituted "state action" affecting constitutionally-protected property in-

terests, and that HMO decisions did not comport with the Due Process Clause.

a. The parties filed cross-motions for summary judgment, and the district partially granted respondents' motion, while denying the Secretary's motion. App. 24a-58a. The challenged HMO decisions, the court concluded, are properly attributable to the federal government, and HMO decisional processes therefore must comport with the Due Process Clause. *Id.* at 29a-34a. The court further held that the decisionmaking procedures then in effect did not afford respondents the process that was due under *Mathews* v. *Eldridge*, 424 U.S. 319 (1976). Among other things, the district court faulted the notices of decision issued by HMOs as difficult to understand, see App. 46a-50a, and criticized the time used to resolve urgent requests, *id.* at 43a-45a, 51a.

On March 3, 1997, the district court entered a mandatory injunction that imposed detailed new notice and hearing requirements. App. 59a-64a. Among other things, the injunction commands the Secretary to require that HMOs provide (in all but "exceptional circumstances") a written notice of any decision that denies, terminates or reduces services or treatment within "five working days" of an oral or written request for that care—without regard to whether the beneficiary would be adversely affected if the HMO took longer to resolve the matter. *Id.* at 60a. If the beneficiary seeks reconsideration of the decision, and the request is urgent, the HMO must issue a reconsideration decision within three working days. *Id.* at 62a. (The injunction provides no deadline for resolution of non-urgent reconsideration requests.) And where "acute care services" are at issue, the HMO must provide a hearing before denying the request; it may not discontinue such services until *after* the initial decision and the reconsideration process is completed. *Id.* at 63a. Any notice informing a beneficiary of any such decision, moreover, must be printed in 12-point type, specify

the basis for the decision, and advise the beneficiary of his appeal rights. *Id.* at 60a-61a.

The injunction further requires the Secretary to monitor and investigate compliance with all requirements, and bars the Secretary from contracting with, or renewing a contract with, any HMO that does not comply substantially with the notice and hearing requirements. App. 63a. The order specifies that the district court will retain jurisdiction over the case for a three-year period, and permits respondents to return to the court for additional relief if the order does not redress their claimed injuries. *Id.* at 64a.

b. The Secretary moved the district court to stay its injunction pending appeal, and the district court granted the motion. App. 65a-69a. In seeking the stay, the Secretary pointed out that on April 30, 1997—just after the district court entered its injunction—the Secretary had issued new HMO regulations in interim final form. See 62 Fed. Reg. 23,368 (1997). The Secretary noted that those regulations made several significant changes in notice and appeal procedures. Among other things, the revised regulations provided a new procedure for expedited review in urgent cases: Although HMOs would have 60 days within which to make ordinary determinations, they would have only 72 hours to make decisions where delay could seriously jeopardize the beneficiary's life, health, or functioning. See *id.* at 23,370-23,371; see also *id.* at 23,375 (adding 42 C.F.R. 417.608, 417.609). The district court concluded that a stay was warranted, reasoning 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 implemented without delay." App. 68a.

3. The Secretary appealed the district court's March 3, 1997 Order. While the appeal was pending, Congress (on August 5, 1997) overhauled Medicare's statutory structure with respect to HMOs as part of the Balanced Budget Act of

1997 (BBA), Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275-330. See App. 70a-101a (reproducing relevant portions).

a. To replace Section 1395mm(g), the BBA creates new Part C of the Medicare Act and establishes the "Medicare+Choice" program. "Medicare+Choice" is designed to offer beneficiaries a widely expanded choice of alternatives to traditional fee-for-service Medicare. Those options include participation in HMOs and other private managed-care and fee-for-service plans at government expense, and a new medical savings account option. See 111 Stat. 276 (Section 1851(a)(2), to be codified at 42 U.S.C. 1395w-21(a)(2)); H.R. Conf. Rep. No. 217, 105th Cong., 1st Sess. 585 (1997). The new law directs the Secretary to implement the Medicare+Choice program by establishing a process through which Medicare beneficiaries can, at their option, have the Secretary acquire coverage for them through participating private healthcare organizations in place of original fees-for-services Medicare. 111 Stat. 278 (Section 1851(c)(1), to be codified at 42 U.S.C. 1395w-21(c)(1)). HMOs may not accept Medicare beneficiaries as enrollees and may not receive payments under the program absent a valid Medicare+Choice contract with the Secretary. See 111 Stat. 319 (Section 1857(a), to be codified at 42 U.S.C. 1395w-27(a)).

Part C provides an enhanced statutory framework—an entire Section entitled "Benefits and Beneficiary Protections"—to govern such issues as quality assurance, disputes over treatment, grievances and appeals. See 111 Stat. 293 (Section 1852(g), to be codified at 42 U.S.C. 1395w-22(g)). As before, HMOs must in the first instance determine for themselves whether they believe that a requested treatment is appropriate (just as they would with respect to non-Medicare enrollees). But, as a condition of participation, HMOs must provide Medicare enrollees with a prompt, clear, and understandable statement concerning adverse decisions. 111 Stat. 293 (Section 1852(g)(1), to be codified at 42 U.S.C. 1395w-22(g)(1)). As before, an enrollee

dissatisfied with such a decision may seek reconsideration. But, unlike the statute before the district court, which did not prescribe a deadline for reconsideration decisions, the new statute requires HMOs to issue reconsideration decisions within 60 days (or earlier if the Secretary so directs). 111 Stat. 293 (Section 1852(g)(2)(A), to be codified at 42 U.S.C. 1395w-22g(2)(A)). Moreover, unlike the statute and regulations that were the subject of the district court's decision, the new statute contains expedition provisions that require HMOs to issue decisions "not later than 72 hours [after] receipt of the request for the determination or reconsideration" in urgent cases. 111 Stat. 294 (Section 1852(g)(3)(B), to be codified at 42 U.S.C. 1395w-22(g)(3)(B)).

Unlike the prior statute and regulations, the new statute also addresses the qualifications of the HMO reconsideration decisionmaker. In particular, where the basis for the initial decision to reduce or deny services is lack of medical necessity, the reconsideration decision must be made by an HMO physician with "appropriate expertise in the [relevant] field of medicine." 111 Stat. 293 (Section 1852(g)(2)(B), to be codified at 42 U.S.C. 1395w-22(g)(2)(B)). In addition, the physician addressing the reconsideration request may not be the same physician who made the initial decision. *Ibid.*

All private HMO reconsideration decisions denying or reducing services are subject to review by a neutral, independent entity selected by the Secretary. 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)). Any enrollee (but not an HMO) dissatisfied with the result of the determination of the independent entity may seek a hearing before an ALJ in HHS if the amount in controversy exceeds $100, and the HMO becomes a party to any such hearing. 111 Stat. 294 (Section 1852(g)(5), to be codified at 42 U.S.C. 1395w-22(g)(5)). ALJ decisions are subject to review by the DAB and, if the amount remaining in controversy after administrative review exceeds $1000,

either the HMO or the beneficiary may (if aggrieved) seek judicial review of the agency's decision. *Ibid.*

New Medicare Part C also provides the Secretary with substantial enforcement authority, including the ability to impose monetary penalties and to terminate contracts with HMOs that fail to comply with statutory or regulatory requirements. See 111 Stat. 323-325 (Section 1857(g) and (h), to be codified at 42 U.S.C. 1395w-27(g) and (h)). The new procedures also provide the Secretary with substantial flexibility. Although the district court and the court of appeals read Section 1395mm(c) as barring the Secretary from contracting (or renewing a contract) with any HMO that failed substantially to comply with Medicare requirements, see App. 19a-20a, 54a (citing 42 U.S.C. 1395mm(c)), the new law omits the language upon which those courts relied and does not otherwise provide that termination is a mandatory consequence of non-compliance.[1]

Finally, the new law eliminates the Secretary's authority to renew risk-sharing contracts under Section 1395mm(g)—the principal statutory provision at issue in the district court—as of January 1, 1999. 111 Stat. 328 (amending Section 1876 by adding new subsection (k)(1), to be codified at 42 U.S.C. 1395mm(k)(1)).[2] We have been informed by HHS

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[1] Section 1395mm(c)(1) provided that "[t]he Secretary *may not* enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection." (emphasis added). The new law merely provides that the Secretary's contracts with healthcare organizations under the Medicare+Choice program "shall provide that the organization agrees to comply with the applicable requirements and standards of [Part C] and the terms and conditions of payment as provided for in [Part C]." 111 Stat. 319 (Section 1857(a), to be codified at 42 U.S.C. 1395w-27(a)).

[2] New subsection (k)(1) states that, "on or after the date standards for Medicare+Choice organizations and plans are first established * * * , the Secretary shall not enter into any risk-sharing contract under this section," and further provides that "for any contract year beginning on or

that all risk-sharing contracts entered into under Section 1395mm(g) expired effective December 31, 1998, and that no such contracts were renewed for 1999.[3]

b. On June 26, 1998—while the appeal to the Ninth Circuit was still pending—the Secretary issued interim final regulations implementing the new Medicare Part C Medicare+Choice program. See 63 Fed. Reg. at 34,968 (relevant portions reproduced at App. 110a-139a). The regulations became applicable on January 1, 1999, at the beginning of the initial contracting cycle for Medicare+Choice HMOs. See 63 Fed. Reg. at 34,968, 34,969, 34,976, 52,610.

Building on new Medicare Part C's enhanced statutory protections for Medicare beneficiaries, the Secretary's regulations require participating HMOs to issue prompt and understandable initial decisions and reconsideration decisions. While the BBA provides no statutory deadline for initial HMO decisions, and the Section 1395mm regulations before the district court allowed delays of up to 60 days, the Secretary's new regulations require HMOs to make initial decisions in non-urgent cases "as expeditiously as the [beneficiary's] health condition requires, but no later than 14 calendar days after the date the organization receives the request." 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.568(a)). While the BBA (like the regulations before the district court) sets 60 days as the maximum time limit for resolution of ordinary reconsideration requests, the Secretary's new regulations now require that such decisions be made within 30 days in non-urgent cases. *Id.* at 35,110

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after January 1, 1999, the Secretary shall not renew any such contract." 111 Stat. 328 (to be codified at 42 U.S.C. 1395mm(k)(1)).

[3] We have been informed by HHS that it granted a temporary extension of a Section 1395mm(g) contract with a New Jersey HMO that became insolvent and is currently being operated by the State. The temporary extension—which proved necessary to permit a transition of enrollees to new, qualifying Medicare+Choice plans or traditional fee-for-service Medicare—will not extend beyond February 28, 1999.

(adding 42 C.F.R. 422.590(a)(2)). Finally, all HMO notices informing enrollees of denials of requested services must, among other things, state "the specific reasons for the denial in understandable language," and inform enrollees of their reconsideration and appeal rights. *Id.* at 35,108 (adding 42 C.F.R. 422.568(d)(1)); see also 111 Stat. 293 (Section 1852(g)(1) (B), to be codified at 42 U.S.C. 1395w-22(g)(1)(B)). The regulations before the district court, in contrast, required a statement of reasons, but did not specifically require that it be understandable to ordinary people. 42 C.F.R. 417.608 (1996); see also App. 46a-50a (criticizing prior HMO notices).

Unlike the Section 1395mm regulations the district court found inadequate, the new Medicare+Choice regulations also address the need for expedition in urgent cases. Consistent with the BBA itself, the Medicare+Choice regulations provide that, where delays may threaten the beneficiary's health, HMOs must make initial and reconsideration decisions within 72 hours of the relevant request. See 63 Fed. Reg. at 35,108-35,109 (adding 42 C.F.R. 422.572 pertaining to initial decisions); *id.* at 35,110 (adding 42 C.F.R. 422.590(d) pertaining to reconsideration). Moreover, where an enrollee is receiving authorized in-patient hospital care, the Secretary's new regulations provide that the HMO may not decide that the care is unnecessary absent the concurrence of the physician responsible for the in-patient treatment. *Id.* at 35,112 (adding 42 C.F.R. 422.620(b)). Even then, the enrollee may seek immediate review by an independent peer review organization, and the care may not be discontinued until that organization issues its decision. *Id.* at 35,112-35,113 (adding 42 C.F.R. 422.622).

The new regulations address other aspects of the HMO decisional process as well. Among other things, they require HMOs to afford enrollees seeking reconsideration "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." 63 Fed. Reg. at 35,110 (adding 42 C.F.R. 422.586). And, implementing the BBA, they provide that reconsideration decisions must be made by qualified medical personnel in appropriate circumstances, and by personnel other than the individuals who made the initial decision. *Id.* at 35,111 (adding 42 C.F.R. 422.590(g)(1) and (2)).[4]

4. On August 12, 1998—after enactment of the new Medicare Part C, and after the Secretary's issuance of implementing regulations—the court of appeals affirmed the judgment of the district court. App. 1a-21a. The court of appeals declined to consider the case in light of the intervening revisions to the regulations that had been before the district court. See *id.* at 20a. Instead, the court of appeals addressed the case as if the original regulations before the district court were still in place.[5]

The court of appeals held that a private HMO's decision to reduce or deny services constitutes government action. The court explained that, to establish government action, the plaintiff must show that "there is a sufficiently close nexus between the State and the challenged action of the regulated

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[4] The statute and regulations also provide mechanisms for monitoring and enforcing HMO compliance with grievance and appeal requirements. The statute, for example, requires HMOs to establish and maintain provisions for monitoring and evaluating both clinical and administrative aspects of health plan operations, and the regulations make clear that such "quality assurance" programs must monitor and evaluate the grievance and appeal process. See 111 Stat. 291 (Section 1852(e), to be codified at 42 U.S.C. 1395w-22(e)); 63 Fed. Reg. at 35,082 (adding 42 C.F.R. 422.152). In addition, an HMO's failure to comply substantially with appeal and grievance provisions is potentially a ground for terminating its contract. *Id.* at 35,104 (adding 42 C.F.R. 422.510).

[5] The statutory amendments were enacted shortly before the government filed its reply brief in the court of appeals. The government accordingly informed the Court that the statute would later modify the requirements for HMO grievance and appeal procedures, but that it had not yet taken effect and therefore did not, at that time, bear on the issues presented. See Gov't C.A. Reply Br. 10 n.9.

entity so that the action of the latter may be fairly treated as that of the State itself." App. 8a (quoting *Blum* v. *Yaretsky*, 457 U.S. 991, 1004 (1982)). It further noted that, while government regulation is not by itself sufficient to attribute private action to the government, "[g]overnment 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.'" *Id.* at 8a-9a (quoting *Burton* v. *Wilmington Parking Auth.*, 365 U.S. 715, 725 (1961)).

Applying those standards, the court held 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." App. 9a-10a. The Ninth Circuit reasoned that the Secretary "extensively regulates the provision of Medicare services by HMOs"; the HMOs must "comply with all federal laws and regulations"; the Secretary pays HMOs "for each enrolled Medicare beneficiary (regardless of the services provided)"; and the "federal government has created the legal framework—the standards and enforcement mechanisms—within which HMOs" must operate. *Id.* at 10a. The court of appeals rejected the Secretary's argument that HMO decisions to deny or reduce treatment are private determinations, made without government compulsion or influence. It held that, in this context, such decisions "are more accurately described as * * * interpretations of the Medicare statute" rather "than * * * * medical judgments," and thus could be properly attributed to the government. *Id.* at 11a. Turning to the due process question, the court of appeals held that, under the balancing test established by *Mathews* v. *Eldridge*, 424 U.S. 319 (1976), the process HMOs provided to Medicare beneficiaries under Section 1395mm and the Secretary's pre-April 1997 regulations was less than their

constitutional due, largely for the reasons given by the district court. App. 12a-18a.

The court of appeals also rejected the Secretary's challenge to the nature and scope of the injunctive remedy imposed. Because Congress had delegated implementation of Section 1395mm to the Secretary, she argued that the district court should have remanded the matter to her for an expedited rulemaking to cure the identified ills; and she disputed the appropriateness of the district court's three-year injunction, which prescribed detailed deadline, notice, hearing, and proceeding requirements. The Ninth Circuit declined to afford any deference to the Secretary's views of appropriate process, App. 13a n.3, and rejected her request for a remand, *id.* at 18a & n.4.

5. The Secretary sought rehearing and rehearing en banc. The petition emphasized that the new statute and implementing regulations contain substantially different and more detailed hearing and grievance procedures than those considered in the panel's decision. It asserted that the court's holding, by effectively "constitutionalizing" HMO decisions, impaired the ability of Congress and the Secretary to tailor procedural safeguards to the complex and varied relations between HMOs and their patients. And it urged the court of appeals either to rehear the case or to vacate the injunction and remand the matter to the district court with instructions to consider the new statute and implementing regulations. Gov't Pet. for Reh'g 9-19. The court of appeals denied the petition. App. 22a-23a.

## REASONS FOR GRANTING THE PETITION

Affirming the district court's issuance of a detailed and highly prescriptive nationwide injunction, the Ninth Circuit in this case held (1) that Health Maintenance Organizations and similar healthcare organizations (HMOs) engage in government action when they deny Medicare enrollee requests for services, and (2) that the HMO procedures

required by the Secretary's now statutorily-superseded regulations under 42 U.S.C. 1395mm were insufficient to meet the requirements of due process. Those rulings and their practical consequences are of broad significance in the administration of the Medicare Program and ordinarily would warrant plenary review by this Court. The legal issues presented by this case, however, are similar to those before this Court in *American Manufacturers Mutual Insurance Co., et al.* v. *Sullivan, et al.*, No. 97-2000 (argued Jan. 19, 1999). Accordingly, we suggest that the petition in this case be held pending the Court's decision in *Sullivan*.

Moreover, shortly after the district court ruled in this case, Congress comprehensively revised Medicare's treatment of HMOs by enacting an entirely new Part C of the Medicare Act, introducing the new Medicare+Choice program. Those new provisions, and the Secretary's regulations implementing them, provide dramatically greater procedural protections for beneficiaries who choose to enroll in HMOs; they eliminate the asserted defects that prompted the request for judicial relief in this case; and they deprive 42 U.S.C. 1395mm(g), upon which the district court and the court of appeals relied, of any future effect. As a result of those changes, the challenge to the regulations adjudicated by the district court and court of appeals is now moot. Accordingly, we ask that, after holding the petition pending this Court's decision in *Sullivan*, the Court vacate the judgment of the court of appeals and remand the case with directions to (1) vacate the judgment of the district court and (2) remand the case to that court for consideration of any challenges respondents might raise to the new statute and its implementing regulations in light of the decision in *Sullivan*.

### A. The Petition Should Be Held Pending This Court's Decision In *American Manufacturers Mutual Insurance Co., et al.* v. *Sullivan, et al.*, No. 97-2000 (Argued Jan. 19, 1999)

Government action and due process questions similar to those raised in this case are currently before the Court in *American Manufacturers Mutual Insurance Co., et al.* v. *Sullivan, et al.*, No. 97-2000 (argued Jan. 19, 1999). There, the Third Circuit held that payment decisions made by workers' compensation insurers, as permitted by state law, were both attributable to the State and inconsistent with due process. See *Sullivan* v. *Barnett*, 139 F.3d 158 (1998).

The court of appeals decisions in *Sullivan* and in this case are remarkably similar on the government action issue. Neither decision examines the "three principles" identified by this Court for determining whether otherwise private conduct "is governmental in character": (1) "the extent to which the actor relies on governmental assistance," or accedes to the government's coercive powers or encouragement, in effectuating its will, (2) "whether the actor is performing a traditional governmental function," and (3) "whether the injury caused is aggravated in a unique way by the incidents of governmental authority." *Edmonson* v. *Leesville Concrete Co.*, 500 U.S. 614, 621-622 (1991); see also *Blum* v. *Yaretsky*, 457 U.S. 991, 1004 (1982) (government "normally can be held responsible for a private decision only when it has exercised coercive power or has provided such significant encouragement * * * that the choice must in law be deemed to be that of the [government]"). Rather, both predicate a finding of government action largely on the government's regulatory role. Compare *Sullivan*, 139 F.3d at 168, with App. 9a-10a.

In concluding that medical treatment decisions by private HMOs concerning their Medicare-beneficiary members are properly attributed to the federal government, the Ninth Circuit appears to have relied primarily on the "rather vague

generalization," *Blum*, 457 U.S. at 1010, that there was a "high degree of interdependence" and a "symbiotic relationship," App. 9a, that made the government "a joint participant in the challenged activity." *Burton* v. *Wilmington Parking Auth.*, 365 U.S. 715, 725 (1961). The facts the Ninth Circuit relied upon for that conclusion, however, are largely common to heavily regulated industries. See App. 10a (relying on the facts that the "Secretary extensively regulates," that "HMOs are required * * * to comply with all federal laws," that the Secretary is obligated to ensure that "HMOs provide * * * meaningful * * * procedures," that the "federal government has created the legal framework," and that the Secretary has adjudicatory authority with respect to HMO decisions). Compare *Jackson* v. *Metropolitan Edison Co.*, 419 U.S. 345, 357 (1974); see *id.* at 350.

Significantly here, the relationship between an HMO and its Medicare-beneficiary members is the product of a private choice by those members. Medicare beneficiaries may choose among providers and forms of coverage, and the government neither requires them to enroll in an HMO nor precludes them from disenrolling. In this respect, the HMO's relationship with its Medicare-beneficiary members resembles its relationship with members who elect HMO coverage under employer-sponsored or other private health plans. With respect to each, the HMO simply determines what treatment is appropriate under its professional and contractual obligations, without government participation or assistance.[6] And although money is paid out of the Medicare

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[6] Indeed, the first sentence of the Medicare statute prohibits the "exercise [of] any" governmental "supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. 1395. In *Blum* v. *Yaretsky*, the Court held that the exercise of ordinary medical judgment is not state action, even where it may affect eligibility for government benefits. Although the Ninth Circuit sought to distinguish *Blum* by characterizing HMO determinations as more in the nature of interpretations of the Medicare Act, rather than medical

Trust Funds to cover the flat monthly rate charged for the Medicare beneficiary's enrollment in the HMO, the financial consequences of a determination by the HMO to furnish or deny particular services to that beneficiary once he has enrolled are borne by the HMO alone.[7]

On the merits of the due process issue, the Ninth Circuit rejected the Secretary's contention that her view of the appropriate and meaningful procedures should be accorded substantial weight, declaring that there is "nothing in *Mathews* v. *Eldridge* or subsequent cases to suggest that such is necessary or advisable." App. 13a n.3. That was error. The Court expressly stated in *Mathews* v. *Eldridge*, 424 U.S. 319, 349 (1976), that, "[i]n assessing what process is due * * *, substantial weight must be given to the good-faith judgments of the individuals charged by Congress with the administration of social welfare programs that the proce-

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judgments, see App. 11a, the primary criterion employed by HMOs in this context—whether medical services are "reasonable and necessary," 42 U.S.C. 1395y(a)—essentially requires an exercise of medical, not legal judgment. The complaint in this case, moreover, demonstrates that the named respondents seek to challenge medical judgments. C.A. E.R. 10-11, ¶ 29 (physical therapy denied because patient could not follow therapeutic directions), 12-13, ¶¶ 40-41 (failure to prescribe adequate pain medication or order physical therapy), 13-15, ¶¶ 48-54 (skilled nursing care found not medically necessary), 16, ¶ 62 (speech therapy denied because it would not be effective).

[7] In *Blum*, the Court rejected the contention that decisions made by physicians and nursing homes were attributable to the State, despite "state subsidization of the operating and capital costs of the facilities" and coverage for "the medical expenses of more than 90% of the patients." 457 U.S. at 1011. That the government pays for coverage neither encourages HMOs to deny requests for treatment, nor prevents the financial impact of HMO decisions from being visited exclusively on the HMO. If the fact that the government pays for coverage were a sufficient basis for attributing HMO conduct to the government, HMOs providing services to government employees under the Federal Employees Health Benefits Act of 1959, 5 U.S.C. 8901 *et seq.*, would also all be government actors.

dures they have provided assure fair consideration." For similar reasons, the imposition of a detailed judicial injunction providing new requirements, rather than a remand order directing the Secretary to promulgate new procedures through a participatory and fully public rulemaking process, was error as well. Congress delegated implementation of 42 U.S.C. 1395mm(g) and the creation of "meaningful" procedures in the first instance to the Secretary, not to the courts. Cf. *SEC* v. *Chenery Corp.*, 332 U.S. 194, 199 (1947) (where agency action is set aside, "the [agency is] bound to deal with the problem afresh, performing the function delegated to it by Congress"); *Florida Power & Light Co.* v. *Lorion*, 470 U.S. 729, 744 (1985) (proper course where agency errs is to "remand to the agency").[8]

The arguments that the *Sullivan* petitioners make in support of reversal there apply with equal force in this case as well.[9] Indeed, so closely related are the cases that lead

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[8] The district court also exceeded its authority in ordering the Secretary to terminate contracts with HMOs that fail to comply with the procedures it imposed. See *Blessing* v. *Freestone*, 520 U.S. 329, 343-344 (1997).

[9] See 97-2000 Pet. Br. 20-21 (arguing that State does not influence insurer's non-payment decision), 17-22 (arguing that insurer decisions are not governmental benefits determinations), 22-25 (no unique aggravation of injury by government), 26-32 (regulated nature of industry does not render private action attributable to State). And there are clear similarities between the due process arguments as well. For example, in this case the lower courts implicitly concluded that respondents could have a constitutionally-protected property interest in receiving Medicare services *before* their legal entitlement to those services was established, and that pre-deprivation processes were required in certain contexts, App. 63a. Petitioners in *Sullivan* challenge similar conclusions reached by the court of appeals there. See 97-2000 Pet. Br. 35-38 (arguing that due process does not apply to disputed applications for treatment where the legal entitlement to the treatment, and thus a property interest therein, has not been established), 42-44 (arguing that pre-deprivation process is not required); see also *Lyng* v. *Payne*, 476 U.S. 926, 942 (1986) (noting that

counsel in this case filed an amicus brief in *Sullivan*, emphasizing the potential impact of the Court's decision there on the Medicare program at issue here.[10] For the foregoing reasons, we suggest that the petition in this case be held pending the decision in *Sullivan*.

### B. The Judgments Below Should Be Vacated And The Case Remanded To The District Court For Consideration Of Intervening Statutory and Regulatory Changes

Absent the obvious similarities between this case and *Sullivan*, the Ninth Circuit's decision in this case ordinarily would warrant plenary review by this Court at the present time. It declares unconstitutional the Secretary's implementation of a major federal statutory program; it affirms a detailed nationwide injunction requiring the Secretary to impose certain procedures on participating HMOs; and it constitutionalizes on a nationwide basis the conduct of hundreds of private healthcare organizations offering services to millions of individuals.

On August 5, 1997, however, Congress comprehensively reformed this area of law—enacting the new Medicare Part C and establishing the new "Medicare+Choice" program. See Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275-330. The new statute and the Secretary's regulations promulgated thereunder dramatically expand the procedural and substantive protections afforded to Medicare beneficiaries who choose to enroll in private HMOs. Indeed, Congress gave specific attention to the procedures it considered necessary to protect beneficiary

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the Court has not resolved whether "applicants for benefits, as distinct from those already receiving them, have a legitimate claim of entitlement protected by the Due Process Clause").

[10] See 97-2000 Amici Curiae American Association of Retired Persons, The Center For Medicare Advocacy, Inc., *et al.*, Br. at 4, 7.

rights, enacting a section of new Medicare Part C entitled "Benefits and Beneficiary Protections." 111 Stat. 286 (Section 1852, to be codified at 42 U.S.C. 1395w-22). Consequently, the new statute and the implementing regulations it required the Secretary to promulgate now separately address the alleged deficiencies identified by the lower courts. See pp. 7-12, *supra*. Among other things, they specifically require HMOs to issue understandable notices of decision, 111 Stat. 293 (Section 1852(g)(1), to be codified at 42 U.S.C. 1395w-22(g)(1)); 63 Fed. Reg. 35,108 (1998) (adding 42 C.F.R. 422.568(d)); they provide that medical necessity decisions must be made by qualified medical personnel, 111 Stat. 293 (Section 1852(g)(2)(B), to be codified at 42 U.S.C. 1395w-22(g)(2)(B)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.590(g)(2)); and they mandate prompt initial decisions (within 14 days) and reconsideration decisions (within 30 days) in all cases, and expedited decisions (within 72 hours) if delay could jeopardize the health of the beneficiary. 63 Fed. Reg. at 35,108-35,110 (adding 42 C.F.R. 422.568(a), 422.572, 422.590(a)-(d)); 111 Stat. 293-294 (Section 1852(g)(2) and (3), to be codified at 42 U.S.C. 1395w-22(g)(2) and (3)).[11] Moreover, HMO determinations adverse to the enrollee are subject to automatic review by an independent third party acting as the Secretary's agent, 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.592), and dissatisfied beneficiaries may obtain a hearing before an ALJ

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[11] The district court's concern that HMO physicians might face disincentives to assisting enrollees in pursuing their requests, App. 49a; see *id.* at 62a (enjoining HMO retaliation against healthcare providers), is addressed by the new statute and regulations as well. See 111 Stat. 295 (Section 1852(j)(3), to be codified at 42 U.S.C. 1395w-22(j)(3)); see, *e.g.*, 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.570(f)) (barring punitive action against physician for assistance in requesting expedition).

and judicial review, as provided in and subject to the limits set forth in the statute. See pp. 8-9, *supra*.[12]

The legal regime that respondents challenged and the district court and Ninth Circuit reviewed thus has been superseded by a new statutory framework and new regulations fleshing out that framework. No court has passed on the constitutional sufficiency of the new procedures or their implementation. As a result, the law has "been sufficiently altered" pending appeal "so as to present a substantially different controversy than the one the [lower courts] originally decided." *Northeastern Fla. Chapter of the Associated Gen. Contractors* v. *City of Jacksonville*, 508 U.S. 656, 662 n.3 (1993); *id.* at 670-671 (O'Connor, J., dissenting). See also App. 66a (district court recognition that "on appeal much of the March 3, 1997 Order might be moot" because "of other efforts on the part of state and federal legislatures [to] address[] the same issues addressed by this Court"); see also *id.* at 68a ("the entire case may become largely moot" if even the April 1997 rule changes were "implemented without delay").

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[12] Although these new provisions address most areas covered by the district court's injunction, they take a fundamentally different approach to several key issues. For example, the Secretary's expedition provisions are more favorable to beneficiaries inasmuch as they require reconsideration decisions within three calendar days, see p. 11, *supra*, whereas the district court's order requires such decisions in three working days, App. 62a. While the district court required that detailed written notices of initial decisions be provided within five days even where the beneficiary's health is not in imminent jeopardy, and Congress specified no specific time frame in such cases, see H.R. Conf. Rep. No. 217, 105th Cong, 1st Sess. 605 (1997) (noting that Congress left that issue to the Secretary), the Secretary selected a 14-day deadline, 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.568(a)). Finally, although the Secretary has required certain inpatient hospital services to continue during the pendency of an administrative appeal, she did not extend similar requirements to a broad, unspecified range of "acute care" services. Compare 63 Fed. Reg. at 35,112-35,113 (adding 42 C.F.R. 422.620(b), 422.622), with App. 63a.

Under circumstances such as these, the Court has "set aside the judgment of the Court of Appeals with direction to enter a new judgment setting aside the order of the District Court and remanding to that court for such further proceedings as may be appropriate in light of the supervening event." *McLeod* v. *General Electric*, 385 U.S. 533, 535 (1967) (per curiam); see, *e.g.*, *Calhoun* v. *Latimer*, 377 U.S. 263, 264 (1964) (per curiam) ("vacat[ing] the judgment and remand-[ing] the cause to the District Court for further proceedings" to consider "the nature and effect" of a supervening change in school board policy); *Heckler* v. *Lopez*, 469 U.S. 1082 (1984) (mem.) (vacating judgment and remanding case "to the * * * Court of Appeals * * * to be remanded to the * * * District Court" for appropriate action in light of new legislation); see also *United States Dep't of the Treasury* v. *Galioto*, 477 U.S. 556, 559-560 (1986) (vacating judgment on direct appeal and remanding to district court because a new "enactment significantly alter[ed] the posture of th[e] case"). As the Court explained in *Lewis* v. *Continental Bank Corp.*, 494 U.S. 472, 482 (1990), "in instances where mootness is attributable to a change in the legal framework governing the case, and the plaintiff may have some residual claim under the new framework that was understandably not asserted previously, our practice is to vacate the judgment and remand for further proceedings in which the parties may, if necessary, amend their pleadings or develop the record more fully."

In fact, it may be that the new statute renders moot not merely the appeal, but the entire case as well. Certainly the subject matter on which the district court and the Ninth Circuit focused their analysis—Section 1395mm(g), the Secretary's implementing regulations, and HMO conduct thereunder, see App. 35a-40a, 46a-50a (district court); *id.* at 3a-5a, 13a (court of appeals)—no longer forms a legitimate basis for judicial relief. The new statute eliminates the Secretary's authority to enter into risk-sharing contracts

under Section 1395mm(g), and no such contracts were renewed for 1999. See pp. 9-10, & nn.2-3, *supra*. As a result, the regulations and notice and appeal procedures that the district court found inadequate are without force or effect; the protections required by the new Medicare Part C and Medicare+Choice control instead. *Princeton Univ.* v. *Schmid*, 455 U.S. 100, 103 (1982) (per curiam) (where "the regulation at issue is no longer in force" and the "lower court's opinion" does not "pass on the validity of the revised regulation," the "case has lost its character as a present, live controversy of the kind that must exist if we are to avoid advisory opinions on abstract questions of law").[13] Moreover, the conduct that respondents challenged and the lower courts found unconstitutional (*e.g.*, the allegedly inadequate notice and time limits) are now addressed by the new statute and regulations. See *Associated General Contractors*, 508 U.S. at 663 n.3 (cases moot where "the statutes at issue * * * were changed substantially, and * * * there was therefore no basis for concluding that the challenged conduct

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[13] The change in the statute, moreover, eliminates the district court's and the court of appeals' rationale—their *ratio decidendi*—for prohibiting the Secretary from entering into or renewing a contract with *any* HMO that violates the procedural requirements those courts believed to be required by Section 1395mm. See App. 63a. To justify that prohibition, the district court and court of appeals both relied on Section 1395mm(c)(1)'s declaration that "[t]he Secretary *may not* enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection." *Id.* at 20a, 54a (quoting 42 U.S.C. 1395mm(c)(1)). See also *id.* at 54a-55a (justifying additional procedural requirements by declaring that the Secretary's failure to impose them in her HMO contracts is a "violation of 42 U.S.C. § 1395mm(c)(1)"); *id.* at 55a-56a (similar). The BBA, however, omits the prohibitory language of Section 1395mm(c)(1) upon which those courts relied, and nowhere suggests that termination and non-renewal are mandatory consequences of HMO non-compliance. See p. 9 & n.1, *supra*. It thus wholly eliminates the statutory provision upon which both lower courts expressly rested their remedial decisions.

was being repeated"); *Bowen* v. *Kizer*, 485 U.S. 386, 387 (1988) (per curiam) (new legislation that provides relief sought by the plaintiffs renders lawsuit moot).[14]

Of course, if the entire case (rather than just the appeal) were indisputably moot, the proper disposition would be to remand the case with a direction that the complaint be dismissed. *United States* v. *Munsingwear, Inc.*, 340 U.S. 36, 39-40 (1950). Given the possibility that the district court may need to dispose of residual claims on remand, see, *e.g.*, C.A. E.R. 21 (request for attorney's fees), and because respondents might seek to amend their complaint to challenge the constitutionality of the new statute and the regulations implementing the new statute, see, *e.g.*, *Calhoun*, 377 U.S. at 264; *Lewis*, 494 U.S. at 482, the Court should neither direct nor preclude dismissal but rather permit the district court to conduct such "further proceedings as may be appropriate in light of" the statutory and regulatory reforms. *McLeod*, 385 U.S. at 535. See also *Burlington Truck Lines, Inc.* v. *United States*, 371 U.S. 156, 172 (1962) (when confronted with intervening facts, court of appeals should not review administrative agency decision but should vacate order and remand to agency for further consideration in light of changed conditions). The district court could then undertake any such further proceedings in light of both the new statute and the new regulations as well as this Court's decision in *Sullivan*.

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[14] See also *United Transp. Union* v. *State Bar*, 401 U.S. 576, 584 (1971) ("An injunction can issue only after the plaintiff has established that the conduct sought to be enjoined is illegal and that the defendant, if not enjoined, will engage in such conduct."); *Legal Assistance for Vietnamese Asylum Seekers* v. *Department of State*, 45 F.3d 469, 472 (D.C. Cir. 1995) (Plaintiffs are "certainly not entitled to prospective relief based on a no longer effective version of a later amended regulation.").

## CONCLUSION

The Court should hold the petition for a writ of certiorari pending the decision in *American Manufacturers Mutual Insurance Co., et al.* v. *Sullivan, et al.*, No. 97-2000 (argued Jan. 19, 1999). The Court should then grant the petition for a writ of certiorari, vacate the judgment of the court of appeals, and remand to the court of appeals with instructions to (1) vacate the judgment of the district court and (2) remand the case to the district court for consideration of Sections 4001 and 4002 of the Balanced Budget Act of 1997 and the regulations of the Secretary of Health and Human Services implementing those provisions in light of the Court's decision in *Sullivan*.

Respectfully submitted.

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