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Health-Grijalva

"B"

No.

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

SETH P. WAXMAN
Solicitor General
Counsel of Record
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

HARRIET S. RABB
General Counsel
Department of Health and Human Services
Washington, D.C. 20201

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PETITION FOR A WRIT OF CERTIORARI

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).

a. 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(g) 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-services 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.[8]

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

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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)).

[8] 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.

made within 30 days in non-urgent cases. *Id.* at 35,110 (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

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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.

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." 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 re-

quests 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)

1. The Due Process Clause does not apply to purely private conduct; it applies only where the actor is governmental, or the conduct can be fairly attributed to the government. *NCAA* v. *Tarkanian*, 488 U.S. 179, 191 (1988). The Ninth Circuit held that medical treatment decisions of private HMOs are properly attributed to the federal government in this case because the "Secretary extensively regulates the provision of Medicare services by HMOs" and pays HMOs "for each enrolled Medicare beneficiary (regardless of the services provided)"; HMOs must "comply with all federal laws and regulations"; and the "federal government has created the legal framework—the standards and enforcement mechanisms—within which HMOs" operate. App. 10a. The Ninth Circuit's analysis departs from this Court's usual approach in this area, which focuses on three factors:

a. The first factor is whether the government "has exercised coercive power or has provided such significant encouragement * * * that the choice must in law be deemed to be that of the [government]." *Blum* v. *Yaretsky*, 457 U.S. 991, 1004 (1982); see also *Edmonson* v. *Leesville Concrete Co.*, 500 U.S. 614, 621 (1991). When an HMO makes an initial determination whether to provide a requested medical service to a member covered by Medicare, it does so without governmental participation or assistance. Indeed, the first section 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.[6]

[6] In *Blum* v. *Yaretsky*, *supra*, this 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

b. The second factor is whether the otherwise private actor exercises some power "traditionally exclusively reserved to the State." *Jackson* v. *Metropolitan Edison Co.*, 419 U.S. 345, 352 (1974). 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 dis-enrolling. 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. Moreover, when an HMO decides whether to provide particular medical services requested by a member who has enrolled through Medicare, it does not act as an agent of the government or distribute government resources or funds. The HMO responds as it would to a similar request by a privately-enrolled member. The HMO exercises its own judgment as to whether the services are reasonable and necessary, and thus within the scope of its professional and contractual obligations. Although money is

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distinguish *Blum* by characterizing HMO determinations as more in the nature of interpretations of the Medicare Act, rather than medical judgments, see App. 11a, the primary criterion employed by HMOs in this context—whether the medical services are "reasonable and necessary," 42 U.S.C. 1395y(a)—requires essentially medical, not legal, judgment. The complaint in this case, moreover, demonstrates that the named respondents seek to challenge medical judgments. One named plaintiff, for example, alleged that she was denied physical therapy because she could not follow therapeutic instructions. C.A. E.R. 10-11, ¶ 29. Another plaintiff alleged that treating physicians failed to prescribe adequate pain medication or to order physical therapy. C.A. E.R. 12-13, ¶¶ 40-41. Another plaintiff, much like the plaintiffs in *Blum*, alleged that the HMO erroneously concluded that skilled nursing care was not medically necessary. C.A. E.R. 13-15, ¶¶ 48-54. And yet another named plaintiff alleged that the HMO denied speech therapy services on the ground that the therapy would not be effective. C.A. E.R. 16, ¶ 62.

paid out of the Medicare Trust Funds to cover the flat monthly rate 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]

Nor does an HMO exercise traditionally-governmental adjudicatory powers with respect to its members who choose to enroll through Medicare. See App. 10a-11a. The HMO's medical treatment decisions regarding such a member represent its own judgment about what is medically appropriate. A Medicare beneficiary who disputes an HMO denial may request an ALJ hearing in HHS, and the HMO then becomes a formal party, adverse to the beneficiary. See pp. 4, 8-9, *supra*. That adjudication, of course, is government action, and the Secretary may order the HMO to provide the requested service, but that does not convert the HMO's otherwise-private initial determination into government conduct.[8] Indeed, the HMO's role is little different than that

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[7] See *Blum*, 457 U.S. at 1011 (rejecting contention that decisions made by physicians and nursing homes are 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"). 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.

[8] Administrative appeal statistics indicate that, in 1996 and 1997, the Secretary reversed HMO determinations in whole or in part in nearly 80% of all cases. The Center for Health Dispute Resolution, *Medicare HMO/CMP Reconsideration Data 1996-1997* (1998). In some instances, the HMO and the Secretary may be adverse parties in contested legal proceedings. If the HMO wishes to challenge one of the Secretary's decisions, it may sue the Secretary in an action for judicial review, 42

of a private defendant confronting potential liability in a civil suit. The defendant would always make an initial determination as to whether it considers itself liable and thus whether to satisfy the asserted obligation voluntarily. If it declines to do so and the plaintiff files suit, that decision may effectively be "reversed"—and a contrary course compelled —by the court. But that does not convert the initial private decision whether to meet the obligation voluntarily, or instead to dispute it, into government action. See *Edmonson*, 500 U.S. at 627 (decisions "whether to sue at all, the selection of counsel, and any number of ensuing tactical choices in the course of discovery and trial may be without the requisite governmental character").

c. Finally, the third factor—whether "the injury caused is aggravated in a unique way by the incidents of governmental authority," *Edmonson*, 500 U.S. at 622, does not support a finding of government action here. This is not a case, like *Edmonson*, in which a dignitary injury or stigma of the sort caused by racial discrimination might be exacerbated by an appearance of governmental endorsement. See *id.* at 628. The government simply provides adjudicatory mechanisms through which a Medicare beneficiary who has elected to enroll in an HMO may challenge medical treatment decisions made by the HMO.

d. At bottom, the Ninth Circuit's decision to attribute to the federal government an HMO's medical treatment decisions about its members who have enrolled through Medicare appears to have rested 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 partici-

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U.S.C. 1395mm(c)(5)(B); and if the Secretary believes that the HMO is not meeting its legal obligations, she may impose civil money penalties or other sanctions, see 42 U.S.C. 1395mm(i)(6)(A)(i); accord 111 Stat. 323-325 (Section 1857(g) and (h), to be codified at 42 U.S.C. 1395w-27(g) and (h)).

pant 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; pp. 13-16, *supra*. Even the most intensive governmental regulation of an industry is an insufficient basis for attributing otherwise private decisions and conduct to the government "where the initiative comes from" the private party "and not from the [government]" itself. *Jackson*, 419 U.S. at 357; see *id.* at 350.

2. The Ninth Circuit's due process holding is also inconsistent with this Court's decisions. Rejecting the Secretary's contention that her view of appropriate and meaningful procedures should be accorded substantial weight, the Ninth Circuit declared 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. *Mathews* v. *Eldridge*, 424 U.S. 319, 349 (1976), expressly states 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 procedures 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, 201 (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").[9]

3. 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 court of appeals 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 (3d Cir. 1998). Not only are the court of appeals decisions in *Sullivan* and in this case remarkably similar,[10] but the precise arguments that the *Sullivan* petitioners make in support of reversal there apply with equal force in this case as well.[11] Indeed, so closely related are the cases that lead

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[9] 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).

[10] Neither court of appeals decision examines the three state-action "principles" identified in *Edmonson*, 500 U.S. at 622, and traditionally relied upon by this Court, see pp. 16-20, *supra*, and 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.

[11] See 97-2000 Pet. Br. at 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,

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.[12] Accordingly, we suggest that the petition 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

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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 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").

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

the procedures it considered necessary to protect beneficiary 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. 10-12, *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)).[13] 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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[13] 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 p. 8-9, *supra*.[14]

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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[14] 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. 10, *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").[15] 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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[15] 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).[16]

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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[16] 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.

SETH P. WAXMAN
Solicitor General

HARRIET S. RABB
General Counsel
Department of Health and Human Services

FEBRUARY 1999

Health-Grijalva

DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE GENERAL COUNSEL
PHONE: 202/690-7741
FAX: 202/690-7998

TO: Elena Cagan

DATE: February 10 1999

DEPARTMENT/OFFICE: Domestic Policy Counsel

PHONE: 456-5584

FAX: 456-2878

FROM: HARRIET S. RABB
GENERAL COUNSEL

COMMENTS: Bruce / Chris —
There are the most disingenuous "discussion points" I can imagine. If anyone believes them, I have a bridge to sell.
Elena

PAGES INCLUDING COVER: 2

DISCUSSION POINTS -- NOT ON THE RECORD

THESE ARE NOT THE PUBLIC TALKING POINTS

Q. Why go the Supreme Court now rather than back to the District Court?
A. The answer to that question have both Medicare and Medicaid components:

A. **Medicare** The current posture of the case leaves us having to go to the Supreme Court or go back to try to define the Constitutional parameters of Medicare in front of a district court judge. There's a large risk that the court will maintain its prescriptive but inadequate order on procedural requirements rather than accept or adopt our current regulations, leaving beneficiaries less well protected than they would be under the Balanced Budget Act (Medicare + Choice) and our regulations.

We believe that the Supreme Court will not accept this case on the merits. We hope the Ninth Circuit decision will be vacated, and we'll have a chance to put the case in a posture where we'll be focused on the new statute [the Balanced Budget Act] and regulations.

A major concern with the Ninth Circuit decision is that the basis for the state action finding was the amount of federal regulation of the HMOs. At the very least, we want to re-focus state action debate on the more traditional indicators of state action found in earlier opinions and that we think will be found in Sullivan. We don't want Grijalva to be used as an argument against appropriate regulation of HMOs.

This case will not necessarily end up saying there's no constitutional protection for Medicare beneficiaries. Once the Court decides Sullivan, we will examine whether, under the Supreme Court's ruling, Medicare HMOs are state actors when they deny, reduce or terminate benefits. If Sullivan leads us to find that the HMOs are state actors in those situations, we will go forward under that view.

B. **Medicaid** Our current Medicaid regulations are not adequate. They offer less protection to beneficiaries than do our current Medicare regulations. We have an NPRM out now in our effort to improve Medicaid beneficiary notice and appeal protections. We are working toward conforming the Medicaid protections with the best and most protective aspect of those in Medicare.

If we go back to the District Court now, in arguing whether to set aside the court's order in favor of our Medicare regulations, we will surface some very sensitive issues that have echoes in Medicaid. One is the type of notice recipients are entitled to when services are denied, reduced or terminated. Another is the question of in what circumstances benefits and services should continue during the pendency of an appeal. We aren't ready to have that argument in a court within the next month and in a context in which the circumstances and interests of Medicaid beneficiaries are not part of the record before the court.

Health Grijalva

Record Type: Record

To: Elena Kagan/OPD/EOP, Christopher C. Jennings/OPD/EOP, Jeanne Lambrew/OPD/EOP

cc:

Subject: First Lady's office views on Medicare issue

I talked to Melanne and she said she is going to try to talk to the First Lady in the next few hours (she's asleep on the plane right now) and if we do get an answer, it is not likely to be before 6pm. However, Melanne did want to convey her own view which is that she supports either option 2 or 3. If option 2 is not possible or not really workable, then she believes we should not file.

Health - Grijalva

THE WHITE HOUSE

WASHINGTON

February 9, 1999

MEMORANDUM TO THE PRESIDENT

FROM: Daniel Marcus DM
Senior Counsel

RE: American Mutual Ins. Co. v. Sullivan and Grijalva

In American Mutual Ins.Co.v. Sullivan, argued last month, the Supreme Court is reviewing a decision by the Third Circuit holding that the actions of insurance companies that administer a state workers' compensation program are "state action" subjecting the insurers to the requirements of the Due Process Clause in making decisions whether medical treatment of employees is reasonable and necessary. (The Third Circuit went on to hold that suspension of payments of benefits to employees during the review process violated due process.)

The Department of Labor was very concerned that the Third Circuit decision called into question longstanding (since the 1920s) provisions of the Longshore and Harbor Workers Compensation Act (LHWCA), which similarly permit employers to suspend workers' compensation benefits to employees in some circumstances pending a final determination of medical necessity. At DOL's urging, the Solicitor General filed an amicus brief in Sullivan arguing that the insurance companies were not state actors. The SG also participated in the oral argument last month. As in Grijalva, the Solicitor General was also influenced by his view that it is in the overall interest of the Government, given its increasing use of private contractors and partners, to resist expansion of the state action doctrine.

Interestingly, one of the underlying due process issues in Grijalva (if the action of Medicare HMOs is state action) parallels the underlying issue in Sullivan and the LHWCA cases -- i.e., is it OK to withhold payment for services the insurer (or the employer or the HMO) believes to be medically unnecessary during the appeal process? The payor has a big stake in that question, because if the employee or beneficiary loses his appeal, the payor realistically has no chance of recovering money paid out for benefits in the meantime. By the same token, employees and beneficiaries have a big stake in getting coverage during the review period.

If the Supreme Court finds state action in Sullivan, a state action finding in Grijalva would follow a fortiori. If, as most observers expect, the Supreme Court finds no state action in Sullivan, the same finding in Grijalva would not necessarily follow. For in the workers' compensation or LHWCA context, it is harder than it is in the Medicare context to argue that the insurer or employer is carrying out an essential governmental function. Workers' compensation is funded basically by employers, while Medicare HMOs are in a sense operating with federal funds. But, like other government contractors, this does not necessarily mean that they are acting as the government. HHS and the Justice Department will be prepared to argue that the differences between Medicare and workers'compensation do not dictate a different result on the state action question.

Health - Gijalva

ROUTING AND TRANSMITTAL SLIP DATE February 9, 1999

TO: (Name, office symbol, room number, Agency/Post)	Initials	Date
1. **Dan Marcus (via fax)** ***confidential attorney-client and attorney work-product communication***		

REMARKS:

This is bare bones. The version I sent you this morning is clearly preferable, but this would be much better than not filing a petition at all.

John -

This is somewhat better, but still not a true "Option 2" brief. It makes quite clear that we believe there is no state actic in this case -- not just that we believe the issue here is related to one already before the Court. Elena

DO NOT use this form as a RECORD of approvals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post) cc: Bruce / Chris

Seth Waxman
Solicitor General
Department of Justice

Room No. - Bldg. **5712-Main DOJ**

Phone No. **202-514-2201**

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RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
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Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002a. fax	Coversheet from Seth Wasman to Dan Marcus re: 9th Circuit decision (1 page)	02/09/1999	P5

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elena Kagan
OA/Box Number: 14363

FOLDER TITLE:
Health - Grijalva [2]

2009-1006-F
ke658

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002b. paper	Legal brief re: 9th Circuit decision (5 pages)	02/09/1999	P5

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elena Kagan
OA/Box Number: 14363

FOLDER TITLE:
Health - Grijalva [2]

2009-1006-F
kc658

RESTRICTION CODES

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Health - Grijalva

DRAFT

No.

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

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

v.

GREGORIA GRIJALVA, ET AL.

Govt - Lewis for Murray

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

Lindh Bagley

PETITION FOR A WRIT OF CERTIORARI

SETH P. WAXMAN
Solicitor General
Counsel of Record
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

HARRIET S. RABB
General Counsel
Department of Health and Human Services
Washington, D.C. 20201

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.

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 and similar healthcare organizations (HMOs) under which they received a fixed, per-person monthly fee for each Medicare beneficiary who chose to enroll in (and to receive medical services from) the HMO in place of traditional fee-for-services Medicare. 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.

Alleging that HMOs with contracts under Section 1395mm(g) had failed to provide beneficiaries with a meaningful opportunity to contest decisions to reduce or deny medical services, plaintiffs filed this nationwide class action lawsuit. They alleged that the HMOs were "state actors" subject to the requirements of the Due Process Clause of the Fifth Amendment, and that the procedures that the HMOs employed were inconsistent with the requirements of that Clause. After plaintiffs filed suit and the district court issued an injunction in plaintiffs' favor, however, Congress comprehensively reformed the relevant statutory and regulatory framework. The new statutory scheme withdraws the Secretary's authority to enter into contracts under Section 1395mm(g), and replaces that provision with a new Medicare Part C, which establishes the "Medicare+Choice" program and offers vastly expanded procedural protections for beneficiaries enrolled in private HMOs.

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 the district court properly issued an injunction, creating new procedural requirements that HMOs must follow and the Secretary must enforce through Section 1395mm(g) contracts, on due process grounds.

3. Whether 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, renders the current appeal moot or otherwise warrants an order vacating the judgment below with directions to remand the matter to district court for consideration of the effect of the new statutory and regulatory scheme.

IN THE SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1998

No.

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v.

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

PETITION FOR A WRIT OF CERTIORARI

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, 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).

a. 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(g). (Section 1395mm(g) 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-services 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 the Secretary would reimburse 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 the denial, and notify the 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. at § 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, 42 C.F.R. 417.614-417.626 (1996), and, subject to certain amount-in-controversy requirements, a hearing before an 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, could seek review by the DAB and then judicial review. 42 C.F.R. 417.632(c)(2), 417.623, 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 Dec. 15, 1994, C.A. E.R. 36; App. 25a n.1. They alleged that the HMOs were not providing legally 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 interests, and that the processes leading to those 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 order provides that 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 such a 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. See App. 70a-101a (reproducing relevant portions).

a. Replacing 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, other private managed-care organizations, and private 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 treatment 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. 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 (Sections 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 in exercising that authority. 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

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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)).

new subsection (k)(1), to be codified at 42 U.S.C. 1395mm(k)(1)).[2] We have been informed by HHS 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. 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 id. at 34,968, 34,969, 34,976, 52,610.

Building on new Medicare Part C's enhanced procedural 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 deadline for initial HMO decisions, and the Section 13955mm 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

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[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 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.

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 (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 before the district court, the new regulations also address the need for expedition in particular cases. Following the BBA, the Secretary's Medicare+Choice regulations provide that, where delays may threaten the health of the beneficiary, 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 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 from 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 also address the HMO decisional process. 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)). Finally, any disputed reconsideration decision by an HMO must be referred to an independent outside review organization that acts, under contract, as an agent of the Secretary. Id. at 35,111 (adding 42 C.F.R. 422.592); 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)). An enrollee dissatisfied with the result of the outside review organization's decision may seek a hearing before an ALJ, and either the enrollee or the HMO may seek administrative review before the DAB, and judicial review, as set forth and subject to the limits provided by statute. See pp. __-__, supra.[4]

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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

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 App. 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 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

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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, the Secretary may treat an HMO's failure to comply substantially with appeal and grievance provisions as a ground for terminating its contract. 63 Fed. Reg. 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.

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 Author., 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. App. 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 much 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 and Suggestion of Reh'g En Banc 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 that case.

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 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).

1. The Fifth Amendment's prohibition against deprivations of property without due process does not apply to purely private conduct; it applies only where the actor is governmental, or the conduct can be fairly attributed to the government. NCAA v. Tarkanian, 488 U.S. 179, 191 (1988); Jackson v. Metropolitan Edison Co., 419 U.S. 345, 349 (1974). Concluding that the decisions of otherwise private HMOs to reduce or deny treatments are properly attributed to the federal government, the Ninth Circuit reasoned that the federal government and the HMOs "are essentially engaged as joint participants to provide Medicare services." App. 9a. In particular, the Ninth Circuit found "a symbiotic relationship with a high degree of interdependence," ibid., because the "Secretary extensively regulates the provision of Medicare services by HMOs"; 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 Ninth Circuit's analysis departs from this Court's established approach to the "fair attribution" and "government action" inquiries. In determining whether otherwise private

conduct "is governmental in character," this Court normally looks to (1) "the extent to which the actor relies on governmental assistance" or the government's coercive powers in effectuating its will, (2) "whether the actor is performing a traditional governmental function," (3) and "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 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]"); Jackson, 419 U.S. at 353 (government action may be found where a private entity exercises functions that are "traditionally the exclusive prerogative of the State."). The Ninth Circuit looked at none of those "three principles," Edmonson, 500 U.S. at 622, and none of them supports the Ninth Circuit's holding.

a. The first factor -- whether the government "has exercised coercive power or has provided such significant encouragement * * * that the choice must in law be deemed to be that of the [government]," Blum, 457 U.S. at 1004 -- points squarely against the Ninth Circuit's finding of government action here. When HMOs decide whether to provide a requested service, they make and effectuate their determinations without governmental participation or assistance. Indeed, the first section 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.[6]

b. Likewise, HMO decisions in this context do not constitute the exercise of some power "traditionally exclusively reserved to the State." Jackson, 419 U.S. at 352. When an HMO decides whether to provide a requested treatment, it does not act as an agent of the government in pursuit of a governmental interest; nor does it distribute government resources or Treasury funds. To the contrary, HMOs confronted with requests for Medicare services conduct themselves precisely as they would in the ordinary and concededly private, non-Medicare context: They exercise their own private judgment as to whether they believe the service is necessary or reasonable, and thus within the scope of their contractual and professional obligations. Moreover, the financial consequences of any such decision is borne by the HMO and the HMO

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[6] For that reason, this case is difficult to distinguish from Blum v. Yaretsky, 477 U.S. 991 (1982), in which this Court held the exercise of ordinary medical judgment is not state action, even where it may affect eligibility for government benefits. Although the Ninth Circuit attempted to distinguish Blum by characterizing HMO determinations as more in the nature of interpretations of the Medicare Act, rather than medical judgments, see App. 11a, the primary criterion employed by HMOs in this context -- whether the medical services are "reasonable and necessary," 42 U.S.C. 1395y(a) -- requires essentially medical, not legal, judgment. The complaint in this case, moreover, demonstrates that respondents seek to challenge purely medical judgments. One named plaintiff, for example, alleged that she was denied physical therapy because she could not follow therapeutic instructions. C.A. E.R. 10-11, ¶ 29. Another plaintiff alleged that treating physicians failed to prescribe adequate pain medication or to order physical therapy. C.A. E.R. 12-13, ¶¶ 40-41. Another plaintiff, much like the plaintiffs in Blum, alleged that the HMO erroneously concluded that skilled nursing care was not medically necessary. C.A. E.R. 13-15, ¶¶ 48-54. And yet another named plaintiff alleged that the HMO denied speech therapy services on the ground that the therapy would not be effective. C.A. E.R. 16, ¶ 62. Whatever the merits of those contentions, they plainly challenge decisions that turn on the exercise of professional medical judgment that is indistinguishable from the medical judgments that this Court held to be private rather than state action in Blum.

alone. Any services that the HMO provides are paid for from its assets, and any savings realized accrue to it alone; neither federal funds nor resources are implicated.

Nor is it correct to suggest that HMOs somehow exercise traditionally-governmental adjudicatory powers, see App. 11a, or that the Secretary's role as adjudicator of HMO-beneficiary disputes somehow converts HMO decisions into government conduct, see id. at 10a. An HMO decision represents the HMO's own determination of what it believes its obligations to be, and thus hardly concludes the matter. To the contrary, under both the prior and current statutes and regulations, beneficiaries who dispute HMO denials may invoke the adjudicatory machinery established by law, and the HMO then becomes a formal, adverse party in the dispute. See 42 U.S.C. 1395mm(c)(5)(B); 42 C.F.R. 417.630-417.636 (1996); 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)); 63 Fed. Reg. 35,111 (adding 42 C.F.R. 422.602(c)). The adjudication, of course, may well involve considerable government action, and the Secretary may order the HMO to provide the requested service, but that does not convert the HMO's otherwise private, initial decision into governmental conduct. Indeed, the HMO's role is little different than that of, for example, a private defendant confronting potential liability in a civil suit. Such a defendant would always make an initial determination as to whether it considers itself liable and thus whether to satisfy the asserted obligation voluntarily. If it declines to do so and the plaintiff seeks an adjudication, that decision may effectively be "reversed" -- and a contrary course compelled -- by the government (a court) acting in its role as

neutral arbiter. But that does not convert the initial private decision whether to meet the obligation voluntarily, or instead to dispute it and insist on adjudication, into government action. See Edmonson, 500 U.S. at 627 (decisions "whether to sue at all, the selection of counsel, and any number of ensuing tactical choices in the course of discovery and trial may be without the requisite governmental character"). For the same reason, the Secretary's role as adjudicator of HMO-beneficiary disputes does not convert private HMO determinations into governmental decisions. Indeed, given the distinct role of the HMO (as a party) and of the Secretary (as the adjudicator) -- and given the statutory and regulatory provisions making the Secretary and HMOs adversaries in many contexts -- the claim that HMOs exercise delegated governmental functions is especially ill-founded.[7]

c. Finally, there can be no argument that "the injury caused is aggravated in a unique way by the incidents of governmental authority." Edmonson, 500 U.S. at 622. This is not a case, like Edmonson, in which a dignitary injury or stigma of the sort caused by racial discrimination might be exacerbated by an appearance of governmental endorsement. See id. at 628. Instead, it is a case

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[7] Administrative appeal statistics indicate that, in 1996 and 1997, the Secretary reversed HMO determinations in whole or in part in nearly 30% of all cases. Center for Health Dispute Resolution, Medicare HMO/CMP Reconsideration Data 1996-1997 (1998). In some instances, the HMO and the Secretary may be adverse parties in contested legal proceedings. Under the prior statute, if the HMO wished to challenge one of Secretary's decisions, it could sue the Secretary in an action for judicial review, 42 U.S.C. 1395mm(c)(5)(B); and if the Secretary believed that a particular HMO was not meeting its legal obligations, she could impose civil money penalties or other sanctions, see 42 U.S.C. 1395mm(i)(6)(A)(i). The new statute contains a similar provision. 111 Stat. 323-325 (Sections 1857(g) and (h), to be codified at 42 U.S.C. 1395w-27(g) and (h)).

in which HMOs make their own judgments as to the appropriateness of medical care, and the government provides adjudicatory mechanisms through which those decisions may be challenged.[8]

d. At bottom, the Ninth Circuit's decision to attribute HMO decisions and conduct to the federal government appears to have rested 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). Even the most intensive governmental regulation of an industry is an insufficient basis for attributing otherwise private decisions and

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[8] Nor does it make a difference that the government pays the HMO a flat, monthly rate for each covered Medicare beneficiary. See Blum, 457 U.S. at 1011 (rejecting contention that decisions made by physicians and nursing homes are 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"). 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.

conduct to the government "where the initiative comes from" the private party "and not from the [government]" itself. Jackson, 419 U.S. at 357; see id. at 350.

2. The Ninth Circuit's due process holding is also inconsistent with this Court's decisions. Rejecting the Secretary's request that her view of the appropriate and meaningful procedures be accorded substantial weight, the Ninth Circuit declared 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: Mathews v. Eldridge, 424 U.S. 319, 349 (1976) expressly states 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 procedures 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, 332 U.S. 194, 199 (1947) (where prior 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").[9]

3. Government action and due process questions very 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 court of appeals 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 (3d Cir. 1998). Not only are the court of appeals decisions in Sullivan and in this case remarkably similar,[10] but the precise arguments that the Sullivan petitioners made in support of reversal there apply with equal force in this case as well.[11]

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[9] 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).

[10] Neither court of appeals decision examines the three state-action "principles" identified in Edmonson, 500 U.S. at 622, and traditionally relied upon by this Court, see pp. __-__, supra, and 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.

[11] The state action arguments raised by the Sullivan petitioners precisely mirror those raised in this petition. See 97-2000 Pet. Br. at 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 medical 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. at 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

Indeed, so closely related are the cases that lead 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.[12] Accordingly, we suggest that the petition be held pending the decision in Sullivan.

B. The Judgments Below Should Be Vacated And The Matter Remanded To 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 would warrant this Court's plenary review 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 thousands of private healthcare organizations offering services to hundreds of thousands of private 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. At the time the district court ruled, the governing statute merely required that HMOs provide "meaningful procedures for hearing and resolving grievances." 42 U.S.C. 1395mm(c)(5)(A). Neither that statutory provision nor the regulations promulgated

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required); see also Lyng v. Payne, 476 U.S. 926, 942 (1986) (noting that 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").

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

under it required notices of adverse decisions to be framed in understandable terms; neither addressed the qualifications of HMO reconsideration decisionmakers; and neither provided any rules regarding expedition in urgent cases. See pp. __-__, supra. In the view of the district court and the court of appeals, the practices that prevailed under that scheme did not afford plaintiffs constitutionally adequate notice or a constitutionally sufficient opportunity to be heard. See pp. __-__, supra. To remedy the alleged deficiencies, the district court imposed and the Ninth Circuit affirmed a detailed and highly prescriptive injunction to regulate beneficiary appeals, specifying the form, content, and timing of HMO notices and hearings.

The new statute and the Secretary's regulations promulgated thereunder, however, dramatically expand the procedural and substantive protections afforded to Medicare beneficiaries enrolled in private HMOs. Indeed, Congress gave specific attention to the sorts of procedures it considered necessary to protect beneficiary 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. __-__, 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 (Sections 1852(g)(2) and (3), to be codified at 42 U.S.C. 1395w-22(g)(2) and (3)).[13] 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 and judicial review, as provided and subject to the limits set forth in the statute. See pp. __-__, supra.[14]

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[13] 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. 35,108 (adding 42 C.F.R. 422.570(f)) (barring punitive action against physician for assistance in requesting expedition).

[14] Although these new provisions address most areas covered by the district court 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. __, 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. 65 (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

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 become moot" because "of 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.").

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

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Secretary has required certain in-patient 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 App. 63a, with 63 Fed. Reg. at 35,112-35,113 (adding 42 C.F.R. 422.620(b), 422.622).

supervening change in school board policy); Heckler v. Lopez, 469 U.S. 1082 (1984) (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 -- the procedures imposed on HMOs under 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 contracts under Section 1395mm(g), and no such contracts were renewed for 1999. See pp. __-__, & n.__, supra. As a result, the regulations and notice and appeal procedures that were before the district court are without force or effect; they protections required by the new

Medicare Part C 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."). [15] 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 was being repeated."); Bowen v. Kizer, 485 U.S. 386, 387 (1988) (per curiam) (new legislation that provides the relief sought by

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[15] 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 they 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 * * *." App. 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 require impose them in her HMO contracts is a "violation of 42 U.S.C. § 1395mm(c)(1)."); id. at 55a-56a (similar). The new statute, 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 penalties for HMO non-compliance. See pp. __-__, supra. The statutory change thus wholly eliminates statutory provision upon which both lower courts expressly rested their remedial decisions.

the plaintiffs renders lawsuit moot).[16]

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, the regulations implementing the new statute, and HMO conduct thereunder, 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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[16] 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 matter 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.

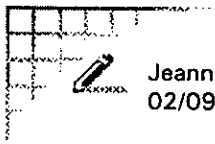
Respectfully submitted.

SETH P. WAXMAN
Solicitor General

HARRIET S. RABB
General Counsel
Department of Health and
Human Services

FEBRUARY 1999

Health - Grijalva



Jeanne Lambrew
02/09/99 01:48:10 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Christopher C. Jennings/OPD/EOP, Devorah R. Adler/OPD/EOP
Subject: response to HHS's argument about Medicaid

From Chris as well:

HHS argues that a decision about state action in Medicare is not applicable to Medicaid because Medicare beneficiaries can always return to fee-for-service, while Medicaid beneficiaries cannot not. (Note: Under the BBA, by 2001, beneficiaries will be locked into managed care plans for nine months from when they join the plan).

Medicaid is not that different from Medicare -- millions of Medicaid beneficiaries have a choice of managed care or fee-for-service.

- **Only 2 states have 100 percent of beneficiaries in managed care** (Tennessee and Washington). States need 1115 waivers to require Medicare-Medicaid "dual eligibles" and children with special needs to join Medicaid managed care plans. In 10 states, less than 25 percent of beneficiaries are enrolled in managed care.

- **Half (25) of states do not enroll any elderly or disabled Medicaid beneficiaries in managed care.** This, plus the choice of fee-for-service for some adults and children account for the fact that 50 percent of Medicaid beneficiaries are not enrolled in managed care.

Absurd to make the case based on whether a beneficiary chooses managed care. In Medicaid, some children with special needs can choose but cannot be forced to enroll in managed care -- while healthy children may be required to enroll. Under HHS's logic, it would be alright to have no private right of action for the sick child whose parents' chose managed care but not alright to take away the right of action from the healthy child.

Some Medicare-Medicaid dual eligibles are enrolled in managed care. For some elderly and people with disabilities, Medicare covers their basic health services and Medicaid pays for prescription drugs, Medicare cost sharing, etc. In this situation, the managed care plan could be sued as a state actor in Medicaid but not in Medicare.

Health - Grijalva

TALKING POINTS AND Qs and As -- FINAL
GRIJALVA APPEAL
January 22, 1999

Background: *Today in the New York Times, it was reported that the Administration is in a bitter dispute over the rights of Medicare beneficiaries. There is no bitter dispute. Secretary Shalala has asked the Solicitor General to petition the Supreme Court in the case of Grijalva v. Shalala. In Grijalva, a nationwide class action suit, the plaintiffs challenged a since-superceded appeals process that applied when risk-based HMOs decided not to provide or arrange for services. The Department believes that the courts should give appropriate consideration to the effect of the strong new Medicare+Choice appeals provisions.*

CONTACT: Lynnette Williams, HHS 690-7850

Talking points:

- There is no dispute within the administration. Secretary Shalala has requested that the Solicitor General petition the Supreme Court, and we anticipate that such a determination will occur shortly.

- Neither is there a conflict between our decision to appeal the case and our support for the Patients' Bill of Rights. The Clinton Administration has always supported the right of Medicare beneficiaries to appeal decisions by their HMOs. That's why we issued regulations to ensure that Medicare beneficiaries in managed care have fair and prompt appeal rights and called on Congress to pass a Patients' Bill of Rights to ensure that all Americans have adequate procedural protections.

- We are requesting that the Solicitor General act in this case *not* because we believe that the appeal rights of beneficiaries should be diminished, but because we think that it is critical that Congress and the Administration retain the flexibility to shape appeals procedures that are tailored to the ever-changing health care environment. We also continue to have concerns about the repercussions of a ruling that essentially finds that HMOs should be considered agents of the government.

- The original *Grijalva* case was decided based on statutes and regulations that have since been replaced by new, stronger protections. These regulations include some faster and more comprehensive appeal rights than the court-ordered procedures, but do not impose the administrative burdens of the court's approach.

GRIJALVA QUESTIONS AND ANSWERS
January 22, 1999

Q: How can you support the Patients' Bill of Rights and appeal the *Grijalva* decision? If you didn't fight, wouldn't this decision give beneficiaries new appeal rights?

A: The Clinton Administration has always supported the right of Medicare beneficiaries to appeal decisions by their HMOs. That's why we issued regulations to ensure that Medicare beneficiaries in managed care have fair and prompt appeal rights and called on Congress to enact a Patients' Bill of Rights to ensure that all Americans have adequate procedural protections.

We are requesting that the Solicitor General act in this case *not* because we believe that the appeal rights of beneficiaries should be diminished, but because we think that it is critical that Congress and the Administration retain the flexibility to shape appeals procedures that are tailored to the ever-changing health care environment. We also continue to have concerns about the repercussions of a ruling that essentially finds that HMOs should be considered agents of the government.

The original *Grijalva* case was decided based on statutes and regulations that have since been replaced by new, stronger statutory and regulatory protections. These rules include some faster and more comprehensive appeal rights than the court-ordered procedures, but do not impose the administrative burdens of the court's approach.

Background: In October 1996, the district court ruled in favor of the plaintiffs. It held that when a Medicare HMO denies or reduces a beneficiary's services, that denial constitutes governmental action and the beneficiary is therefore entitled to due process relating to timely notice and appeal rights. Applying those principles to the Medicare appeals rules then in effect, the court found those rules inadequate and established its own appeals process as a remedy in the case. In August 1998, the appeals court affirmed the district court's ruling. Before the court of appeals issued its decision, Congress enacted the new Medicare+Choice program containing new appeals provisions. These provisions were implemented by new HCFA regulations on June 26, 1998. The court of appeals declined to consider the effect of these new provisions.

Q: Doesn't the *Grijalva* ruling give beneficiaries more rights -- and guarantee them under the constitution?

A: Our new regulations implementing the new Medicare+Choice law give Medicare beneficiaries enrolled in HMOs appeal rights that are, in significant ways, superior to what the *Grijalva* court ordered. For example, the court would allow plans to delay their coverage decisions for up to 60 days, while the new HCFA rules limit these delays to 14 days. Medicare beneficiaries with emergency appeals have far more protections under the new rules – Medicare would require these appeals to be decided as fast as the medical condition of the patient requires, but never any longer than 72 hours. Under the court's

procedures, even these emergency appeals could take up to 5 days.

The constitutional "guarantee" is based on a finding that HMOs are, in effect, the government. We believe that finding to be erroneous. This administration has provided protections to beneficiaries without relying on an incorrect state action analysis.

Q: What would be so bad about doing what the court ordered?

A: The new Medicare+Choice statute and regulations provide appeal rights that we believe are superior to what the court ordered in many ways, and they can be improved through a participatory, public, regulatory process -- rather than through expensive and less flexible judicial action -- as HMO service delivery processes evolve. The *Grijalva* decision found fault with an appeals process that has been replaced by the new Medicare+Choice requirements. The new requirements, which were not in effect at the time of the court's ruling, give Medicare beneficiaries the strongest appeal rights of any HMO patients in the country, including the right to appeal to an independent third party.

Q: Didn't you issue the new rules just to help you in this court case?

A: No. The new rules were promulgated under new legislation passed by Congress in July 1997, and to comply with the President's order to implement the Quality Commission's recommendations in the Medicare program to the greatest extent possible.

Q: Won't appealing Grijalva undercut protections for Medicaid beneficiaries in managed care?

A: The Grijalva court case addresses grievance and appeals within the Medicare program. Medicaid beneficiaries continue to have full appeal and due process protections under the Medicaid statute and regulations, that cannot be affected by any ruling in Grijalva. The Clinton Administration will continue to guarantee and improve those protections. We have proposed additional important protections in regulations implementing Medicaid managed care provisions in the Balanced Budget Act (BBA). Among other things, these regulations provide for expedited decisions and reconsiderations in time-sensitive cases.

Q: Isn't HCFA's opposition to the court's ruling similar to private health plans' opposition to legislation and regulation?

A: No, it is not. HCFA is more than willing to be directed in its administration of the Medicare program by congressional and public input, as occurs in the legislative and regulatory processes. This is evidenced by the strong appeal rights -- some mandated by Congress, and others through regulation -- currently in place in the Medicare program.

The difference between those processes and the court process is that the regulatory and legislative processes are more responsive and flexible in dealing with the ever-changing health care environment.

Q: Are there any other court cases that impact or relate to Grijalva?

A: Yes. There is one currently pending in the Supreme Court, Sullivan v. American Manufacturers Mutual Insurance, which involves a finding that private workers' compensation insurer decisions constitute state action triggering due process obligations. In Sullivan, like Grijalva, the court of appeals also found that due process required that payment be made pending an external appeal.

Also, there was a 1996 decision by a district court in Arizona that found Medicaid-contracting HMOs to be state actors subject to due process requirements. However, any decisions in Sullivan or Grijalva would only result in the possibility of reopening the Arizona finding if someone chose to re-litigate the case, based on any new findings in Grijalva or Sullivan.

Health-grijalva latest 1/28

No.

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

SETH P. WAXMAN
Solicitor General
Counsel of Record

HARRIET S. RABB
General Counsel

EDWIN S. KNEEDLER
Deputy Solicitor General

ANNA D. KRAUS
Deputy General Counsel

JEFFREY A. LAMKEN
Assistant to the Solicitor General

KENNETH Y. CHOE
Special Assistant to the General Counsel

BARBARA C. BIDDLE
JEFFREY CLAIR
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

DONALD G. KOSIN, JR.
Office of the General Counsel
Department of Health and Human Services

PARTIES TO THE PROCEEDINGS

QUESTIONS PRESENTED

Before 42 U.S.C. 1395mm was superseded, it authorized the Secretary of Health and Human Services to enter into contracts with private HMOs and similar healthcare organizations under which they would receive a fixed, per-person monthly fee for each Medicare beneficiary who chose to enroll in (and to receive medical services from) the HMO in place of traditional fee-for-services Medicare. The HMO, in turn, was required to provide enrolled beneficiaries with all medical services that Medicare ordinarily would cover. Any disputes between the HMO and the beneficiary regarding services ultimately would be resolved by the Secretary or her agents.

Alleging that HMOs participating in the Section 1395mm program failed to provide beneficiaries with a meaningful opportunity to contest decisions to reduce or deny service, plaintiffs filed this nationwide class action lawsuit. They alleged that the HMOs were "state actors" subject to the requirements of the Due Process Clause of the Fifth Amendment, and that the procedures the HMOs employed were inconsistent with the requirements of that Clause. After plaintiffs filed suit and the district court issued an injunction in plaintiffs' favor, however, Congress comprehensively reformed the relevant legal and regulatory framework governing reductions or denials of service. The new statutory scheme withdraws the Secretary's authority to enter into contracts under Section 1395mm, and replaces that provision with a new Medicare Part C and a new "Medicare + Choice" program that offers vastly expanded procedural protections for enrolled beneficiaries.

The questions presented by this case are:

1. Whether the decision by a Section 1395mm risk-sharing HMO to refuse 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 the district court properly issued a mandatory injunction, creating new procedural requirements that HMOs must follow and the Secretary must enforce under Section 1395mm, on due process grounds.

3. Whether Congress's enactment of new Medicare Part C, which supersedes the Secretary's authority to contract under Section 1395mm, and establishes a new "Medicare + Choice" program that provides greatly enhanced procedural protections for Medicare beneficiaries enrolled in private HMOs, renders the current dispute moot, warranting vacation of the judgment below and a remand to the district court for consideration of the new statutory and regulatory scheme.

IN THE SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1998

No. 98-

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

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.

OPINIONS BELOW

The opinion of the court of appeals (App., infra, 1a-__) is reported at 152 F.3d 1115. The opinion of the district court (App., infra, __-__) 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 and suggestion for rehearing en banc was denied on November 12, 1998. App., infra, __. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant portions of the Medicare Act, as it existed when the district court ruled, 42 U.S.C. 1395mm (1994), are reproduced in the Appendix to this petition. App., infra, __-__. Relevant

provisions of the Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4003, 111 Stat. 270 (the BBA), amending the Medicare Act, are also reproduced in the Appendix to this petition. App., infra, __-__.

STATEMENT

The Ninth Circuit in this case affirmed a nationwide injunction that prescribes additional terms that the Secretary of Health and Human Services was required to include, and enforce, in the contracts she entered into with Health Maintenance Organizations and similar "managed care" providers (collectively HMOs) under 42 U.S.C. 1395mm(g). Affirming that injunction, the Ninth Circuit in this case held that (1) HMO decisions to deny enrollee claims for medical services constitute "government action" that must meet the requirements of due process; and (2) that the procedural mechanisms imposed on HMOs by the Secretary at the time this case was filed did not provide enrollees with the process that was their constitutional due. Before the Ninth Circuit decided this case, however, Congress enacted legislation to supersede the provision (42 U.S.C. 1395mm) that prompted the district court to enter the injunction, replacing it with a wholly new statutory framework (Medicare Part C) which provides Medicare beneficiaries who choose to enroll in HMOs with dramatically greater procedural safeguards, protections, and review mechanisms. Moreover, to implement the new statute, the Secretary has since promulgated new regulations that provide still greater safeguards for the Medicare beneficiary community. Because those intervening legislative and regulatory changes alter the fundamental nature of the current dispute and render it moot, we respectfully request that the Court

vacate the judgment of the courts below and remand the case to the district court for consideration of the intervening legislative and regulatory reforms. In addition, because of the close relationship between the decision below and the issues before the Court in American Manufacturers Mutual Insurance Company v. Sullivan, et al., No. 97-2000 (argued Jan. 19, 1999), we respectfully request that the petition in any event be held pending decision in that case and be disposed as appropriate in light of the Court's decision there.

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. For many years, Medicare operated in a manner similar to fee-for-service medical insurance. Under fee-for-service arrangements, the beneficiary first obtains needed medical care. The beneficiary or his health care provider then submits a claim for reimbursement to the Medicare program. Claims would then be 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. This traditional payment system is governed under Medicare Part A if the payment is for covered care furnished by hospitals and other institutions, and by Part B with respect to supplemental medical insurance for covered physician services and certain other medical benefits.

a. 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 HMOs. See Pub. L. No. 97-248, § 114(a), codified at 42 U.S.C. 1395mm (1994). (Section 1395mm has now been superseded by new Medicare Part C and the new "Medicare + Choice" program, as discussed in greater detail below.) HMOs usually consist of a network of health-care providers and institutions. While a patient using a fee-for-service health plan normally chooses his own physician and then submits a bill for reimbursement, patients using HMOs generally must use a physician or hospital that has an agreement with (i.e., that participates in the provider network pertaining to) his or her HMO. Because HMOs often operate efficiently and are able to obtain discounts for medical services from participating providers, they can offer their enrollees a more comprehensive package of services -- including extras like coverage for prescriptions -- at the same or even lower cost.

To permit Medicare beneficiaries to enroll in HMOs at government expense, Section 1395mm authorized the Secretary to enter into contracts with qualified HMOs. Medicare beneficiaries would have the choice between traditional Medicare and having the Secretary purchase private coverage for them from a participating HMO. Two types of HMO contracts were authorized. First, the Secretary could enter into a cost-based contract, under which the Secretary would reimburse the HMO's reasonable costs (based on submitted reports) for services actually rendered to the enrollee. See 42 U.S.C. 1395mm(h); 42 C.F.R. 417.530-417.576. Second, the Secretary could enter into "risk-sharing" contracts. Under those contracts, the HMO would be paid a flat-rate, monthly capitation

payment -- that is, a monthly payment for each Medicare beneficiary that chose to enroll with the HMO -- and the HMO, in return, would provide each enrollee with the full range of services covered by Medicare. 42 U.S.C. § 1395mm(g). Under such a risk-sharing contract, the HMO rather than the Secretary bears the risks of increased patient needs, as the monthly payments from the government are not adjusted based on services actually used. Instead, if the cost of providing required services to enrolled beneficiaries exceeds the aggregate payments from the Secretary, the HMO bears the loss. This case concerns only patients enrolled in risk-sharing HMOs, i.e., HMOs that have entered into contracts pursuant to 42 U.S.C. 1395mm(g), under which they bear the risks of increasing costs.

Placing the risk of increased patient need gives HMOs an incentive to provide preventive healthcare that can avoid costly procedures later on. It also eliminates the incentive to over-utilize expensive medical treatments, an undesirable feature of fee-for-service systems. Finally, because HMOs must compete for Medicare enrollees -- Medicare beneficiaries can always switch to another participating HMO or return to traditional fee-for-service Medicare, 42 C.F.R. 417.461 (1997) -- competitive forces should compel HMOs to pass some of the cost savings back to enrollees in the form of better or more comprehensive services as a way of attracting or retaining them. Nonetheless, some health care experts and patient advocates point out that flat-rate capitation arrangements may create economic incentives for HMOs to cut costs by improperly restricting access to necessary medical care. See generally Stayn, Securing Access To Care In Health Maintenance

Organizations: Toward A Uniform Model Of Grievance and Appeal Procedures, 94 Col L. Rev. 1674 (1994).

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. 1394mm(c)(5)(A). The HHS regulations before the district court provided that, when an HMO denied a request for services, it had to give the enrollee notice of the decision, including the reasons for the denial and information about reconsideration rights, within 60 days. 42 C.F.R. §§ 417.608-417.612 (1995). Neither the statute, nor the regulations, however, provided a deadline for the issuance of reconsideration decisions. Neither the statute nor the regulations provided an expedited decision mechanism for cases involving urgent medical needs. See 63 Fed. Reg. 23,369 (noting that deficiency in the former regulations). And neither the statute nor the regulations attempted to address, in any way, the qualifications or identity of HMO decisionmakers, or the ability of plan enrollees to participate in or present evidence during that process. They did provide, however, that HMO enrollees who were dissatisfied with the HMO's decision could bring the matter before the Secretary or her agents for resolution. See 42 U.S.C. 1395mm(c)(5)(B).[1]

2. Respondents are the named representatives of a nationwide

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[1] The Secretary's regulations provided that any adverse HMO decision, after reconsideration, would be turned over to HCFA (or its agent) for review, and that the member would have the right to present evidence in person as well as in writing. 42 C.F.R. §§ 417.614-417.626 (1995). Finally, any member aggrieved by HCFA's or its agent's decision could, subject to a relatively low amount in controversy requirements, seek a hearing before an Administrative Law Judge (ALJ), review before the ALJ Appeals Council, and then judicial review. 42 C.F.R. §§ 417.630-417.636 (1995).

class of individuals covered by Medicare who chose to enroll in risk-based HMOs under Section 1395mm. They alleged that the HMOs were not providing legally 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, because the initial HMO decisions constituted "state action" affecting constitutionally protected property interests, the processes leading to these decisions had to meet the strictures of the Due Process Clause. The then-existing processes, respondents asserted, did not.

a. After certifying respondents as the representatives of a nationwide class, the district court granted their motion for partial summary judgment. App., infra, at __. The challenged HMO decisions, the court concluded, are properly attributable to the federal government; as a result, it also concluded that HMO decisional processes must comport with the Due Process Clause. App., infra, at __. The court further held that the decision-making procedures then in effect did not afford plaintiffs the process that was their constitutional due under Mathews v. Eldridge, 424 U.S. 319 (1976). The district court faulted the forms of notice used by HMOs, see App., infra, at __-__; the claimant's inability to present evidence, or have his physician present evidence, to the HMO for purposes of reconsideration, App., infra, at __-__; and delays in decisionmaking with respect to patients needing immediate medical care, App., infra, at __-__.

Accordingly, on March 3, 1997, the district court imposed a mandatory injunction that created detailed notice and hearing requirements. The injunction commands the Secretary to require

that HMOs provide a written notice of any decision that "denies, terminates or reduces services or treatment" within five days of an oral or written request for that care unless "exceptional circumstances" warrant additional time. App., infra, at __. The notice must be printed in 12-point type, explain the basis of the decision, and advise beneficiaries of their appeal rights. Id. The injunction also requires that HMOs honor reconsideration requests, and permit "informal, in-person communication" between the beneficiary and the decisionmaker. Id. If a doctor asserts (or other evidence suggests) that services are urgently needed, the HMO must resolve the reconsideration request within three working days. Id. at __. Finally, where "acute care services" are at issue, the HMO must provide a hearing before denying the request; it cannot discontinue those services (or decline payment therefor) until after the initial decision and the reconsideration process is completed. App., infra, at __.[2]

The injunction further requires the Secretary to undertake enforcement actions against HMOs that do not substantially comply with these requirements. In particular, the Secretary is required to monitor and investigate compliance with all requirements, and is barred from contracting with, or renewing a contract with, a deficient HMO. App., infra, at __. 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

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[2] The injunction also requires the Secretary to ensure that HMOs do not prevent health professionals (such as HMO doctors) from assisting members in obtaining evidence for the appeals process, and bars the Secretary from contracting with any HMO that, in any single instance, has retaliated against a doctor who aids a beneficiary in the appeal process. App., infra, at ___.

additional relief if implementation of the required appeal and grievance procedures does not redress their claimed injuries. App., infra, at __.

b. The Secretary moved the district court to stay its injunction pending appeal, and the district court granted the motion. App., infra, at __. In seeking the stay, the Secretary pointed out that on April 30, 1997 -- just after the district court entered its injunction -- the Secretary issued new HMO regulations in interim final form. 60 Fed. Reg. 23,368. The Secretary noted that the regulations made several significant changes in notice and appeal procedures. Among other things, the revised regulations provided a new procedure for expedited review in appropriate 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 47 C.F.R. 417.608 and 417.609). The district court concluded that a stay was warranted in light of these regulatory modifications, 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., infra, at __.

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 and regulatory structure with respect to HMOs as part of the Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4003, 111 Stat. 270 (the BBA).

a. To replace Section 1395mm, the BBA creates an entirely new Part to the Medicare Act -- Part C -- and establishes the "Medicare + Choice" program. "Medicare + Choice" is designed to offer beneficiaries a widely expanded choice of alternatives to traditional Medicare fee-for-services coverage. These options include participation in traditional, privately-run fee-for-service plans, HMOs, and other private managed care organizations at government expense, as well as new medical savings account plans. See 111 Stat. 276 (to be codified at 42 U.S.C. 1395w-21(a)(2)). See also H.R. Rep. No. 217, 105th Cong., 1st Sess., 585 (1997).

The new law directs the Secretary to implement that program by establishing a process through which Medicare beneficiaries can, at their option, have the Secretary acquire coverage for them through participating private HMOs and other healthcare organizations. 111 Stat. 278 (to be codified at 42 U.S.C. 1395w-21(c)(1)). HMOs cannot accept Medicare beneficiaries as enrollees under the program, and may not receive payment, absent a valid "Medicare + Choice" contract with the Secretary. See 111 Stat. 319 (creating new Section 1857(a), to be codified at 42 U.S.C. 1395w-27).

The Act also provides a new and greatly 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. 286 (to be codified at 42 U.S.C. 1395w-22(g)). As before, HMOs must in the first instance determine for themselves whether or not they believe that the requested treatments are appropriate (just as the would with respect to non-Medicare enrollees). But, as a condition of participation, HMOs must provide Medicare enrollees with a

clear, understandable statement concerning adverse decisions on a timely basis. Id. at 293 (to be codified at 42 U.S.C. 1395w-22(g)(1)). As before, any enrollee dissatisfied with the decision can seek reconsideration. But, unlike the statute or regulations before the district court, which did not give a deadline for reconsideration decisions, the new statute requires HMOs to issue such reconsideration decisions within 60 days (or earlier if the Secretary so directs). Ibid. (to be codified at 42 U.S.C. 1395w-22g(2)(A). Moreover, unlike the statute and regulations before the district court, the new statute contains expedition provisions which require HMOs to issue decisions "no later than 72 hours [after] receipt of the request for the determination or reconsideration" in urgent cases. Id. at 293-294 (to be codified at 42 U.S.C. 1395w-22(g)(3)).

Unlike the prior statute and regulations, the new statute also addresses the qualifications and identity 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 a HMO physician with "appropriate expertise in the [relevant] field of medicine." Ibid. (to be codified at 42 U.S.C. 1395w-22(g)(2)(B)). In addition, the physician addressing the reconsideration request cannot be the same physician who made the initial treatment decision. Ibid.

As before, all private HMO treatment decisions denying or reducing services are subject to review by a neutral, independent entity selected by the Secretary. Id. at 294 (to be codified at 42 U.S.C. 1395w-22(g)(4)). Any enrollee (but not an HMO) dissatisfied

with the result of that independent reviewer's decision may seek a hearing before an ALJ if the amount in controversy exceeds $100.00. 111 Stat. 294 (to be codified at 42 U.S.C. 1395w-22(g)(5)); see also 63 Fed. Reg. 35,110 (adding 47 C.F.R. 422.600). ALJ decisions are subject to review by the Departmental Appeals Board (DAB) and, if the amount in controversy exceeds $1,000, the DAB's decision is subject to judicial review. 111 Stat. 294 (to be codified at 42 U.S.C. 1395w-22(g)(5)); see also 63 Fed. Reg. (adding 47 C.F.R. 422.608, 422.612). HMOs and other healthcare organizations participating in the program are strictly prohibited from interfering with the efforts of healthcare professionals from providing advise to beneficiaries. See 111 Stat. 294 (to be codified at 42 U.S.C. 1395w-22(j)(3)).

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. 324-325 (adding new Section 1857(g) and (h), to be codified at 42 U.S.C. 1394w-27(g) and (h)). The new procedures also provide the Secretary with substantial flexibility in exercising her enforcement authority. 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., infra, at 19a, ___ (citing 42 U.S.C. 1395mm(c)), the new statute omits the language upon which those courts relied, and nowhere provides that termination is a mandatory penalty for non-

compliance.[3]

Finally, the new law eliminates the Secretary's authority to contract with HMOs under Section 1395mm -- the principal statutory provision at issue in the district court -- as of December 31, 1998, subject to limited exceptions. 111 Stat. 328 (adding new subsection (k)(1) to Section 1395mm, to be codified at 42 U.S.C. 1395mm(k)(1)).[4] The Department of Health and Human Services advises that all risk contracts entered into under Section 1395mm expired effective December 31, 1998, and that no such contracts were renewed for 1999.[5]

b. On June 26, 1998 -- while the appeal to the Ninth Circuit was still pending -- the Secretary issued interim final regulations implementing new Medicare Part C and the Medicare + Choice program. See 63 Fed. Reg. 34,968 (June 26, 1998). These regulations took

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[3] Section 1395mm(c) 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 applicable requirements and standards of [Part C] and the terms and conditions of payment as provided for in [Part C]." 111 Stat. 319 (new Section 1857(a), to be codified at 42 U.S.C. 1395w-27(a)).

[4] New Subsection (k)(1) of Section 1395mm states that, "on or after the date standards for the Medicare + Choice organizations and plans are first established * * * the Secretary shall not enter into any risk-sharing contracts under this Section," and further provides that "for any contract year beginning on of after January 1, 1999, the Secretary shall not renew any such contract." 111 Stat. 328 (creating new 42 U.S.C. 1395mm(k)(1)).

[5] The Secretary has granted a temporary, one month extension of a 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.

effect on January 1, 1999, at the beginning of the contracting cycle for HMOs participating in Medicare + Choice. See 63 Fed. Reg. 52,610 (Oct. 1, 1998); 63 Fed. Reg. 34,968, 34,969, 34,976 (June 26, 1998).

Building on the statute's enhanced procedural protections for Medicare beneficiaries, the Secretary's regulations require participating HMOs to issue prompt initial decisions and reconsideration decisions. Although the BBA provides no deadline for initial HMO decisions and the Section 13955mm 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. 35,108 (adding 42 C.F.R. 422.568(a)). And while the BBA sets 60 days as the time limit for resolution of ordinary reconsideration requests, and the Section 1395mm regulations before the district court gave no deadline, the Secretary's new regulations now require such decisions to be made within 30 days, 63 Fed. Reg. 35,110 (adding 42 C.F.R. 422.590(a)(2)).

Unlike the Section 1395mm regulations before the district court, the new regulations also address the need for expedition in particular cases. Following the BBA, the Secretary's new regulations provide that, where delays may threaten the health of the beneficiary, HMOs must make initial and reconsideration decisions within 72 hours of the relevant request. See 63 Fed. Reg. 35,108-35109 (adding 42 C.F.R. 422.572 pertaining to initial decisions); 63 Fed. Reg. 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 cannot decide that the care is unnecessary absent concurrence of the physician responsible for the in-patient treatment. 63 Fed. Reg. 35,110 (adding 47 C.F.R. 422.620(b)). Even then, the enrollee can seek immediate review from an independent peer review organization, and the care cannot be discontinued until that organization issues its decision. Id. at 35,110-35,111 (adding 47 C.F.R. 422.622).

The new regulations also address enrollee participation in the decisional process. While the Section 1395mm regulations before the district court nowhere provided enrollees with the right to present evidence or argument to HMO decisionmakers, the Secretary's new regulations require HMOs to give enrollees seeking reconsideration "a reasonable opportunity to present evidence and allegations of fact or law, related to the dispute, in person as well as in writing." 63 Fed. Reg. 35,110 (adding 47 C.F.R. 422.586). Finally, any disputed reconsideration decision must be sent for adjudication by an independent outside review organization that acts, under contract, as an adjudicatory agent for HCFA. 63 Fed. Reg. 35,111 (adding 47 C.F.R. 422.592); 111 Stat. 294 (to be codified at 42 U.S.C. 1395w-22(g)(4)). An enrollee dissatisfied with the result of the outside review organization's decision can seek a hearing before and ALJ, and judicial review, as set forth in the statute. See pp. __-__, supra.[6]

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[6] 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 imple-

4. On August 12, 1998 -- after enactment of new Medicare Part C and the "Medicare + Choice" program, and after the Secretary's issuance of new implementing regulations -- the court of appeals affirmed the judgment of the district court. The court of appeals declined to remand the case for reconsideration in light of the new statute and the Secretary's revised regulations. See App., infra, at ___. Instead, the court of appeals addressed the case as if the statute and the regulations that were before the district court were still in place.[7]

Beginning with the question of "state action," the court of appeals held that a private HMO's medical judgment that a particular medical treatment is not necessary constitutes "state 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 entity so that the action of the latter may be fairly treated as that of the State itself.'" App., infra, at 8a (quoting Blum v. Yaretsky, 457 U.S. 991, 1004 (1982)). It further noted that, while

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menting regulations make clear that these "quality assurance" programs must include evaluation of the grievance and appeal process. See 111 Stat. 291 (adding new Section 1852(e), to be codified at 42 U.S.C. 1395w-22(e)); 63 Fed. Reg. 35,082 (adding 42 C.F.R. 422.152(c)(I)(ii)). In addition, the regulations make it clear that the Secretary may treat an HMO's failure to comply substantially with appeal and grievance provisions as a ground for terminating its contract. 63 Fed. Reg. 35,104 (adding 42 C.F.R. 422.510).

[7] The statutory amendments were enacted shortly before the government filed its reply brief in the court of appeals. The government accordingly advised the Court that the statute would eventually 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.

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.'" App., infra, at 8a-9a (quoting Burton v. Wilmington Parking Authority, 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 be fairly attributed to the federal government." App., infra, at 9a. The Secretary, the Ninth Circuit reasoned, "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. App., infra, at 9a-10.

The court of appeals rejected the Secretary's argument that HMO decisions to deny treatment are private determinations, made without government compulsion or influence. Although such decisions may involve the same sort of judgment that HMOs ordinarily make with respect to non-Medicare enrollees, the court of appeals held that in this context those decisions "are more accurately described as * * * interpretations of the Medicare statute" rather "than * * * * medical judgments" and thus could be

properly attributed to the government. App., infra, 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. App., infra, at 12a-18a. It reasoned that: (1) the beneficiaries had a substantial interest in Medicare coverage, (2) the previously employed notices of adverse decisions created a substantial risk of erroneous deprivation by failing to state the reasons for denial and by failing to apprise beneficiaries of their appeal rights, and (3) the Secretary had failed to demonstrate that additional procedures would be unduly burdensome. Ibid.

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 -- and because it was the Secretary's implementation of that provision that was found wanting -- the Secretary 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 cases upon which the Secretary relied, the Ninth held, were distinguishable. App., infra, at 18a.

5. The Secretary sought rehearing and rehearing en banc. The petition noted that the new statute and implementing regulations contain substantially different and much 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 to either 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. The court of appeals denied the petition. App., infra, at ___.

DISCUSSION

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) constitute "state actors" when they deny or dispute claims for treatment made by Medicare enrollees and (2) that the now-superseded HMO procedures imposed under 42 U.S.C. 1395mm were insufficient to meet the requirements of due process. Because the court of appeals' decision raises issues similar to those that this Court will be addressing in American Manufacturers Mutual Insurance Company v. Sullivan, et al., No. 97-2000 (argued Jan. 19, 1999), the petition should be held pending the Court's decision in that case. Moreover, shortly after the district court ruled in this case, Congress comprehensively revised Medicare's treatment of HMOs by enacting an entirely new Part of the Medicare Act -- Medicare Part C -- and 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 grievances that prompted the request for judicial relief in this case; and they deprive 42 U.S.C. 1395mm, upon which the district court and the court of appeals passed and relied, of future effect. As a result of those changes, the current dispute is moot. Accordingly, we ask that, in addition to disposing of the petition as appropriate in light of this Court's decision in Sullivan (once it is issued), the Court also vacate the judgments of the court of appeals and the district court as moot and remand the case to the district court for consideration of the new statute and implementing regulations.

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

The state action and due process issues presented by this case are strikingly similar to the issues before the Court in American Manufacturers Mutual Insurance Company v. Sullivan, et al., No. 97-2000 (argued Jan. 19, 1999). Sullivan concerns a constitutional challenge to the payment procedures established by Pennsylvania's Workers' Compensation Act, Pa. Stat. Ann., tit. 77, § 531(5), (6) (West Supp. 1998) (77 Pa. Stat.). That statute establishes an exclusive system of no-fault liability for work-related injuries, under which employers or their insurers must pay "for reasonable surgical and medical services" for any employee disabled on the job "within thirty (30) days of receipt of [the] bills." 77 Pa. Stat. § 531(1)(i), (5) (Supp. 1998); 77 Pa. Stat. §§ 431, 481(a), 501 (Supp. 1998). If the "employer or insurer disputes the reasonableness or necessity of the treatment provided" for a covered injury, however, it may defer payment -- that is refuse to

pay for the treatment -- and file a request for "utilization review." Id. §§ 531(5), (6)(i); 34 Pa. Code § 127.208(e). The dispute is then resolved by a neutral "utilization review organization" and, if appropriate, through a hearing before a workers' compensation judge. 77 Pa. Stat. §§ 529-531.

1.a. The first question before the Court in Sullivan is whether private workers' compensation insurers, when they choose to withhold payment for medical treatment based on a challenge to the "necess[ity] or reasonable[ness]" of the treatment under Pa. Code § 531(5), (6), are engaged in "state action." Although the insurers' payment decisions were not by any means conclusive -- they could be challenged in a state-sponsored adjudicative proceeding -- the Third Circuit held that the insurer decisions were properly attributable to the State. Workers' compensation, the court of appeals reasoned, is "a complex and interwoven regulatory web enlisting the Bureau, the employers, and the insurance companies." Barnett v. Sullivan, 139 F.3d 158, 168 (3d Cir. 1998). Because the State "extensively regulates and controls" the system and because the insurers participating therein "provid[e] public benefits which honor State entitlements," the court concluded that the insurers "become an arm of the State, fulfilling a uniquely governmental obligation under an entirely state-created, self-contained public benefit system." Ibid.

Here, the Ninth Circuit employed similar reasoning to reach an identical result, concluding that the decisions of private HMOs to reduce or deny treatments constitute government action. Even though HMO decisions can be challenged by the beneficiary through government-sponsored adjudication, the Ninth Circuit held that

those HMOs decisions are attributable to the federal government because the government and the HMOs "are essentially engaged as joint participants to provide Medicare services." App., infra, at __. In particular, the Ninth Circuit noted, the "Secretary extensively regulates the provision of Medicare services by HMOs"; 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. App., infra, at __. Indeed, the issues presented and the reasoning of the courts of appeals in this case and Sullivan are sufficiently similar that lead counsel in this case filed an amicus brief in Sullivan to emphasize the potential impact of the Court's decision in Sullivan on the Medicare program and on the result the Ninth Circuit reached below.[8]

b. Moreover, the arguments presented by the petitioners and their amici in favor of reversal in Sullivan apply here as well. Petitioners in Sullivan identify three factors this Court has examined in determining whether the conduct of a private party can fairly be attributed to the government: Whether the private actor's decision is the product of governmental compulsion or

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[8] See Br. Amici Curiae Of the American Association of Retired Persons, The Center For Medicare Advocacy, Inc., *et al*, at 7 (emphasizing that "the Medicare program is aggressively encouraging increased beneficiary participation in private managed care structures" and concluding that "[t]he evolution in the administration of government benefit programs thus renders the state action determination important to a rapidly expanding number of individuals."); id. at 4 (identifying amici's involvement in this case as a basis for their interest in Sullivan).

encouragement; whether the private actor exercises a traditionally exclusive state power; and whether the government has some involvement that uniquely aggravates the injury. As to the first factor, petitioners in Sullivan argue that an insurer's initial decision to withhold payment and dispute a claim is not the result of "significant encouragement" by the State, as the State does not attempt to influence the insurers' decision; the initial decision whether to pay or dispute the claim is the insurers' and the insurers' alone. Pet Br. 20-21 (quoting Blum v. Yaretsky, 457 U.S. 991, 1004-1005 (1982)). The same is true of HMO decisions to deny Medicare beneficiary claims. When an HMO decides whether or not to provide a requested service, it makes that determination without governmental participation. Instead, like any other private entity, HMOs rely on their own expertise and their own assessment of the relevant circumstances. Indeed, the very first provision of the Medicare statute *prohibits* the "exercise of any supervision or control over the practice of medicine or the manner in which medical services are provided * * *." 42 U.S.C. 1395.

Likewise, the second factor identified by the Sullivan petitioners -- whether the private party exercises a power "traditionally exclusively reserved to the State," Pet. Br. 18 (quoting Jackson v. Metropolitan Edison Co., 419 U.S. 345, 352 (1974)) -- weighs against finding government action here just as much as it does in Sullivan. An insurers' decision to dispute a claim and decline payment, the Sullivan petitioners argue, is the sort of uniquely private judgment that insurers of all varieties make on a regular basis: whether to pay a bill submitted for payment, or instead to withhold payment and dispute the bill. See

Pet. Br. 17-22; U.S. Br. 13-16. The same is true with respect to HMO treatment decisions for Medicare enrollees. When an HMO decides whether or not to provide a requested treatment, it does not act as an agent of the government or exercise governmental authority to adjudicate a dispute; it is not expected to act in the government's interest; and it does not distribute Treasury or governmental funds. To the contrary, the HMO exercises its own judgment, as a private actor, as to the reasonableness of the service and whether it is obligated to provide it. If the HMO chooses to provide the treatment, it (like the insurers in Sullivan) must bear the cost itself. And if the HMO decides not to provide treatment, the HMO's judgment (again like that of the insurers in Sullivan) is hardly conclusive. Instead, the HMO's decision can be challenged through the adjudicatory machinery established by the government, and only the decision of a true governmental authority, acting in its capacity as neutral arbiter of the dispute, can finally resolve the matter and leave the parties without further recourse. See 42 C.F.R. §§ 417.614-417.626-417.636 (providing for automatic review of adverse organization reconsideration decisions by agent of the Secretary and, in appropriate cases, a hearing before an ALJ and judicial review); see also 42 U.S.C. 1395mm(c)(5)(B) (same). (The conclusive adjudication of the dispute by the government or its agents, of course, is government action that is subject to the requirements of the due process clause. See Tr. Oral Arg., Sullivan, at __-__.)

Even the substantive criteria employed by HMOs in this case are indistinguishable from those applied by the insurers in

Sullivan -- and from those applied by private actors in other contexts. Here, HMOs must provide medical services that are "reasonable and necessary." 42 U.S.C. 1395y(a). That is an indistinguishable standard from the obligation at issue in Sullivan, where the statute requires insurers to pay for treatments that are "reasonable or necessary." Pa. Stat. Ann. § 531(5), (6)(1) (Supp. 1998); 34 Pa. Code § 127.208(e). And it is indistinguishable from the sort of appropriateness determination that private physicians, in the regular course of their practices, must make on a regular basis. See Blum v. Yaretsky, 477 U.S. 991 (1982) (exercise of ordinary medical judgment not state action, even where it affects eligibility for medical benefits). Indeed, even a cursory review of the complaint in this case demonstrates that to be the case -- each of the decisions respondents challenge was made on purely medical grounds.[9] Thus, contrary to the Ninth Circuit's decision, an HMO's decision on the appropriateness of, or its obligation to provide, a particular form medical care does not constitute a delegated "interpretation of the Medicare statute," App., infra, 11a, any more than a Pennsylvania Workers'

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[9] One named plaintiff, for example, alleges that she was denied physical therapy because she could not follow therapeutic instructions. C.A. E.R. 10-11, ¶ 29. Another plaintiff alleges that treating physicians failed to prescribe adequate pain medication or to order physical therapy. C.A. E.R. 12-13, ¶¶ 40-41. Another plaintiff, much like the plaintiffs in Blum, alleges that the HMO erroneously concluded that skilled nursing care was not medically necessary. C.A. E.R. 13-15, ¶¶ 48-54. And yet another named plaintiff alleges that the HMO denied speech therapy services on the ground that the therapy would not be effective, C.A. E.R. 16, ¶ 62. Whatever the merits of these contentions may be, they plainly challenge decisions that turn on the exercise of professional medical judgment, and that thus are indistinguishable from the medical decisions this Court held to be private rather than state action in Blum.

Compensation insurers' view of "reasonable[ness] or necess[ity]" constitutes an adjudication of Pennsylvania law.[10]

Finally, the Sullivan petitioners and their amici contend that the Third Circuit erred in relying on the "rather vague generalization," Blum, 457 U.S. at 1010, that the system "inextricably entangles the insurance companies in a partnership" that makes the government "a joint participant in the challenged activity," Burton v. Wilmington Parking Auth., 365 U.S. 715, 725 (1961), and on the heavily regulated nature of the industry. See Pet. Br. 22-25, 26-29; U.S. Br. 17-20. Unlike Burton and similar cases, neither Sullivan nor this case involve the sort of dignitary injury or stigma, such that which results from racial discrimination, that can be "uniquely aggravated" by governmental endorsement or even passive involvement. See U.S. Br. in Sullivan, at 19-20; Pet. Br. 22-24. And, the governmental regulation of the industry in this case is neither qualitatively nor quantitatively different from the regulation of workers' compensation insurers at issue in Sullivan. Besides, relying on the scope of government regulation is particularly inappropriate. See Pet. Br. 26-29 (citing, inter alia, Jackson v. Metropolitan Edison Co., 419 U.S. 345 (1975); Rendell-Baker v. Kohn, 457 U.S. 830, and Blum, supra).

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[10] Simply put, HMOs like any other provider of service under contract, traditionally has the option of either providing the service (thereby avoiding a dispute with the enrollee) or instead denying it instead (and thereby requiring the claimant to invoke the dispute resolution machinery established by the government). Because "a private party's decision" to deny the validity of the claim or refuse service and to await litigation of the issue instead "has never, to our knowledge, been considered 'state action' under the Fourteenth Amendment," U.S. Br. at 17-18, an HMOs decision to do the same thing in this context should not be considered government action here.

Indeed, holding the government liable for private conduct simply because it has regulated in the area would tend to deter government intervention precisely at a time when beneficiaries need its protection most.

In any event, if the insurer conduct in Sullivan does not constitute state action, it would seem to follow a fortiori that the HMO decisions at issue here do not constitute government conduct either. One of the primary reasons given by the Third Circuit for finding state action is the involuntary and mandatory nature of the system; workers cannot "opt out" of workers' compensation and rely on their tort remedies instead. See Sullivan, 159 F.3d at 169 (likening workers' compensation claimants to "prisoners" of the Workers' Compensation scheme); Br. Resp. 33 (similar argument). In contrast, Medicare beneficiaries always have been permitted to "opt out" of private HMO coverage and select traditional Medicare fee-for-service benefits instead. See pp. __-__, supra.[11]

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[11] One other difference between this case and Sullivan is that, in this case, the government pays for the HMO policy, whereas in Sullivan both private and public employers pay for the insurance policy. It is hard to see why that distinction would make a difference. As explained in our amicus brief in Sullivan (at 18), neither "a private insurer's satisfaction of a claim with its own funds" nor its "decision to defer payment pending review of a disputed claim" is properly attributed to the State even if "the State pays for the underlying insurance policy," because "individual payment determinations are made by, and the financial consequences of those decisions are borne by, the private insurer and not the State. See Blum, 457 U.S. at 1011 (rejecting contention that decisions made by physicians and nursing homes are 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')." For similar reasons, insurers who provide health benefits to government employees under the Federal Employee Health Benefits Act, 5 U.S.C. __, do not become "state actors" simply because the government pays for the coverage. Indeed, if the rule were otherwise, the fact

this page problematic

2. The second issue in Sullivan, whether Pennsylvania's workers' compensation regime is consistent with the requirements of due process, likewise resembles the due process and remedial questions decided by the Ninth Circuit and the district court below. Among other things, the district court apparently thought it appropriate to require HMOs to pay for services until after both the initial determination and the reconsideration decisions were made, if the decisions involved "acute care services." App., infra, at __. One of the questions before this Court in Sullivan is whether due process requires workers' compensation insurers likewise to continue paying for medical services until after some sort of outside review has taken place. See U.S. Br. 21-30; Pet. Br. 29-50. While the Secretary does not dispute the desirability of such a requirement in appropriate circumstances -- the Secretary's new regulations implementing Medicare Part C provide for precisely such a procedure in cases involving in-patient hospital care, see pp. __-__ -- the fact that this Court may pass on whether such a procedure is constitutionally required in Sullivan is another reason to hold the petition pending the Court's decision there. Moreover, the Secretary believes that the Ninth Circuit and the district court fundamentally erred in imposing judicial requirements rather than remanding to the Secretary -- especially given the new legislation -- so that appropriate procedures could be tailored and refined through a participatory and fully public rulemaking process rather than through the more cumbersome and less public judicial process.

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that the government pays physicians and hospitals directly under Medicare Parts A and B might be thought to convert those clearly private actors into government actors.

B. Because This Case Became Moot Pending Review, The Court Should Vacate the Lower Court's Judgments And Remand The Case to the District Court For Consideration Of Intervening Statutory and Regulatory Changes

Even absent the obvious similarities between this case and Sullivan, the Ninth Circuit's decision in this case ordinarily would warrant further review. It declares unconstitutional the Secretary's implementation of a federal statutory mandate; it affirms a nationwide injunction requiring the Secretary to impose certain procedures on participating HMOs, denying the Secretary the ability to design and tailor the procedures herself in the first instance; it constitutionalizes the conduct of otherwise private actors; and it may have a substantial impact on an extensive and increasingly important federal program.

1. On August 5, 1997, however, Congress comprehensively reformed this area of law -- creating a new Medicare Part C and establishing the new "Medicare + Choice" program -- and thereby rendered this case moot. See Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4003, 111 Stat. 270. At the time the district court ruled, the governing statute merely required that Medicare HMOs provide "meaningful procedures for hearing and resolving grievances * * * ." 42 U.S.C. 1395mm(c)(5)(A) (1994). Neither the statute nor the regulations promulgated thereunder specified the precise circumstances under which notices of adverse decisions would be required. Neither provided any detail regarding the content of such notices. Neither regulated the extent to which enrollees could present evidence or argument to the HMO on reconsideration. Neither addressed the identity or qualifications of HMO reconsideration decisionmakers. And neither provided any rules regarding expedition in urgent cases. In the view of the

district court and the court of appeals, the practices that prevailed under that regulatory scheme did not afford plaintiffs constitutionally adequate notice or a constitutionally sufficient opportunity to be heard. To remedy the alleged deficiencies, the district court imposed and the Ninth Circuit affirmed a detailed and highly prescriptive injunction to regulate beneficiary appeals, specifying the form, content, and timing of HMO notices.

The new statute and the Secretary's regulations promulgated thereunder, however, dramatically expand the procedural and substantive protections afforded to Medicare HMO enrollees. See pp. __-__, supra. Indeed, Medicare Part C adds an entirely new Section of the Medicare Act entitled "Benefits and Beneficiary Protections," 111 Stat. 286 (to be codified at 42 U.S.C. 1395w-22(g)). That new law, together with the Secretary's regulations, address each of the alleged deficiencies identified by the lower courts.

With respect to the questions of notice and timing of HMO decisions, for example, the new statute and the Secretary's new regulations require all HMOs denying requested services to provide enrollees with a clear, understandable statement concerning adverse decisions on a timely basis. 111 Stat. 286 (to be codified at 42 U.S.C. 1395w-22(g)(1)); 63 Fed. Reg. 35,108 (adding 47 C.F.R. 422.588(d)). The notice must be provided within 14 days of a request in ordinary cases, and within 72 hours in urgent cases. 63 Fed. Reg. 35,108-35,109 (adding 47 C.F.R. 422.568(a) and 42 C.F.R. 422.572); 111 Stat. 293-294 (to be codified at 42 U.S.C. 1395w-22(g)(3)). And reconsideration decisions must be issued 30 days ordinarily, and within 72 hours in expedited cases. 63 Fed. Reg.

35,110 (adding 47 C.F.R. 422.590(a)(1), (d); 111 Stat. 293 (to be codified at 42 U.S.C. 1395w-22(g)(2)(A), (3). Moreover, when it comes to authorized in-patient hospital care, the HMO cannot discontinue treatment absent concurrence of the physician responsible for the in-patient treatment, 63 Fed. Reg. 35,110 (adding 47 C.F.R. 422.620(b)), and even with that consent cannot discontinue treatment over the enrollee's objections until after the matter has been reviewed by an independent peer review organization, id. at 35,110-35,111 (adding 47 C.F.R. 422.622).

The new statute and regulations address HMO decisionmaking processes as well. While the statute and regulations before the district court said nothing about enrollee participation in the reconsideration process, the new regulations specify that the HMO must give the enrollee "a reasonable opportunity to present evidence and allegations of fact or law, related to the dispute, in person as well as in writing." 63 Fed. Reg. 35,110 (adding 47 C.F.R. 422.586). Moreover, unlike the statute and regulations before the district court, the new statute and regulations address the qualifications and identity of the reconsideration decisionmaker. The reconsideration decisionmaker cannot be the same person who made the initial treatment decision. 111 Stat. 293 (to be codified at 42 U.S.C. 1395w-22(g)(2)(B)); 63 Fed. Reg. 35,111 (adding 47 C.F.R. 422.590(g)(1)). And where the basis for the decision to reduce or deny services was lack of medical necessity, the reconsideration decision must be made by a physician with "appropriate expertise in the [relevant] field of medicine." 111 Stat. 293 (to be codified at 42 U.S.C. 1395w-22(g)(2)(B)); 63 Fed. Reg. 35,111 (adding 47 C.F.R. 422.590(g)(2)).

Moreover, as before, HMO organization determinations are hardly conclusive. All disputed reconsideration decisions are subject to prompt and appropriate review by the Secretary and her agents, id. at 294 (to be codified at 42 U.S.C. 1395w-22(g)(4), including automatic review by an independent entity acting as HCFA's agent, 63 Fed. Reg. 35,111 (adding 47 C.F.R. 422.592)). And, as before, a hearing before an ALJ is available where the amount in controversy exceeds $100.00, and judicial review is available for any matter valued at more than $1,000.00. See pp. __-__, supra.

As a result of that sweeping change in federal law and Medicare policy, the practices of which plaintiffs complained and which precipitated the district court's exercise of its remedial power have been superseded through enactment of a dramatically different statutory and regulatory scheme.[12] No court has passed on the constitutional sufficiency of those new procedures. 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 Florida

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[12] Although these new provisions address many areas covered by the district court injunction, they take a fundamentally different approach to several key issues. Unlike the district court, which required that detailed written notices be provided within five days even where the beneficiary's health is not in imminent jeopardy, Congress specified no specific time frame in such cases, see H. Conf. Rep. No. 105-217, 105th Cong, 1st Sess. 65 (1997) (noting that Congress delegated that issue to the Secretary), and the Secretary selected a 14-day deadline, Fed. Reg. 35,108-35,109 (adding 47 C.F.R. 422.568(a)). Moreover, while the Secretary has required certain in-patient 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 with App., infra, at __, with 63 Fed. Reg. 35,110-35,111 (adding 47 C.F.R. 422.620(b), 422.622).

Chapter of Associated General Contractors v. City of Jacksonville, 508 U.S. 656, 662 n.3 (1993); see also id. at 670-671 (O'Connor, J., dissenting). Under such circumstances, it has been this Court's consistent practice to declare the case moot, vacate the judgments below, and remand the matter to the district court for such further proceedings as are appropriate. "[I]n instances where the mootness is attributable to a change in the legal framework governing the case, and where 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." Lewis v. Continental Bank Corp., 494 U.S. 472, 492 (1992); see, e.g., Department of the Treasury v. Galioto, 477 U.S. 556, 559-560 (1986) (vacating judgment and remanding to district court because a "new enactment significantly alter[ed] the posture of the case" by removing the concerns that prompted injunctive relief in district court); Calhoun v. Latimer, 377 U.S. 263 (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); Arizonans for Official English v. Arizona, 117 S. Ct. 1055, ___ (1997) ("Vacatur is in order when mootness occurs through happenstance * * *.").

2. The Court should follow that settled practice here. It is now well established that "[a]n 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." United Transportation Union v. The State

Bar of Michigan, 401 U.S. 576, 584 (1971). Here, no apparent basis for injunctive relief -- the only relief granted -- remains. The allegedly unlawful practices and regulations have been erased by subsequent legislative and regulatory changes. As a result, the claim for injunctive relief is moot, and no longer a proper matter for further judicial consideration. See Princeton University 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."); see also Associated General Contractors, 508 U.S. at 663 n.3 (prior cases considered moot where "the statutes at issue * * * were changed substantially, and * * * there was therefore no basis for concluding that the challenged conduct was being repeated."); 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"). Indeed, the district court in this very case itself anticipated that, given subsequent legislation and regulatory changes, "the entire case may become largely moot." App., infra, at __. And just that has occurred.

Respondents, of course, may argue that even the new statutory and regulatory structure is constitutionally inadequate. See, e.g., Calhoun, supra. Even setting aside the implausibility of such a claim, it remains true that the nature of the dispute has been fundamentally altered by the intervening change in law.

Indeed, the district court's decision is specifically addressed to, and rules only on, the claims of Medicare beneficiaries enrolled in HMOs with risk contracts under 42 U.S.C. §1395mm. See App., infra, at __ (limiting the class to persons who were "enrolled in Medicare risk-based health maintenance organizations or competitive medical plans during the three years prior to the filing of the lawsuit"). And the district court's analysis focused exclusively on the appeal provisions the Secretary provided under Section 1395mm, App., infra, at 33a-38a, as did the analysis of the court of appeals, App., infra, at __-__. New Section 1395mm(k)(1)(B), however, provides that the Secretary cannot renew Section 1395mm contracts after January 1, 1999.[13] And, as of December 31, 1998, all of the Secretary's Section 1395mm contracts expired, and no new Section 1395mm contracts have been signed.[14] As a result, the actual "case or controversy" the district court and the Ninth Circuit adjudicated, like the Section 1395mm risk-contracts that precipitated the dispute, has ceased to exist.

The fundamental change in the regulatory and legal regime also eliminates the district court's and the court of appeals' rationale

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[13] Cost-based contracts under Section 1395mm(h), which are not at issue in this case, are permitted to continue until the end of 2001. 42 U.S.C. 1395mm(h)(5)(B). If the HMOs in which respondents are or were enrolled still contract with Medicare, they now do so as "Medicare+Choice" organizations under new "Part C" of the Medicare statute, the provisions of which have not been addressed by the court of appeals or the district court.

[14] One HMO that became insolvent and is now being operated by the state of New Jersey had its Section 1395mm contract "extended" in order to permit enrollees time to move to qualified "Medicare + Choice" HMOs under Medicare Part C or to return to the traditional Medicare fee-for-services program. HHS advises that this temporary extension will expire on February 28, 1999 and that, as of March 1, 1999, there will be no enrollees under Section 1395mm risk contracts.

for the highly prescriptive injunctive relief imposed in this case. Justifying the decision to bar the Secretary from renewing HMO risk contracts or entering into such contracts with any HMO that violates the procedural requirements imposed by the district court's order, the district court and court of appeals alike 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 * * *." App., infra, at __ (court of appeals); id. at 52a (district court); see also id. at 53a (justifying notice requirements by declaring that the Secretary's failure to require impose them in her HMO contracts is a "violation of 42 U.S.C. § 1395mm(c)(1)."); id. at 54a (declaring that failure of Secretary to require certain hearing procedures in HMO contracts is a "violation of 42 U.S.C. § 1395mm(c)(1)."). The new statute, however, omits the prohibitory language upon which those courts relied, and nowhere suggests that termination and non-renewal are mandatory penalties for HMO non-compliance.[15] In fact, the new statute strongly suggests that the Secretary has flexibility in responding to non-compliance, as it provides the Secretary with a range of options and sanctions. See 111 Stat. 324-325 (adding new Section 1857(g) and (h), to be codified at 42 U.S.C. 1394w-27(g) and (h)).

problematic

3. Following settled practice here would likewise further the interests underlying the practice. Here, through no fault of

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[15] 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 applicable requirements and standards of [Part C] and the terms and conditions of payment as provided for in [Part C]." 111 Stat. 319 (new Section 1857(a), to be codified at 42 U.S.C. 1395w-27(a)).

the Secretary's, the case became moot pending this Court's review; the matter was simply overtaken by a comprehensive legislative reform. In such a circumstance, the Secretary ought not be bound by a judgment that she cannot appeal. See United States v. Munsingwear, 340 U.S. 36, 40 (1951); see also Arizonans for Official English, 117 S. Ct. at 1071 ("Vacatur 'clears the path for future relitigation' by eliminating a judgment the loser was stopped from opposing on direct review."). That is especially true given the present circumstances. The rulings below address an issue of substantial national importance, as respondent's lead counsel has already conceded in filings with this Court. See Br. Amici Curiae of the American Association of Retired Persons, The Center For Medicare Advocacy, Inc., et al., in Sullivan, supra, at 7 (emphasizing that, because "the Medicare program" increasingly involves "beneficiary participation in private managed care structures," the state action issue is increasingly "important to a rapidly expanding number of individuals."). And the ruling, despite the mootness of the actual controversy, threatens to have continuing repercussions for this important federal program: HMOs may well be deterred from participating in the new program by the Ninth Circuit's constitutional holding.

Even in less compelling circumstances, this Court has unhesitatingly concluded that it was appropriate to vacate the judgments below and remand the matter to the district court for further proceedings in light of intervening events. Thus, in McLeod v. General Electric, 385 U.S. 533, 535 (1967) (per curiam), this Court declined to review the standard under which a preliminary injunction had been issued under Section 10(j) of the

National Labor Relations Act because, after the lower courts had passed on the issue, a "supervening event" -- a new labor agreement -- had drawn into question "the appropriateness of injunctive relief" vel non. Given that change, the Court determined that the proper resolution was to "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." Similarly, in Calhoun, 377 U.S. at 265, the Court determined that the school board's adoption of a new policy while the case was pending on review had substantially altered the nature of the controversy; the Court therefore "vacate[d] the judgment and remand[ed] the cause to the District Court for further proceedings." Id. at 264; cf. Burlington Truck Lines 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). Likewise here the new statute enacted by Congress and the Secretary's new regulations promulgated thereunder fundamentally both the relevant legal framework and the nature of the dispute between the parties. Accordingly, a like order vacating the lower court judgments, and remanding the matter to the district court for consideration of those intervening developments, is appropriate in this case as well.[16]

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[16] It is no answer to suggest that the "state action" question remains "live" under the new statute, even if changed facts alter the due process analysis of the lower courts. This court reviews judgments, not statements in opinions. Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842 (1984).

CONCLUSION

The Court should hold the petition pending decision in American Manufacturers Mutual Insurance Company v. Sullivan, et al., No. 97-2000 (argued Jan. 19, 1999). Once the Court issues its decision in Sullivan, it should grant the petition, vacate the judgment below as moot, and remand to the court of appeals with instructions to set aside the district court judgment and to remand the matter to the district court for consideration of intervening statutory and regulatory changes and, to the extent appropriate, for reconsideration in light of this Court's decision in Sullivan.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General
Counsel of Record

FEBRUARY 1999

In this case, the judgment of the district court commands the Secretary to impose certain procedures on participating HMOs. It should go without saying that the change in procedures mandated by the new statute dramatically affects the propriety of that judgment. After all, if the new procedures are constitutional, and no court has determined that are not, then that judgment cannot be sustained.

1) How does inj compare to new stat/inj scheme -
e.g. Does have to terminate k?

2) What would happen if vacated + remanded
new challenge to new scheme?

3) What would happen if GT alone -
what does this affect?

health-grijalva

To Interested Parties
Re: Grijalva and Medicaid
February 8, 1999

While the Grijalva v. Shalala case involves *Medicare* HMO's, potential appeals of the case to the Supreme Court could have significant implications for patient protection in *Medicaid*. In filing any appeal of Grijalva, the Administration should be cautious that it not undermine the existing private right of action that allows Medicaid beneficiaries access to Federal court to enforce the guarantees of Federal law.

Background

Despite HHS's arguments to the contrary, the Ninth Circuit Court of Appeals ruled in Grijalva that actions taken by an HMO in the administration of the Medicare program constitute government action and, therefore, must be provided with due process. The Court went on to say that HHS's standards for patients' rights were inadequate under a due process review (e.g., because the HMO's notices were illegible and HHS did not require notices to be legible). In a potential appeal of the case to the Supreme Court, HHS appears to be preparing to argue again that HMO's are not government actors.

It should be noted that due process claims (which rely on a finding of government action) are not the only route for Medicare beneficiaries to gain Federal review. The Medicare statute (Title 18 of the Social Security Act) provides for grievance and appeals procedures that guarantee beneficiaries some form of Federal oversight and examination.

By contrast, the Medicaid statute (Title 19 of the Social Security Act) does ***not*** provide a direct route for Medicaid beneficiaries to gain Federal review of any disputes. Rather, the ***only*** route to Federal review is through a private right of action created by 42 U.S.C. 1983 (commonly known as Section 1983).[1] Section 1983, however, provides access to Federal review ***only*** of actions by the State government or someone acting in lieu of State government; private actions may not be addressed in Federal court through Section 1983.

[1]Section 1983 was created in 1870 to address the constitutional issues posed by States discriminating against African-Americans. Since that time, however, it has been broadly interpreted by the courts to allow citizens to address other Federal rights, including statutory rights such as those provided by the Federal Medicaid law. Section 1983 actions have been brought against State Medicaid authorities for such varied problems as a State arbitrarily denying services because of the patient's type of illness, a State refusing to provide essential transportation services, and a State's refusal to provide access to AZT for people with AIDS.

As part of the 1995 Congressional attempt to turn Medicaid into a block grant, the Republicans in Congress and the Governors argued vigorously that Medicaid beneficiaries should be limited to State causes of action in State courts. Replying that the opportunity for Federal review was an essential element of preserving a Federal entitlement, the Clinton Administration and the Democrats defeated this proposal.

Problem

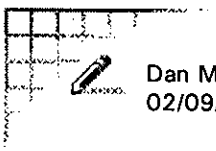
If the Supreme Court were to agree with HHS's arguments that a Medicare HMO is not a government actor, there will remain other ways for Medicare beneficiaries to get Federal review of disputed HMO actions.

However, if a precedent were established that a *Medicare* HMO is not a government actor, it will be difficult to make a distinction and argue that a *Medicaid* HMO is a State actor. If that distinction cannot be successfully drawn, Medicaid beneficiaries would be able to enforce their rights only in HMO-granted or State-granted venues, which may be less sympathetic or less procedurally protective than Federal courts. It bears noting also that Medicaid beneficiaries are vulnerable people who are poor (in both senses of the word) advocates for themselves.

There would, admittedly, remain a possibility of suing the State directly to force it to enforce patient protections within Medicaid HMO's, but it is easy to imagine many possibilities of vagueness in State protections and inattention to the need for ongoing oversight. Finally, there remains the possibility of HCFA enforcing its standards directly, but such enforcement has been at best intermittent in the past.

In sum, whatever the effect of the HHS argument on Medicare, it could result in at least a partial reversal of the successes of the 1995 battle to preserve a Federal private right of action to enforce the Federal guarantee of rights under Medicaid. Rather than appealing the "State action" rulings of the Ninth Circuit, the Administration should, at most, petition for the case to be remanded in light of later Medicare quality rules that might have made this case substantively moot.

Health - Grijalva



Dan Marcus
02/09/99 09:16:20 AM

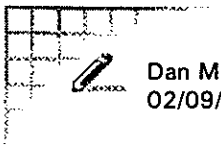
Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Christopher C. Jennings/OPD/EOP
Subject: Rabb

I just spoke to Harriet, who confirmed that she and HHS are now passionate that it is critical that we do at least option 2, i.e., that we file. If the existing stay expires tomorrow and they have to go running to the plaintiffs for a deal or the District Court for relief, she fears disaster will result. And any flak we would get from filing for cert (even with the state action argument) wiould, she says, be exceeded by the flak we would get if we're bback in District Court arguing anew against some of the requirements of the District Court's existing injunction -- at the same time as we are pushing for the patients'bill of rights. And HCFA, of course, is totally unprepared to comply with the injunction.
She is also persuaded that we need to at least modestly explain why the decision below on state action is wrong and will create problems. And, she believes, we can explain to the advocate community why we needed to do this.
Harriet is p-lanning to call you, Elena.

Health - grijalva



Dan Marcus
02/09/99 08:56:27 AM

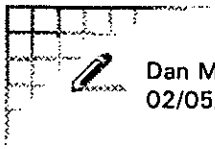
Record Type: Record

To: Elena Kagan/OPD/EOP, Christopher C. Jennings/OPD/EOP

cc:
Subject: Grijalva cert petition

Waxman will shortly fax new draft to me, which I will circulate to you. He feels strongly we should file, and that option of not filing is bad for Govt generally and HHS (he says Donna feels strongly we should file). Seth wants to be heard before decision is made not to file. He also thinks complete bare-bones approach won't work, because Opposition will say this case different from Sullivan, and we'll have to sayin reply what we don't want to say now in any event.

Health - Grijalva



Dan Marcus
02/05/99 01:03:33 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Christopher C. Jennings/OPD/EOP, Devorah R. Adler/OPD/EOP

cc:
Subject: Grijalva draft brief

I am sending the latest draft around to you. See pp. 18-26 for the revised (and beefed-up) state action argument. Reasons HHS and SG (I talked to Kneedler) think it's important to spell out state action point are (1) to make sure Sup Ct appreciates importance of this case and grants cert (rather than denying because it assumes there's state action here even if it finds there isn't in Sullivan); and (2) to influence Ct's writing of Sullivan opinion so that it doesn't say things that will promote arguments for a distinction.

Think it's more likely to make Ct very careful about only deciding the case before it.

Health - grijalva

Dan Marcus
02/08/99 12:58:07 PM

Record Type: Record

To: Elena Kagan/OPD/EOP
cc:
bcc:
Subject: Re: Grijalva and Medicaid

1. I don't know. I assume advocates don't trust state Medicaid agencies and HCFA to enforce beneficiary rights and want the leverage of the consitutional cause of action. But I don't know that there's a big distinction between Medicare and Medicaid in that regard.

2. I told Kneedler we'd like to see stripped-down version by tomorrow morning. I'll call back and emphasize as early as possible. He is, as you might expect, unenthusiastic and emphasizes that we must at least say 9th Circuit wrong on state action and a little bit of why. Elena Kagan

Elena Kagan
02/08/99 12:37:01 PM

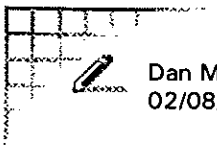
Record Type: Record

To: Dan Marcus/WHO/EOP
cc:
Subject: Re: Grijalva and Medicaid

Why, then, is everyone so insistent about the need for section 1983 actions in medicaid?

And when are we going to see a stripped-down version of the brief?

Health - grijalva



Dan Marcus
02/08/99 12:30:36 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Christopher C. Jennings/OPD/EOP

cc:
Subject: Grijalva and Medicaid

Kneedler expressed doubts that HHS has less ability to require the States in Medicaid to ensure beneficiaries' rights vis-a-vis HMOs than it does in Medicare. I talked to Harriet Rabb and Anna Kraus (her deputy?), who basically confirmed his suspicions: HCFA regs do require State Medicaid agencies to ensure beneficiaries procedural rights re decisions on provision of services -- including appeals from HMO decions to the state agency -- comparable to those in Medicare. Rabb and Kraus say only real difference between Medicare and Medicaid is that there are already one or two court decisions saying Medicaid HMOs are state actors, but none as to Medicare HMOs.