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002. paper	re: Grijalva v. Shalala: Legal Options (4 pages)	n.d.	P5 <i>mus</i> 4/6/15
003. memo	re: Grijalva v. Shalala (partial) (1 page)	02/06/1999	P6/b(6)

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- 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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QUESTIONS PRESENTED

Before 42 U.S.C. 1395mm was superseded in 1997, it authorized the Secretary of Health and Human Services to enter into contracts with private HMOs and similar healthcare organizations under which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 that chose to enroll in (and to receive medical services or coverage from) the HMO in place of traditional fee-for-services Medicare coverage. The HMO, in turn, was required to provide enrolled beneficiaries with all medical treatments and services that Medicare ordinarily would cover. Any disputes between the HMO and the beneficiary regarding coverage 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 their coverage decisions, plaintiffs filed this nationwide class action lawsuit. They alleged that the HMOs participating in the Section 1395mm program were "state actors" subject to the requirements of the Due Process Clause of the Fifth Amendment, and that the procedures employed by the HMOs were inconsistent with the requirements of that Clause. After plaintiffs filed suit and the district court issued an injunction in their favor, however, Congress comprehensively reformed the relevant legal and regulatory framework governing coverage determinations. 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 by this case presented 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).

STATEMENT

The Ninth Circuit in this case affirmed a nationwide injunction that prescribes additional terms that the Secretary of

Health and Human Services must include, and must enforce, in the contracts she enters into with Health Maintenance Organizations and similar "managed care" providers (collectively HMOs) under 42 U.S.C. 1395mm. Affirming that injunction, the Ninth Circuit in this case held that (1) when a contracting HMO contests an enrollee's claim for medical services and denies her request for medical services, it engages in "state action" and that, as a result, its decision must meet the requirements of due process; and (2) that the procedural mechanisms previously imposed on HMOs by the Secretary did not provide enrollees with the process that was their constitutional due. Before the Ninth Circuit decided this case, however, Congress superseded the provision of the Medicare Act that prompted the district court to enter the injunction (42 U.S.C. 1392mm) by enacting 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 that the petition also be disposed as appropriate in light of the Court's decision in Sullivan.

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 established 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.

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 a private healthcare plan such as a Health Maintenance Organization or other managed care provider (HMO). 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, and thus are able to offer their enrollees with "one-stop shopping" for health services. 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 obtain HMO coverage at government expense, Section 1395mm authorized the Secretary to enter into contracts with qualified HMOs under which contracting HMOs would make their plans available to Medicare beneficiaries. Medicare beneficiaries thus would have the option of continuing traditional Medicare coverage or instead 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 compensate the HMO on a fee-for-service basis 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 contracts that provided the HMO with a flat-rate, monthly capitation payment -- that is, a monthly payment for each Medicare beneficiary that chose to enroll with the HMO -- in return for which the HMO was

required to provide each enrollee with the full range of services covered by Medicare. 42 U.S.C. § 1395mm(g). Under the latter type of 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. Conversely, if the cost of providing services is less than the aggregate payments from the Secretary, the HMO turns a profit. This case concerns only patients enrolled in such risk-bearing 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 preventative healthcare that can help avoid costly procedures later on. It also eliminates the incentive to over-utilize expensive medical treatments, an unfortunate feature of fee-for-service systems. When healthcare providers are paid for each treatment rendered, as under a fee-for-service system, the provider may come to view each procedure as a source of profit for itself, rather than as a net cost to society and the healthcare system as a whole; hence the incentives for over-utilization. Where the healthcare provider must internalize the cost of each treatment, as under the flat-rate, capitated arrangements contemplated by Section 1395mm(g), that incentive disappears. Finally, because beneficiaries are free to dis-enroll from an HMO at any time (at the end of the month in which they make such a request), and either go back to fee-for-service coverage, or switch

to another participating HMO in the area, 42 C.F.R. 417.461 (1997), participating HMOs must compete for Medicare enrollees. That competition for enrollees forces HMOs to pass through, to the enrollees, benefits of their cost savings in the form of better or more comprehensive services; the HMO receives payments from the government only if Medicare beneficiaries choose to enroll with its plan, and continues receiving payments only if they stay enrolled.

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). Consistent with that concern, 42 U.S.C. 1395mm required HMOs to provide "meaningful procedures for hearing and resolving grievances" between itself and enrolled members. 42 U.S.C. 1394mm(c)(5)(A). The Secretary's former regulations 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).

In the event the enrollee was dissatisfied with the HMO's decision, the enrollee could bring the matter before the Secretary or her agents for resolution. See 42 U.S.C. 1395mm(c)(5)(B). 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 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). Neither the statute nor the regulations, however, provided an expedited decision mechanism for cases involving urgent medical needs. See 63 Fed. Reg. 23,369 (noting that deficiency in the former regulations).

2. Respondents are the named representatives of a nationwide 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 adverse coverage decisions. More effective procedures, they asserted, were required by Section 1395mm(c)(5)(A). They further claimed that initial HMO decisions concerning coverage constitute "state action" affecting constitutionally protected property interests in Medicare benefits and services and that, as a result, their procedures and processes must meet the strictures of the Due Process Clause. Those procedures and processes, respondents asserted, were constitutionally inadequate.

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, constitute "state action" attributable to the federal government and that, consequently, the notice and appeal rights provided by HMOs 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). In particular, 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 __-__.

The district court therefore 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. App., infra, at __. The injunction also requires that HMOs honor reconsideration requests, and permit "informal, in-person communication" between the beneficiary and the decision-maker. App., infra, at __. If a doctor asserts (or other evidence suggests) that services are urgently needed, the HMO must resolve the reconsideration request within three working days. 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 __.¹

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 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 had issued new HMO appeal regulations in interim final form. The Secretary noted that the regulations made several significant changes in notice and appeal procedures. 60 Fed. Reg. 23,368. Among other things, the new regulations provided a new procedure for expedited review in appropriate cases: Although HMOs would have 60 days within which to make determinations on an ordinary requests, they would have only 72 hours to make decisions where delay could seriously

¹ 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 __.

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 outweighs 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. 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 Act).

a. To replace Section 1395mm, the Act 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 alternative health insurance arrangements to traditional Medicare 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, 11

Stat. 278 (to be codified at 42 U.S.C. 1395w-21(c)(1)); by creating mechanisms for providing information concerning those the various options and benefits, including comparisons of plan options and additional available benefits, to the Medicare-eligible members of the public, id. 278-280 (to be codified at 42 U.S.C. 1395w-21(d)); and by developing procedures for approval of all marketing materials and forms to be used by participating HMOs and healthcare providers, id. at 285 (to be codified at 42 U.S.C. 1395w-21(h)). To encourage the participation of multiple healthcare providers and thereby maximize the available options for Medicare beneficiaries, the statute revamps the methodology for determining monthly capitation payments. See 11 Stat. 299-308 (to be codified at 42 U.S.C. 1395w-23). Healthcare providers cannot accept Medicare beneficiaries as enrollees under the program, and may not receive any payment under it, 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).

Most important for present purposes, 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 coverage, grievances and appeals. See 111 Stat. 286 (to be codified at 42 U.S.C. 1395w-22(g)). As before, the private healthcare organization must in the first instance determine for itself whether or not it the requested treatment is covered (just as it would with respect to non-medicare enrollees). But, as a condition of participation, the organization must provide all medicare enrollees with a clear, understandable statement concerning its decision on a timely basis. Ibid. (to be

codified at 42 U.S.C. 1395w-22(g)(1)). The organization must provide for reconsideration upon request and, where the basis for denial is lack of medical necessity, the reconsideration decision must be made by a physician -- other than the individual who made the initial coverage determination -- who has "appropriate expertise in the [relevant] field of medicine." Ibid. (to be codified at 42 U.S.C. 1395w-22(g)(2)). Although the statute normally permits some delay in the issuance of initial decisions and reconsideration decisions (it provides no deadline for the former, and requires the latter to be issued within 60 days), it requires participating healthcare organizations to reach decisions on an expedited basis, that is "no later than 72 hours [after] receipt of the request for the determination or reconsideration," where expedition is appropriate. Id. at 293-294 (to be codified at 42 U.S.C. 1395w-22(g)(3)).

In addition, all private healthcare organization decisions that deny coverage in whole or in part on reconsideration 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)). The enrollee has the right to be heard and present relevant evidence. Ibid. Any enrollee 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, and judicial review if the amount exceeds \$1,000.00. 111 Stat. 294 (to be codified at 42 U.S.C. 1395w-22(g)(5)). HMOs and other healthcare organizations participating in the program are strictly prohibited from interfering with the efforts of healthcare professionals from providing advice 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 participating healthcare organizations 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 with, 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 suggests that termination is a mandatory penalty for non-compliance.²

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 January 1, 1999, subject to limited exceptions. 111 Stat. 328 (adding new subsection (k)(1) to Section 1395mm, to be codified at 42 U.S.C.

² 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)).

1395mm(k)(1)).³ The Department of Health and Human Services advises that all of the HMO contracts entered into under Section 1395mm expired effective January 1, 1999. As a result, Section 1395mm, as far as both Medicare beneficiaries and relevant participating HMOs are concerned, is now without effect.⁴

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). Some portions of the regulations went into effect on July 27, 1998, before the court of appeals issued its decision. Other provisions, including regulations implementing the amended appeal and grievance procedures, took effect on January 1, 1999, at the beginning of the contracting cycle for HMOs and other managed care providers 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 protections for Medicare beneficiaries who choose for private HMO coverage, the Secretary's regulations require participating HMOs to issue prompt initial

³ 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 or after January 1, 1999, the Secretary shall not renew any such contract." 111 Stat. 328 (creating new 42 U.S.C. 1395mm(k)(1)).

⁴ There is one exception relating to a contract with a New Jersey HMO that is currently in liquidation. The Secretary advises that, as soon as the limited number of Medicare beneficiaries enrolled in that program can be moved to a new healthcare provider or to the traditional Medicare program -- and in no event later than March 1, 1999 -- the contract under Section 1395mm with that HMO will be terminated as well.

decisions and reconsideration decisions in both urgent and non-urgent cases. Although the Act provides no deadline for initial HMO decisions, the Secretary's new regulations require that, even in non-urgent cases, the HMO must make an initial coverage decision "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 (June 26, 1998) (adding 42 C.F.R. 422.568(a)). And while the Act sets 60 days as the time limit for resolution of reconsideration requests, the Secretary's regulations reduce that period to 30 days, 63 Fed. Reg. 35,110 (adding 42 C.F.R. 422.590(a)(2)). The regulations, moreover, require HMOs to give anyone 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).

Where there is a need for expedition, the initial and reconsideration decisions each must be made 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). And, where an enrollee is receiving authorized in-patient hospital care, 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).

In the event a reconsideration request is denied in whole or part, any unresolved issues must be adjudicated 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)). If the amount in controversy is over \$100, any party to the decision by the outside adjudicatory agent -- except the HMO -- may seek a hearing before an ALJ. 63 Fed. Reg. 35,110 (adding 47 C.F.R. 422.600); 111 Stat. 294 (to be codified at 42 U.S.C. 1395w-22(g)(5)). As required by the Act, the ALJ's decision is 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. Ibid. (adding 47 C.F.R. 422.608, 422.612); 111 Stat. 294 (to be codified at 42 U.S.C. 1395w-22(g)(5)).⁵

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 statutory provision and the ensuring regulatory reform.

⁵ 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 implementing 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 Medicare contract. 63 Fed. Reg. 35,104 (adding 42 C.F.R. 422.510).

See App., infra, at _____. Instead, the court of appeals addressed the case as if the Secretary's prior regulations, and the prior statute, were in place.⁶

Beginning with the question of "state action," the court of appeals held that a private HMO's initial decision to decline coverage for a requested treatment 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 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

⁶ 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." 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 coverage decisions are quintessentially private decisions, made without government compulsion or influence. In Blum v. Yaretsky, 477 U.S. 991 (1982), the Secretary noted, this Court held that private physicians who decide whether treatment is medically necessary -- a judgment that ultimately determined whether those treatments would be covered by the government -- are not state actors because such medical aid professional judgments are the type that physicians ordinarily must make. Here, the Secretary pointed out, the coverage determinations are the sort of decision that HMOs and insurers regularly make, whether or not the enrollee is a Medicare beneficiary, and regardless of who happened to have paid for the coverage. See App., infra, at 10a-11a. The court of appeals distinguished Blum, stating that, in that case, the decisions were "medical judgment[s] made by private parties according to professional standards that are not established by the State." Here, the court of appeals held, "the decisions in the case at hand are more accurately described as coverage decisions" that constitute "interpretations of the Medicare statute" rather "than merely medical judgments * * *." 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 1998 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 the coverage denial and by failing to apprise beneficiaries of their appeal rights, and (3) the Secretary had failed to demonstrate that the additional procedures sought by plaintiffs would be unduly burdensome. Ibid.

The court of appeals also rejected the Secretary's challenge to the nature and scope of the injunctive remedy. Because Congress had delegated implementation of Section 1395mm to the Secretary -- and because it was the Secretary's implementation of that provision that the district court had found to be statutorily and constitutionally 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 decide to deny and dispute claims for treatment made by Medicare beneficiary enrollees and (2) that the HMO procedures formerly required by the Secretary under 42 U.S.C. 1395mm were insufficient to meet the requirements of due process. The court of appeals' decision thus raises the same issues this Court will be addressing in American Manufacturers Mutual Insurance Company v. Sullivan, et al., No. 97-2000 (argued Jan. 19, 1999), and the petition should be held pending the Court's decision in that case. Moreover, shortly after the district court ruled in this case and issued the injunction, Congress completely revamped 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. New Medicare Part C and the Medicare + Choice program, as

implemented by the Secretary, provide dramatically greater procedural protections for beneficiaries who choose to enroll in HMOs, thereby eliminating the grievances that prompted the request for judicial relief, and 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, the current dispute is moot. Accordingly, we also ask that, once this Court issues its decision in Sullivan, it vacate the judgments of the court of appeals and the district court and remand the case to the district court for consideration of the intervening change of law and, if appropriate, the decision in Sullivan.

A. This Case Should Be Held Pending, And Disposed In Light Of, 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 similar (if not identical) 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 the 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.

1. The first question before the Court in Sullivan is whether workers' compensation insurers, when they choose to withhold payment for medical treatment pending a challenge to the "necess[ity] or reasonable[ness]" of the treatment under Pa. Code § 531(5), (6), are engaged in "state action." Answering that question in the affirmative, the Court of Appeals for the Third Circuit reasoned that workers' compensation 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 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. That reasoning is very similar to the reasoning employed by the Ninth Circuit in this case. See App, infra, 9a-10 (reasoning that "HMOs and the federal government are essentially engaged as joint participants to provide Medicare services" because (1) the "Secretary extensively regulates the provision of Medicare services by HMOs"; (2) HMOs must "comply with all federal laws and regulations"; Secretary pays HMOs "for each enrolled Medicare beneficiary (regardless of the services provided)"; and (3) the

"federal government has created the legal framework -- the standards and enforcement mechanisms -- within which HMOs" must operate). Indeed, lead counsel in this case filed an amicus brief in this Court in Sullivan, emphasizing the potential impact of the Court's decision in Sullivan on the Medicare program and on the result the Ninth Circuit reached below.⁷

Moreover, petitioners' and their amici's arguments in favor of reversal in Sullivan apply with equal force here. In particular, the Sullivan petitioners identify three factors that this Court has examined in its state action cases -- whether the private actor's decision is the product of governmental compulsion or influence, whether the private actor exercises a traditionally exclusive state power, and whether the government has some involvement that uniquely aggravates the injury. Pet. Br. __-__; U.S. Br. __-__. With respect to the first factor, they argue that the initial decision by a worker's compensation insurer to withhold payment and dispute a claim cannot be fairly attributed to the State under a "significant encouragement" theory because the State does not make any effort to influence the insurers' decision; the initial decision on 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 the HMO's

⁷ 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).

decision to deny a Medicare beneficiary's claim for a particular service. When an HMO decides whether to cover a requested service or to dispute it instead, it makes that determination without governmental participation. Like an insurer confronted with a claim for payment, it makes its determination based on its own expertise and its own assessment of the relevant circumstances and governing law.

Second, the Sullivan petitioners argue that the insurers' decisions to withhold payment cannot be considered the exercise of a power "traditionally exclusively reserved to the State." Pet. Br. 18 (quoting Jackson v. Metropolitan Edison Co., 419 U.S. 345, 352 (1974)). To the contrary, they argue, the insurers' decision involves the sort of uniquely private decision 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. Precisely the same is true with respect to HMO coverage decisions under the Medicare Act. When an HMO decides whether or not to cover a request for 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. Instead, the HMO decides whether it, as a self-interested private actor, believes that it is legally (or perhaps morally) obligated to cover -- and therefore should approve -- the service, or whether it should contest the claim instead. That is precisely the sort of decision HMOs and insurers must make on a daily basis with respect to any enrollee, whether or not the enrollee is a Medicare beneficiary. And if an HMO participating in Medicare does choose

to provide the treatment rather than contest it -- like the insurers in Sullivan -- must bear the cost itself.

Indeed, the substantive coverage decisions made by HMOs and the decisions made by the insurers in Sullivan are virtually indistinguishable. In Sullivan, the statute requires the insurer to cover the treatment if it is "reasonable or necessary." Pa. Stat. Ann. § 531(5), (6)(1) (Supp. 1998); 34 Pa. Code § 127.208(e). Likewise, the Medicare statute generally covers medical treatments that are "reasonable and necessary." 42 U.S.C. 1395y(a). An HMO's decision on reasonableness and necessity no more constitutes a delegated "interpretation of the Medicare statute," App., infra, 11a, than a Pennsylvania Workers' Compensation insurers' view of "reasonable[ness] or necess[ity]" constitutes an adjudication of Pennsylvania law. See Blum, 457 U.S. at ___. Moreover, in neither case does the private actor's view of its own obligations conclusively resolve the matter. To the contrary, under both the Pennsylvania Workers' Compensation Act and the Medicare program, only the decision of a true governmental authority, acting in its capacity as neutral arbitrator 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).⁸

⁸ Of course, when the government or its agents does enter a final and conclusive determination, it is engaging in state action. But the fact that the government participates in the process by adjudicating claims -- that is as a neutral arbitrator of disputes -- serves to underscore the fact that the HMO's decision is quintessentially private. Indeed, an HMO decision to deny a claim

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. And, the governmental regulation of the industry in this case is neither qualitatively nor quantitatively different than the regulation of workers' compensation insurers at issue in Sullivan.

Indeed, 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

in the first instance is indistinguishable from the decision of private civil litigant or a private insurer, confronted with potential liability, to contest the claim and subject itself to the adjudicative process. Civil litigants and insurers always have the option of either allowing the claim (and resolving the dispute) or instead denying it and thereby requiring the claimant to invoke the dispute resolution machinery established by the government. Yet "a private party's decision to defer payment of a potential debt" and to litigate the issue instead "has never, to our knowledge, been considered 'state action' under the Fourteenth Amendment." U.S. Br. at ____.

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.⁹

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, in cases involving "acute care services," the HMO to pay for services until after both the initial determination and the reconsideration decisions were made. App., infra, at __. One of the questions before this Court in Sullivan

⁹ One other difference between this case and Sullivan is that, in this case, the government pays for coverage, whereas in Sullivan both private and public employers purchase insurance. 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 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.

is whether due process requires workers' compensation the insurers likewise to continue paying for medical services until after some sort of outside review has taken place. See U.S. Br. ____-. 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 through the more cumbersome and less public judicial process.

B. Because This Case Became Moot Pending Review, The Court In Any Event 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 the Ninth Circuit's decision in this case and the Sullivan decision under review, the Ninth Circuit's decision ordinarily would warrant review in this Court. 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 of 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 increasing an 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 (the Act). At the time the district court ruled, the governing statute provided only that Medicare HMOs must 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; the content of such notices; the extent to which enrollees could present evidence or argument to the HMO on reconsideration; the identity and qualifications of HMO reconsideration decisionmakers; or the time within which reconsideration decisions had to be rendered. 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 these alleged deficiencies, the district court imposed and the Ninth Circuit affirmed a detailed and highly prescriptive injunction specifying the form, content, and timing of HMO notices, and regulating the subject of beneficiary appeal rights.

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 creates a whole 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)). Those provisions and the Secretary's regulations thereunder require all HMOs denying requested services to provide enrollees with a clear, understandable statement concerning adverse decisions on a timely basis. Ibid. (to be codified at 42 U.S.C. 1395w-22(g)(1)). The notice must be provided within 14 days of a request in ordinary cases, and within 72 hours where expedition is appropriate. Id. at 293-294 (to be codified at 42 U.S.C. 1395w-22(g)(3)); 63 Fed. Reg. 35,108-109 (June 26, 1998) (adding 47 C.F.R. 422.568(a) and 42 C.F.R. 422.572). The statute and regulations require that reconsideration decisions be made by a qualified physician other than the one who made the initial decision. 63 Fed. Reg. ____ (adding 47 C.F.R. ____, ____). They provide beneficiaries with the right to present evidence on to the decisionmaker on reconsideration. 63 Fed. Reg. ____ (adding 47 C.F.R. ____, ____). And they require that reconsideration decisions be issued 30 days ordinarily, and within 72 hours in expedited cases. 63 Fed. Reg. ____ (adding 47 C.F.R. ____, ____). Moreover, 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); 63 Fed. Reg. ____ (adding 47 C.F.R. ____)).

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.¹⁰ No court has passed on the constitutional sufficiency of these 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 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.,

¹⁰ These new provisions address many areas covered by the district court injunction, but 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 decision-making deadlines in non-urgent cases should be resolved by the Secretary after appropriate rulemaking and public consultation), and the Secretary selected a 14-day deadline. 63 Fed. Reg. ____ (adding 47 C.F.R. ____). 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. ____ (adding 47 C.F.R. ____).

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 (per curiam) ("vacat[ing] the judgment and remand[ing] the cause to the District Court for further proceedings" through which that court could consider "the nature and effect" of a supervening change in policy).

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 review. 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.").

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 Memorandum Order on Class Certification, 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, 1999.¹¹ And, as of January 1, 1999, all of the Secretary's Section 1395mm

¹¹ 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 the new ~~Part C~~ of the Medicare statute, the provisions of which have not been addressed by the court of appeals or the district court.

contracts expired, and no such contracts now remain in place.¹² 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 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 new contracts with any HMO that violated the procedural requirements imposed by the district court's order, the district court and court of appeals alike relied 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 "violates of 42 U.S.C. § 1395mm(c)(1)."); id. at 54a (declaring that failure of Secretary to require certain hearing procedures in HMO contracts "violates 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-

¹² One HMO that became insolvent and is now being operated by the state of New Jersey had its section 1395mm contract ~~extended~~ (as distinct from ~~renewed~~) in order to permit enrollees time to make arrangements for their health coverage. We expect that this temporary extension to expire on February 28, and that as of March 1, 1999, there will be no more enrollees under a section 1395mm risk contract.

renewal are mandatory penalties for HMO non-compliance.¹³ 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)).

3. Following settled practice in dealing with moot cases here would likewise further the interests underlying the practice. Here, through no fault of 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). That is especially true given the present circumstances. The ruling's 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

¹³ 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 * * *." 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)).

individuals."). And the ruling, despite the mootness of the actual controversy, threatens to have continuing repercussions for an important federal program: HMOs may well be deterred from participating in the new program by the Ninth Circuit's constitutional holding.

In far 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 the 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 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 v. Latimer, 377 U.S. 263, 265 (1964) (per curiam), 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). Here, the new statute enacted by Congress and the Secretary's new regulations promulgated thereunder likewise fundamentally alter not only the relevant legal framework and the nature of the dispute between the parties. Accordingly, a similar 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.¹⁴

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,

¹⁴ 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). 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 simply could not be sustained. Moreover, it would ill serve the cause of judicial economy for this Court to pass on a state action question unnecessarily where the district court may, on remand, be able to avoid that question through a fact-bound determination that, even if there were state action, then new procedures would provide respondents with the process that is their due.

for reconsideration in light of this Court's decision in Sullivan.

Respectfully submitted.

THE WHITE HOUSE
WASHINGTON

DATE: 2/8/99

TO: Chris Jennings/Deborah Adler
FROM: Don Murray (216)
Office of Counsel to the President
Room 128, OEOB, x6-7900

☒ FYI

☐ Please Call

☐ Appropriate Action

☐ Let's Discuss

☐ Per Our Conversation

☐ Per Your Request

☐ Please Return

☐ Other

THE WHITE HOUSE
WASHINGTON

11/2/99
95 FEB 3 1999

February 4, 1999

MEMORANDUM TO THE PRESIDENT

FROM: Bruce Reed, Chris Jennings, Elena Kagan, Dan Marcus (Counsel's Office)

SUBJECT: Grijalva v. Shalala

John Podesta held a meeting last night with staff from the DPC, Counsel's office, OLA, OVP, OMB, and HHS to discuss whether the Solicitor General and HHS should petition the Supreme Court for a writ of certiorari in Grijalva v Shalala. The cert petition, which is due on Wednesday, would seek to vacate a decision (1) holding that Medicare HMOs are "state actors" and, as such, required to provide enrollees with constitutional due process and (2) requiring the Secretary of HHS to ensure that all Medicare HMOs comply with specific notice and hearing requirements when seeking to deny or reduce medical benefits.

You previously noted (on a copy of a New York Times article attached to this memo) that this is a "tricky issue," and your comment, if anything, understates the difficulty and political sensitivity of the decision. HHS objects to the administrative burdens that the district court's injunction imposes and worries that these onerous requirements -- as well as the fear of being subject to other constitutional standards -- will drive some HMOs from the Medicare program. Many Congressional Democrats and health advocates, however, believe that contesting the ruling below will undermine our effort to enact patients' rights legislation and perhaps threaten federal enforcement of Medicaid requirements.

Background

In Grijalva, a nationwide class of individuals enrolled in Medicare HMOs alleged that the HMOs were failing to provide the notice and appeal rights guaranteed by the Due Process Clause of the Constitution. The district court (Judge Alfredo Marquez) agreed that Medicare HMOs were state actors and, as such, required to provide constitutional due process; he also found that the notice and appeal procedures then in existence failed to meet constitutional requirements. The judge issued an injunction specifying precise notice, hearing, and appeal procedures, including a requirement that review of an HMO's decision to deny, terminate, or reduce services take place prior to implementing that decision. The injunction also commanded the Secretary to terminate contracts with any Medicare HMO failing to comply with these requirements. The District Court stayed this injunction pending completion of the appeals process, so the injunction has not yet gone into effect.

While the Secretary's appeal of the District Court's decision was pending, Congress (in the Balanced Budget Act) overhauled the Medicare HMO program and the Secretary issued a new set of regulations governing Medicare HMOs. Although the new statutory and regulatory scheme provided Medicare enrollees with far greater protections than the original scheme, a panel of the Ninth Circuit upheld the District Court's decision. The Ninth Circuit panel agreed with the District Court that Medicare HMOs were state actors, required to provide constitutional due process, and that the procedural rules in effect at the time of the District Court's decision failed to meet constitutional standards. The panel declined to consider whether the new procedural rules met constitutional requirements and thus rendered the injunction unnecessary, noting that the Secretary could petition the District Court for a ruling on this issue. Concerned about the basic state action issue, the Secretary chose instead to seek a rehearing en banc (which the full Ninth Circuit denied) and now seeks a writ of certiorari.

The Solicitor General's draft cert petition (which we can give you if you want it) notes first that the principal legal issue in Grijalva (whether Medicare HMOs are state actors) is very similar to an issue now before the Court in American Mutual Insurance Co. v. Sullivan (whether workers' compensation insurers are state actors); hence, the SG says, the Court should hold the petition in Grijalva pending the Court's decision in Sullivan. Although this point could be made very simply, the SG's draft uses it as a launching pad to argue the merits of the state action issue; the petition argues for almost 10 pages that Medicare HMOs are not state actors. The SG apparently believes that this extended discussion is desirable to ensure that the Supreme Court appreciates the importance of this case (and therefore holds the petition for Sullivan) and to influence the Court's writing of the Sullivan opinion (so that the decision there effectively forces the district court to lift the injunction).

The draft petition argues next that the new statutory and regulatory scheme governing Medicare HMOs -- which, as noted, provides greater protections than the original regulatory scheme, although some lesser protections than the injunction -- effectively moots the legal challenge adjudicated by the lower courts in this case. The SG thus asks that after holding the petition for Sullivan, the Court vacate the judgment below and remand the case for consideration of any challenge to the new statute and regulations in light of the Sullivan decision.

Discussion and Options

HHS believes that the District Court's injunction imposes a burdensome set of notice and hearing requirements, inconsistent with the Department's current policies and unnecessary to protect Medicare enrollees. HHS notes especially the obligation on health plans under the injunction to give extensive notice to enrollees of changes in service and to continue providing services during the appeals process (effectively forcing HMOs to eat the

cost of these services even if the HMO's initial decision was proper). HHS believes that these additional notice and hearing requirements will increase costs to Medicare HMOs and perhaps drive some out of the Medicare program; in addition, HHS worries that Medicare HMOs will incur other additional costs in the future if they continue to be viewed as state actors. Finally, HHS notes that the injunction imposes considerable administrative burdens on the Department itself, because the district court ordered it to monitor Medicare HMOs' compliance with the injunction and to terminate the contracts of non-complying HMOs.

But this position -- and these arguments -- place the Administration in an awkward position when it comes to pushing Congress to enact a Patients' Bill of Rights. Although the patient protections at issue are different, the Department is making the same kind of arguments against the injunction that private health plans routinely make against the Bill of Rights: that the added protections are excessively burdensome and would raise medical costs without improving the quality of patient care. Of course, the requirements in the one case were imposed by a court, whereas in the other they would be imposed by Congress. But this difference is unlikely to make much of a difference to our critics. In insisting on Supreme Court review of the judgment below, we would be giving credence to the health plans' view of regulation, while making ourselves vulnerable to the charge of hypocrisy.

Perhaps more important, many advocates and some Hill Democrats are worried that our arguments on state action will undermine the Medicaid entitlement. If Medicare HMOs are not state actors, then Medicaid HMOs probably are not either. Although it is possible to make distinctions between the Medicare and Medicaid programs with respect to state action, even HHS admits that these distinctions are strained and may not be convincing. What is more, the enforcement of Medicaid guarantees depends on whether participants in the system (such as HMOs) are state actors in a way that the enforcement of Medicare guarantees does not. Whereas the Medicare statute has built-in enforcement mechanisms that are unaffected by the state action issue, the Medicaid statute has no such mechanisms: federal enforcement relies largely on Section 1983 suits, which can only be brought against state actors. We fought hard, in the Medicaid block grant debate of 1995, to maintain this right of action for Medicaid violations, and we should be reluctant to start down a road that could make it less effective.

We are now considering three options. The first option is to file the cert petition drafted by the SG's office. The second option is to file a stripped-down version of the cert petition, simply making the point that Grijalva and Sullivan are related and asking the Supreme Court to hold the former for the latter. Because this kind of petition would not explicitly argue that Medicare HMOs are private actors or that the district court erred in issuing its injunction, it would inflame advocates less and insulate us somewhat from the charge of hypocrisy. As noted above, however, it might also be less effective in getting the Court to dispose of both this case and Sullivan in the way that stands the best chance of overturning the injunction. The third option is to decline to file any cert petition and instead return to the district court to argue that it should lift (or modify) its injunction in light of the

new statute and regulation. Under this approach, we would say nothing now about the state action issue -- although if the Supreme Court later decides Sullivan in a way that is relevant, we could ask the District Court to reconsider its injunction in light of the decision. This approach best protects our position on the Patients' Bill of Rights and poses the least threat to the Medicaid entitlement, but it is probably the least effective way of helping HHS to escape from the district court's injunction.

Secretary Shalala favors the first option, but she recognizes that this is a difficult decision. We are almost sure that Shalala would prefer the second option to the third, although she has not yet considered this issue. The Solicitor General believes that the first option best protects the government's broad interest in entering into contracts with private parties, but our sense is that the SG is largely taking its direction in this case from HHS. We have not yet discussed with the SG whether he would prefer the second or third options and cannot guess how he would come out on this issue. The DPC and Counsel's Office believe strongly that we should not choose the first option. All of us think that either the second or third options would be acceptable, with Bruce and Dan leaning slightly to the second and Chris and Elena slightly to the third. We expect that John will talk to you about this matter after you have had a chance to read this memo.

1-29-99

Rulings on Medicare Rights Split White House

By ROBERT PEAR

WASHINGTON, Jan. 21 — A bitter dispute has broken out within the Clinton Administration over the legal rights of Medicare beneficiaries, with some officials trying to limit those rights even as President Clinton urges Congress to establish new protections for millions of other patients with private health insurance.

At issue are Federal court rulings that upheld the rights of six million Medicare beneficiaries in health maintenance organizations.

A Federal district judge in Tucson, Ariz., and the United States Court of Appeals for the Ninth Circuit, in San Francisco, said such patients have a constitutional right to receive written notices and hearings on any denial of medical services, because the H.M.O.'s were acting on behalf of the Government.

Medicare officials are urging Donna E. Shalala, the Secretary of Health and Human Services, to appeal the decision to the Supreme Court. But other Administration officials, who work on legislative affairs and domestic policy, strenuously oppose any appeal, saying the Administration will look ridiculous and will outrage consumer groups and Democrats in Congress.

The arguments are set forth in confidential memorandums that provide a rare insight into the legal and political considerations that shape the Government's decisions on litigation before the High Court. They seem to parallel the arguments made for and against a "patient's bill of rights" like the one proposed by Mr. Clinton.

Medicare officials argue that the lower-court orders intrude on their ability to set Medicare policy, and go much further than necessary to protect elderly patients. "The appeals process required by the district court could impose significant administrative and financial burdens on health plans," raising costs by \$4.70 a person per month, or a total of \$343 million a year, said a memorandum by Medicare officials.

Under the lower-court orders, H.M.O.'s must provide a written notice whenever a service requested by a patient or a doctor is denied, or a course of treatment is reduced or terminated.

"Under this standard, beneficiaries could be inundated with written notices whenever a perceived reduction occurs," the Medicare officials said. "Such a situation would be confusing and even stressful to beneficiaries."

In short, Medicare officials do not like being second-guessed by the courts, and they resent judicial supervision just as much as H.M.O. executives resent regulation.

But a memorandum written by other officials of the Department of Health and Human Services emphasizes the political risks of an appeal

to the Supreme Court.

"The department's position could be seen as inconsistent with the Administration's stated policy of expanding consumer protections for health plan enrollees," it says. "As a result, a petition could weaken the department's and the Administration's ability to pass legislation that creates additional protections, such as in the patient's bill of rights."

A rare insight into the considerations that shape decisions on litigation.

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Nancy-Ann Min DeParle, the administrator of the Health Care Financing Administration, which runs Medicare, came down against the lower-court decisions. She told Dr. Shalala that the Administration "should seek relief from the Supreme Court," even though Ms. DeParle acknowledged that there were legal and political risks in this approach.

By contrast, other Administration officials said the rights of Medicare H.M.O. patients should meet constitutional standards for "due process of law" because the stakes were so high: If an H.M.O. denies coverage of a service, the patient may suffer irreparable harm or die.

Further, these officials said in confidential memorandums, if the Administration succeeds in its effort to overturn the court decisions won by Medicare beneficiaries, it could undermine the rights of poor people in Medicaid, who have increasingly been required to get their care through H.M.O.'s.

Moreover, these officials said, "health plans may be exaggerating the financial and administrative burdens" imposed by the lower-court orders.

The case, a nationwide class action, was filed in 1993 by elderly people who said they had been denied medically necessary services. The plaintiffs won a ruling from the Federal District Court in Tucson in October 1996. Dr. Shalala appealed, saying the judge, Alfredo C. Marquez, had usurped her authority.

Last August the appellate court in San Francisco rejected the Administration's argument. Judge Charles E. Wiggins, a former Republican Congressman from California, said Medicare beneficiaries are entitled to due process because the H.M.O. decisions amount to "Government action."

H.M.O.'s are private corporations, but when they deny services to Medicare beneficiaries they are acting on behalf of the Government, the court said.

The Administration has issued rules for Medicare H.M.O.'s, but the order by Judge Marquez provides greater protection to beneficiaries. The judge's order sets tighter deadlines for H.M.O.'s to rule on appeals, and it guarantees that patients can receive urgently needed services while they pursue appeals.

Vicki Gottlich, a lawyer at the National Senior Citizens Law Center, said the court order also "goes much further than current Federal rules in requiring H.M.O.'s to explain what additional evidence you need to support your claim, and how to get that evidence."

A report on the case by Government lawyers says "the worst possible scenario" is that Dr. Shalala will appeal to the Supreme Court and the Justices will decline to accept the case for review.

Lower courts would probably view such action as "a judgment by the Supreme Court that our arguments were unpersuasive," the report said.

The New York Times

FRIDAY, JANUARY 22, 1999

Nancy-Ann Min

Grijalva v. Shalala: Legal Options

This paper outlines the legal options available to the Secretary in the Grijalva case. The options are affected by the Sullivan case, which is currently before the Supreme Court and will be discussed below. We note that all of the options must be considered in light of the Administration's efforts involving both the Patient Bill of Rights and the Medicare+Choice program, as well as the Administration's relationships with both beneficiary advocates and health plans and providers.

- Timeframes
 - Supreme Court: If the Secretary asks for Supreme Court review, she must do so by February 10, 1999.¹
 - District court: If, in the alternative, the Secretary asks the district court to vacate or modify the injunction, she should do so before March 4, 1999, the date on which the mandate will issue (i.e., the injunction will be effective).²
- Arguments that may be made to the Supreme Court or, in the alternative, the district court
 - Sullivan:

Await the decision in American Mfrs. Mut. Ins. Co. v. Sullivan, which raises issues similar to those in Grijalva, on both state action and due process grounds.

Because Sullivan will be argued soon and presents issues similar to those in Grijalva, we may ask either the Supreme Court or, in the alternative, the district court to refrain from acting in Grijalva until the Court has issued its ruling in Sullivan. What we would be waiting for is a possible new standard for determining when to apply state action/due process obligations to what otherwise appear to be non-governmental procedures. A ruling in Sullivan is expected by mid-March 1999, although it could come as late as July 1999 or even next term. It is unknown how the Court is likely to rule.

In Sullivan, the court of appeals ruled that, under a state workers' compensation

¹If the Secretary not only petitions for Supreme Court review, but also asks the Court to "hold" the petition (i.e., put off granting or denying it) until the Court has issued a ruling in Sullivan, the Solicitor General has advised us that the Secretary should do so **as soon as possible but certainly no later than January 19, 1999**, the date on which Sullivan is scheduled to be argued before the Court.

²The Secretary may ask the district court to continue to stay the issuance of the mandate beyond March 3, 1999.

program, the suspension of employees' medical benefits without prior notice or an opportunity to be heard while a utilization review committee reviewed the claim was a violation of procedural due process. The court concluded that the private insurers from which employers purchased insurance coverage were state actors with respect to their determinations of the reasonableness and necessity of employees' medical treatments. The situation is analogous to ours in Grijalva where the courts ruled that benefits should continue to be paid during the pendency of a challenge to the decision to reduce or terminate them.

The Sullivan insurers appealed to the Supreme Court, arguing that they are not state actors. If they are found to be state actors, it is exceedingly likely that Medicare HMOs are state actors when making coverage determinations. The obverse, however, is not true. Even if the Sullivan insurers prevail, it is not clear that Medicare HMOs are not state actors. This is because the insurers at issue in Sullivan are arguably less inextricably linked to government than are the Medicare HMOs at issue in Grijalva.

- Mootness:

The certified class in Grijalva was limited to Medicare beneficiaries in risk-based HMOs and CMPs. Because all risk-based HMOs and CMPs, effective January 1, 1999, are governed by the new Medicare+Choice rules that superseded the old section 1876 rules at issue in Grijalva, we may also ask the Supreme Court or the district court to declare the case moot, in which event, the injunction would be vacated.

- Legal options

- No action:

The Department may opt to live with the state action ruling of the court of appeals and the injunction of the district court as they exist now. If this were the selected approach, the Department could do as the district court has ordered to the extent possible, or could conclude that the injunction does not govern the Medicare+Choice program because the order applies only to the now no longer existing section 1876 risk-based plans. If this were the conclusion, the Secretary could proceed to issue rules for risk-based plans that differ from the terms of the injunction. This approach presents a risk that plaintiffs would return to the district court seeking anything from clarification to modification to contempt.

- Supreme Court:

- If we ask for Supreme Court review, we will ask the Court to grant our

petition for a writ of certiorari, vacate the decision of the court of appeals, and then remand the case to the court of appeals for further consideration in light of either the Sullivan ruling or our mootness argument or both. (We refer to this as "GVR" for "grant, vacate, and remand.") In the Solicitor General's view, even under the most optimistic scenario, i.e., if the decision in Sullivan is helpful to us, the odds of a GVR are no greater than 50%. If, nonetheless, the Court were to GVR Grijalva, the court of appeals would either render a new decision or remand the case to the district court for further consideration, depending on whether the issue to be considered is one of law or fact.

- Despite our GVR request, it is possible that the Supreme Court will accept the case on the merits. We believe, however, that the Court is unlikely to hear the case, given both the Sullivan ruling and our mootness argument.
- It is also possible that the Supreme Court will decline to accept the case. If this occurs, we may then seek relief from the district court as described below.³
- District court:
 - If we seek relief from the district court, we will ask the court to vacate or modify its injunction. There are several ways in which the court can do so, including vacating the injunction for mootness; mandating conformity with procedural due process without specific prescriptions; expressly validating the new Medicare+Choice rules; and expressly limiting the scope of its ruling to grievance procedures or to managed care settings or to both. Even if the court were to vacate or modify its injunction, however, the state action ruling of the court of appeals would continue to stand.
 - It is possible that the district court will decline to modify its injunction either altogether or in a way that satisfies us. If this occurs, we could appeal to the court of appeals. Such an appeal, however, would probably be unsuccessful.

³Although we could argue that the Supreme Court should hear Grijalva, if, at the same time, we argue mootness, we would call into question whether any relief is necessary. Also, to the extent that we argue to "hold" for Sullivan, the Court may decide that the Sullivan decision adequately addresses the issues, making certiorari in Grijalva unnecessary.

- Pros and cons

- Supreme Court:

Appealing to the Supreme Court presents the possibility of both the best and the worst possible outcomes. The best outcome is that the Court will vacate the decision of the court of appeals and remand the case to the court of appeals for further consideration. Under this scenario, the ruling of the court of appeals that Medicare HMOs are state actors when making coverage determinations would no longer be applicable. Furthermore, the court of appeals (or the district court) would be obliged to evaluate the adequacy of the new Medicare+Choice rules, rather than the old section 1876 Medicare rules, perhaps in light of what may be a favorable Sullivan ruling.

Another possible, albeit quite unlikely, outcome is that, despite our request, the Court will accept the case on the merits. It is unknown how the Court would rule, and, therefore, this approach is a risky one.

The worst possible scenario is that the Supreme Court will decline to accept the case. Under this scenario, the district court would be likely to interpret the refusal of the Supreme Court to hear our arguments as a judgment by the Supreme Court that our arguments were unpersuasive. Because our arguments to the district court would be the same as those to the Supreme Court, obtaining relief from the district court after the Supreme Court declines review would be more difficult than if we had sought district court relief in the first instance.

- District court:

Seeking relief from the district court in the first instance avoids the possibility of the worst case scenario while allowing for the possibility of validating the new Medicare+Choice rules. It precludes, however, the possibility of vacating the ruling of the court of appeals that Medicare HMOs are state actors when making coverage determinations.

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ministration succeeds in its effort to overturn the court decisions won by Medicare beneficiaries, it could undermine the rights of poor people in Medicaid, who have increasingly been required to get their care through H.M.O.'s.

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Conservatives Attack Pat Robertson's Clinton Remark

By RICHARD L. BERKE

ARLINGTON, Va., Jan. 21 — The remarks of Pat Robertson, the television evangelist, that the fight to oust President Clinton was all but lost set off a firestorm today among conservatives, who condemned him and asserted that Republicans should not turn back from a full trial.

Yet there were indications here at the annual conference of the Conservative Political Action Conference that even the most vociferous detractors of Mr. Clinton are pulling back from the impeachment matter. Few speakers concentrated on impeachment or on the President's ethics — a departure from similar gatherings recently.

Two candidates running for the Republican Presidential nomination, the publisher Steve Forbes and former Gov. Lamar Alexander of Tennessee, preferred to take shots at the early front-runner, Gov. George W. Bush of Texas, rather than Mr. Clinton.

And several at the convention — the same setting where Paula Corbin Jones first emerged in 1994 to tell reporters that she fended off a sexual advance from Mr. Clinton — said they shared Mr. Robertson's impatience with how the White House scandal had dominated the capital.

For example, Joyce Terry, a retired nurse from Woodbridge, Va., said she agreed with him. "That's my concern," Ms. Terry said. "I feel they should move a little faster. They know the facts. They know what's going on. Let's get with it and get it over with."

Despite those misgivings, the overwhelming sentiment of dozens of rank-and-file conservatives and their leaders was that the Senate has a duty to pursue Mr. Clinton no matter



Associated Press

Pat Robertson's remarks on impeachment have upset allies.

the political consequences. Most convention participants said they were puzzled — if not outraged — by the comments on Wednesday by Mr. Robertson, the chairman of the Christian Coalition, that the President had won "from a public relations standpoint" and "they might as well dismiss" the trial.

"If Pat Robertson said, in fact, it's time for the Republicans to give up — and give in — to Clinton, my membership in the Christian Coalition is over," said Hazel Staloff, a computer worker from Brooklyn. "I don't think the party can be hurt when it stands for what is right. It

can only be hurt when it compromises with evil."

Beverly Kroeger, who worked in the Reagan White House, said of Mr. Robertson: "I think he should have kept quiet because he carried a lot of weight with conservatives. I don't know why he said that because Congress has a duty there. To drop it, where does that leave us?"

The feelings of this potent wing of the Republican Party are important because many politicians, particularly in competitive races, are loath to alienate conservatives, whose votes they need to get elected.

Across the river at the Capitol, Representative Henry J. Hyde of Illinois, the lead prosecutor in the case against Mr. Clinton, said that Mr. Robertson's comments "shows that we're not tools of the Christian Right." Mr. Hyde, added, "We don't necessarily always agree with everything that Pat Robertson says."

Even Mr. Robertson sought today to defend his comments, made on his television program, "The 700 Club." "What I was saying essentially is that the President scored a public relations triumph," Mr. Robertson said, "and the Republicans in the Congress gave him the platform to do that, and consequently they undercut their own authority."

He added: "In a sense it's like saying it's the third quarter and the score is 50 to nothing and there's another quarter to play. The outcome seems at this point settled, but I wasn't saying I favored that."

Many participants at this conference said they favored a full trial with a parade of witnesses. "It doesn't matter to me if it goes on for a year," said Dan O'Brien of Falls Church, Va., who teaches character to corporate executives. "I'm not de-

ceived by the notion that the country's going to stop running because of the impeachment trial."

Preston Noell, who heads a Catholic civic organization, said he was eager for the Senate to delve deeper into the impeachment matter. "I'm not sick and tired of it," Mr. Noell said. "I don't think it's gotten going yet."

Representative Helen Chenoweth, an outspoken conservative from Idaho who addressed the convention, said of Mr. Robertson after her speech: "I was surprised. We wouldn't have even fought the War of Independence if we had taken a poll."

David Keene, chairman of the American Conservative Union, said of Mr. Robertson, "He's wrong," but conceded that conservatives are of two minds: "They want it to go through the process. But they'd like it to be over to the extent that it's all that's talked about."

Presidential candidates also stayed relatively clear of Mr. Clinton. Without mentioning him directly, Mr. Forbes assailed Governor Bush and his "compassionate conservative" ideology, saying, "Mealy-mouthed rhetoric and poll-tested clichés are no substitute for a muscular substantive agenda." Mr. Forbes and Mr. Alexander also attacked Mr. Bush by criticizing his father, former President George Bush, and his slogan about a "kinder and gentler" country.

Gary Bauer, a social conservative who is also preparing to run for President, took issue with Mr. Robertson in an interview. "There are two issues that ought never have to do with p.r.," he said. "Declaring war and the profound question of whether the President has violated the Constitution."

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to the Supreme Court.

"The department's position could be seen as inconsistent with the Administration's stated policy of expanding consumer protections for health plan enrollees," it says. "As a result, a petition could weaken the department's and the Administration's ability to pass legislation that creates additional protections, such as in the patient's bill of rights."

Nancy-Ann Min DeParle, the administrator of the Health Care Financing Administration, which runs Medicare, came down against the lower-court decisions. She told Dr. Shalala that the Administration "should seek relief from the Supreme Court," even though Ms. DeParle acknowledged that there were legal and political risks in this approach.

By contrast, other Administration officials said the rights of Medicare H.M.O. patients should meet constitutional standards for "due process of law" because the stakes were so high: if an H.M.O. denies coverage of a service, the patient may suffer irreparable harm or die.

Further, these officials said in confidential memorandums if the Ad-

ministration succeeds in its effort to overturn the court decisions won by Medicare beneficiaries, it could undermine the rights of poor people in Medicaid, who have increasingly been required to get their care through H.M.O.'s.

Moreover, these officials said, "health plans may be exaggerating the financial and administrative burdens" imposed by the lower-court orders.

The case, a nationwide class action, was filed in 1993 by elderly people who said they had been denied medically necessary services. The plaintiffs won a ruling from the Federal District Court in Tucson in October 1996. Dr. Shalala appealed, saying the judge, Alfredo C. Marquez, had usurped her authority.

Last August the appellate court in San Francisco rejected the Administration's argument. Judge Charles E. Wiggins, a former Republican Congressman from California, said Medicare beneficiaries are entitled to due process because the H.M.O. decisions amount to "Government action."

H.M.O.'s are private corporations, but when they deny services to Medicare beneficiaries they are acting on behalf of the Government, the court said.

The Administration has issued rules for Medicare H.M.O.'s, but the order by Judge Marquez provides greater protection to beneficiaries. The judge's order sets tighter deadlines for H.M.O.'s to rule on appeals, and it guarantees that patients can receive urgently needed services while they pursue appeals.

Vicki Gottlich, a lawyer at the National Senior Citizens Law Center, said the court order also "goes much further than current Federal rules in requiring H.M.O.'s to explain what additional evidence you need to support your claim, and how to get that evidence."

A report on the case by Government lawyers says "the worst possible scenario" is that Dr. Shalala will appeal to the Supreme Court and the Justices will decline to accept the case for review.

Lower courts would probably view such action as "a judgment by the Supreme Court that our arguments were unpersuasive," the report said.

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. memo	re: Grijalva v. Shalala (partial) (1 page)	02/06/1999	P6/b(6)

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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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- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
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Freedom of Information Act - [5 U.S.C. 552(b)]

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- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- 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]

Draft - Left lots for you.

Tim approved the Medicare/Medicaid

DRAFT: February 6, 1999

Entitlement paragraphs -

MEMORANDUM

FROM:

SUBJECT:

he can be reached on
his cell phone if needed

P6/(b)(6)

[003]

Last night, advisors from DPC, HHS, Counsel's office, Leg Affairs, VP's office, OMB and Chief of Staff's office met to discuss a time-sensitive issue: the plan to petition for a writ of certiorari to the Supreme Court in *Grijalva v Shalala*. This case is primarily about whether Medicare managed care plans are considered to be an extension of the government or "state" actors, thus required to provide their enrollees with full Constitution due process. HHS and the Solicitor General (SG) must file this petition by Wednesday, February 10, and we are interested in your guidance.

BACKGROUND

In 1997, the Ninth District Court ruled that when a Medicare HMO denies a claimed benefit for a beneficiary, the denial is tantamount to government action, and so the beneficiary is entitled to full due process under the Constitution. The district court also found that the Medicare appeals rights in place in 1993 were unconstitutional, and entered a mandatory injunction that imposed detailed new requirements. HHS appealed this decision, and its most recent request for a rehearing at the circuit court was denied in December 1997. Thus, this injunction will go into effect on March 4, 1999 without any action.

HHS is planning to ask the Supreme Court to grant that the case be vacated and remanded to the court of appeals, on two grounds. First, they argue that a case pending before the Supreme Court -- *American Mutual Insurance Company vs. Sullivan* -- will have implications for this case, since it is also about the issue of "state action" and the Constitutional right of due process. The Solicitor General's argues in the Sullivan case that, unless certain criteria are met, private government contractors are not considered state actors. Because HHS believes that Medicare HMOs should not be considered state actors and because this case has the potential to set a new standard for determining when to apply Constitutional due process rights, it will ask the Court to allow *Grijalva* to be reconsidered in light of its ruling. Second, HHS argues that the new Medicare rules, passed after the injunction and implemented early this year, dramatically expand the procedural protections for Medicare beneficiaries in managed care plans, thus superseding the defects in the Medicare program that prompted the initial petition.

DISCUSSION

HHS's primary reason for filing this petition is its concern that the court has imposed a burdensome set of appeals process requirements inconsistent with its current policies. Its examples of these extra requirements include the obligation for a health plan to continue providing a health care service during the appeal, and the extensive notice requirements for changes and/or denials of benefits. More generally, it is concerned about the court's intrusion upon the legislative and executive branches' authority to determine Medicare's appeal processes. Privately, HHS also fears that managed care plans will pull out of Medicare at an even greater rate because of the increased regulation burden and the fear of lawsuits. This concern is reinforced by the fact that HIAA is planning to file an amicus brief on these grounds.

While HHS's concerns with the content of the injunction are justifiable, there is some disagreement about its effect on participation in Medicare managed care. Ironically, the argument that regulation and lawsuits will drive managed care plans out of Medicare is exactly the same argument that the HMO industry has used against the patient bill of rights. Congressmen Waxman, Dingell and Stark, among others, have voiced this concern.

There is also a larger question of whether private plans in Medicare -- or other Medicare contractors or Medicaid managed care plans, for that matter -- should be considered state actors. Since the Medicare statute contains enforceable rights to eligibility, benefits, and now an appeals process, it can be argued that the Constitutional due process right serves as a floor or minimum that no longer is needed. However, it is possible that, in the future, the laws will change, leaving the beneficiary with fewer rights than the private right of action ensures.

More dangerous is the implication of this petition for Medicaid. Unlike Medicare, Medicaid relies solely on the private right of action; there is no other mechanism to remedy the denial of services, eligibility or any other statutory requirement. It is this right that we fought for in the Medicaid block grant debate in 1995, when Republicans proposed replacing it with state appeal process. Thus, if we argue that Medicare beneficiaries in private managed care plans have no private right of action, by extension, nor do the 50 percent of Medicaid beneficiaries in managed care plans. Thus, the Grijalva petition could have the unintended effect of undermining the Medicaid entitlement.

OPTIONS

While HHS recognizes the risks associated with their petition, they would like to file it with a detailed argument against considering Medicare managed care plans as state actors. At our meeting last night, however, HHS implied that the Secretary would open to modifying their petition to simply reference the Sullivan case rather than make extensive arguments about its applicability to the Grijalva case. This would have the cosmetic effect of taking out controversial arguments that will inflame advocates; it could have the real effect of decreasing the likelihood that the Sullivan case would apply in the rehearing. Bruce, xxx, think that this would .

An alternative is to not file the petition at all, and request that the circuit court modifies its injunction to include the new Medicare appeals process. This is a risk; if the court does not change the injunction, HCFA will have to change its nationwide appeals system in the course of a month. However, in the long-run it may protect a more important issue -- the private right of action in Medicare and Medicaid. Elena, Chris, xxx.

Private Right of Action in Federal Court

You have taken the position that you support maintaining the guarantee under Medicaid. Since the inception of the Medicaid program, a person eligible for Medicaid has had both a guarantee of access to certain services and the right to enforce this commitment. A "guarantee" without a right to enforce it and a remedy for its deprivation is a hollow promise. We believe that there must be a federal cause of action heard in federal court to enforce Medicaid eligibility for the following reasons:

Consistent Interpretation. Those aspects of the Medicaid program that are common to all states should be subject to consistent interpretation and administration. When the same question arises in different states, efficiency and predictability are best served by using the federal court system. In addition, Medicaid claims interact with, and have ramifications for, other areas of federal law (such as Medicare or Social Security). Federal courts are more experienced in analyzing these statutory schemes and are better able to understand the ramifications for other federal statutes. Finally, there is no indication that federal judges -- the majority of whom were appointed by Republican presidents -- ignore or take lightly the legitimate concerns of state administrators.

Significant Limitation of Remedies. If the Governors intend to eliminate the federal cause of action and require that Medicaid lawsuits be filed under state law, there is an enormous difference in remedies. Very few state laws allow a beneficiaries to obtain injunctions against the continuation of a policy found to be unlawful, and attorneys' fees also are generally not recoverable. This gap in remedies means that state law alone cannot substitute for a federal cause of action. If the Governors intend to require state courts to enforce a federal cause of action, however, the courts must also apply federal remedies.

The Governors (and the conference report) claim to maintain a right to sue in federal court through the Secretary of Health and Human Services. However, the Secretary can sue only if a state is in "substantial noncompliance" -- a higher standard than exists today -- and it is unclear what remedies are available. If the only remedy that the Secretary can seek is the cut-off of federal funds, this would cause significant harm to the beneficiaries that the Secretary is supposed to represent.

Departure from Other Federal Statutes. Eliminating the right to sue in federal court would single out Medicaid as the one federal statute conferring no possibility of federal enforcement by its intended beneficiaries. Eliminating federal court jurisdiction would leave Medicaid as the only cause of action arising under federal law that would be barred from the federal courts. Such an unprecedented step would be seen as a signal of second-class status and would set off massive reaction from beneficiary groups and their allies.

Elimination of Remedies under Civil Rights Law. While it is not clear that the Governors intend to go this far, the conference agreement precludes the right to enforce civil rights laws. Protection against discrimination in state programs has been established under the Civil Rights Act of 1964, the Rehabilitation Act of 1973, the Age Discrimination Act of 1975 and the Americans with Disabilities Act of 1990.

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COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

January 20, 1999

HAND DELIVER

The Honorable Al Gore
Vice President
The White House
Washington, DC 20505

Dear Mr. Vice President:

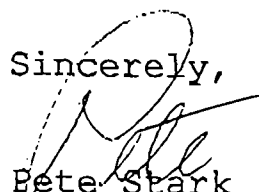
Over the next few days, the Department of Health and Human Services is considering appealing to the Supreme Court a case known as Grijalva v. Shalala.

I have begged the Administration twice not to appeal this District Court case. Twice they have appealed and been rejected by the Courts.

You cannot with a straight face campaign for HMO Consumer Protection legislation while the Administration is trying to overturn this pro-consumer case. *It will make us all look ridiculous.*

Please stop this appeal before the Administration is deeper on the anti-consumer side of this key issue.

Sincerely,


Pete Stark
Member of Congress

Please!

GRIJALVA QUESTIONS AND ANSWERS

January 8, 1999

draft

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

A: Medicare beneficiaries have full appeal and due process protections, whether they are in Medicare fee for service or managed care, and the Clinton Administration will guarantee that. We implemented important protections in the Balanced Budget Act and our Medicare+Choice regulations. Enactment of the President's proposed Patient Bill of Rights would guarantee that all Americans receive the protections that Medicare beneficiaries have under our new regulations.

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

A: When an HMO physician makes a decision about health care for a Medicare beneficiary, that physician is speaking for himself as a health professional, not for the government. The finding in Grijalva that HMOs may be treated as agents of the government could have far-reaching unintended consequences. And while the Grijalva decision does mandate protections for beneficiaries, we think the Medicare+Choice protections implemented after the suit was filed mean that beneficiaries have the strongest protections of any HMO patients in the country.

This process, rather than the courts, is the better, more flexible, responsive and beneficiary-friendly way to protect beneficiaries' rights in a changing health care environment. For example **[double check examples]**:

-- under the Grijalva ruling, plans can extend by up to 60 days the time in which they need to respond to certain appeals; under the Administration's regulation, the extension is limited to 14 days.

-- Medicare beneficiaries have the right to an expedited appeal within 72 hours if they feel their life, health or ability to regain maximum function may be jeopardized. Under Grijalva, that appeal can take up to five days.

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

A: The Grijalva decision was based on an appeals process that has been replaced by the new Medicare+Choice requirements. These new requirements, which weren't 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. [An article the Los Angeles Times last week said the Medicare appeals system

TOTAL P.16

Draft**GRIJALVA APPEAL**

January 8, 1999

Background: The Administration will appeal to the Supreme Court the Grijalva v. Shalala ruling by the Ninth Circuit; the appeal could be filed as early as Wednesday, January 13. In Grijalva, a nationwide class action suit, the plaintiffs challenged the appeals process that Medicare HMOs provide when HMOs decide not to provide or arrange for services.

In October 1997, the district court ruled in favor of the plaintiffs. It held that when a Medicare HMO denies a claimed benefit for a beneficiary, that denial is tantamount to governmental action; applied that reasoning to the Medicare appeal rights statute and regulation that were in effect in 1993 and found them unconstitutional; and established its own appeals process as the remedy in the case. Last year the circuit court affirmed the lower court ruling in August and in November denied the Secretary's request for a rehearing.

Talking points:

- The Clinton Administration has always supported the right of Medicare beneficiaries to appeal decisions by their HMOs. That's why we issued regulation to ensure that Medicare beneficiaries have full appeal and due process protections -- whether they are in Medicare fee for service or managed care -- and proposed in the Patients' Bill of Rights to make sure all Americans have those protections.
- The Grijalva decision was based on an appeals process that has been replaced by the new Medicare+Choice requirements, which are the strongest appeal rights of any HMO patients in the country. These new requirements were not yet in effect at the time of the court's ruling.
- When an HMO physician makes a decision about health care for a Medicare beneficiary, that physician is speaking for himself as a health professional, not for the government. The finding in Grijalva that HMOs may be treated as agents of the government could have far-reaching unintended consequences.