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002. fax	Seth Waxman to Dan Marcus re: draft filing (8 pages)	02/09/1999	P5 AMS 4/6/15
003. draft	re: Shalala v. Grijalva petition for a Writ of Certiorari (37 pages)	10/1998	P5 AMS 4/6/15

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THE WHITE HOUSE
WASHINGTON

From the Office of:

The Domestic Policy Council

Elena Kagan
Deputy Assistant to the President
for Domestic Policy

TO: Devorah for Chris

FAX: 65557

PHONE: _____

PAGES: _____

MESSAGE: Sorry for the delay

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THE WHITE HOUSE
WASHINGTON

'99 FEB 5 P7:40

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.

1-27-99

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 uphold 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.

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

"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 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

Vicky Kuhlman

UNITED STATES DEPARTMENT OF JUSTICE

OFFICE OF THE SOLICITOR GENERAL

10th & Constitution Avenue, N.W.

Washington, DC 20530

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REMARKS:

Enclosed is an alternative version of the state action section. In addition to being significantly shorter, it also makes a point that should be important to those who want to distinguish Medicaid – that under Medicare enrollment in an HMO is voluntary.

It is possible, but in my view not desirable, to file an even more truncated version along the lines of what is footnote 11 in the penultimate draft. Of course, we would still need to say that the 9th Circuit's decision is incorrect, and why. Filing a version of this sort will make the distinction mentioned above more awkward, and it will, I think, provoke a brief in opposition that will require us to present our arguments in a reply anyway. There are also other reasons why it would be less desirable to file that sort of petition. Still, it would be better than not filing anything.

I want to reemphasize the point I made when I called you last evening -- that not filing a petition challenging this 9th Circuit ruling will likely have serious consequences well beyond HHS/HCFA. Given the governmental interests at stake here, it would be stunning if we did not file.

I hope the President will bear in mind that the arguments advanced here are **the same as those we have already made** in the district court, in our merits brief in the court of appeals, and in our rehearing papers. And we are not soliciting plenary review. We are simply trying to get this case back to the district court – absent a damaging state-action precedent -- so that the new statute and regulations can be evaluated on their merits, and the President's program can proceed unhindered.

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FROM: (Name, org. symbol, Agency/Post)	Room No. – Bldg.
	5712-Main DOJ
Seth Waxman **Solicitor General** **Department of Justice**	Phone No. 202-514-2201

1. The Due Process Clause does not apply to purely private conduct; it applies only where the actor is governmental, or the conduct can be fairly attributed to the government. NCAA v. Tarkanian, 488 U.S. 179, 191 (1988). The Ninth Circuit held that medical treatment decisions of private HMOs are properly attributed to the federal government in this case because the "Secretary extensively regulates the provision of Medicare services by HMOs" and pays HMOs "for each enrolled Medicare beneficiary (regardless of the services provided)"; HMOs must "comply with all federal laws and regulations"; and the "federal government has created the legal framework -- the standards and enforcement mechanisms -- within which HMOs" operate. App. 9a-10a. The Ninth Circuit's analysis departs from this Court's usual approach in this area, which focuses on three factors:

a. The first factor is whether the government "has exercised coercive power or has provided such significant encouragement * * * that the choice must in law be deemed to be that of the [government]." Blum v. Yaretsky, 457 U.S. 991, 1004 (1982). When an HMO makes an initial determination whether to provide a requested service, it does so without governmental participation or assistance. Indeed, the first section of the Medicare statute prohibits the "exercise [of] any" governmental "supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. 1395.[1]

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[1] In Blum v. Yaretsky, 477 U.S. 991 (1982), this Court held that the exercise of ordinary medical judgment is not state action, even where it may affect eligibility for government benefits. The Ninth Circuit sought to distinguish Blum by characterizing HMO determinations as more in the nature of interpretations of the Medicare Act, rather than medical judgments, see App. 11a, but the primary criterion employed by HMOs in this context -- whether the medical services are "reasonable

b. The second factor is whether the otherwise private actor exercises some power "traditionally exclusively reserved to the State." Jackson v. Metropolitan Edison Co., 419 U.S. 345, 352 (1974). Significantly here, the relationship between an HMO and its Medicare-beneficiary members is the product of a private choice by those members. Medicare beneficiaries may choose among providers and forms of coverage, and the government neither requires them to enroll in an HMO nor precludes them from dis-enrolling. In this respect, the HMO's relationship with its Medicare-beneficiary members resembles its relationship with members who elect HMO coverage under employer-sponsored or other private health plans. Moreover, when an HMO decides whether to provide particular medical services requested by a member who has enrolled through Medicare, it does not act as an agent of the government or distribute government resources or funds. The HMO responds as it would to a similar request by a privately-enrolled member. The HMO exercises its own judgment as to whether the services are reasonable and necessary, and thus within the scope of its professional and contractual obligations. Although money is paid out of the Medicare Trust Funds to cover the flat monthly cost of the Medicare beneficiary's enrollment in the HMO, the

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and necessary," 42 U.S.C. 1395y(a) -- requires essentially medical, not legal, judgment. The complaint in this case, moreover, demonstrates that respondents seek to challenge medical judgments. One named plaintiff, for example, alleged that she was denied physical therapy because she could not follow therapeutic instructions. C.A. E.R. 10-11, ¶ 29. Another plaintiff alleged that treating physicians failed to prescribe adequate pain medication or to order physical therapy. C.A. E.R. 12-13, ¶¶ 40-41. Another plaintiff, much like the plaintiffs in Blum, alleged that the HMO erroneously concluded that skilled nursing care was not medically necessary. C.A. E.R. 13-15, ¶¶ 48-54. And yet another named plaintiff alleged that the HMO denied speech therapy services on the ground that the therapy would not be effective. C.A. E.R. 16, ¶ 62.

financial consequences of a determination by the HMO to furnish or deny particular services to that enrollee are borne by the HMO alone.[2]

Nor does an HMO exercise traditionally-governmental adjudicatory powers with respect to its members who choose to enroll through Medicare. See App. 10a-11a. The HMO's medical treatment decisions regarding such a member represent its own judgment about what is medically appropriate. A Medicare beneficiary who disputes an HMO denial may request an ALJ hearing in HHS, and the HMO then becomes a formal party, adverse to the beneficiary. See pp. , supra. The adjudication, of course, is government action, and the Secretary may order the HMO to provide the requested service, but that does not convert the HMO's otherwise-private initial determination into government conduct.[3] Indeed, the HMO's role is little different than that of a private defendant confronting potential liability in a civil suit. The defendant would always make an initial determination

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

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

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

c. Finally, there can be no argument that "the injury caused is aggravated in a unique way by the incidents of governmental authority." Edmonson, 500 U.S. at 622. This is not a case, like Edmonson, in which a dignitary injury or stigma of the sort caused by racial discrimination might be exacerbated by an appearance of governmental endorsement. See id. at 628. The government simply provides adjudicatory mechanisms through which HMO decisions may be challenged.

d. At bottom, the Ninth Circuit's decision to attribute to the federal government an HMO's medical treatment decisions about its members who have enrolled through Medicare appears to have rested primarily on the "rather vague generalization," Blum, 457 U.S. at 1010, that there was a "high degree of interdependence" and a "symbiotic relationship," App. 9a, that made the government "a joint participant in the challenged activity." Burton v. Wilmington Parking Auth., 365 U.S. 715, 725 (1961). The facts

the Ninth Circuit relied upon for that conclusion, however, are largely common to heavily regulated industries. See App. 10a; pp. , supra. Even the most intensive governmental regulation of an industry is an insufficient basis for attributing otherwise private decisions and conduct to the government "where the initiative comes from" the private party "and not from the [government]" itself. Jackson, 419 U.S. at 357; see id. at 350.

UNITED STATES DEPARTMENT OF JUSTICE

OFFICE OF THE SOLICITOR GENERAL

10th & Constitution Avenue, N.W.

Washington, DC 20530

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COMMENTS: John - This is Seth's latest. I'm also attaching FN 11 from a prior draft, which he notes in his cover memo is the still more truncated way of making this argument.

Elena

cc: Bruce/Chris

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Seth Waxman **Solicitor General** **Department of Justice**	Phone No. 202-514-2201

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b. The second factor is whether the otherwise private actor exercises some power "traditionally exclusively reserved to the State." Jackson v. Metropolitan Edison Co., 419 U.S. 345, 352 (1974). Significantly here, the relationship between an HMO and its Medicare-beneficiary members is the product of a private choice by those members. Medicare beneficiaries may choose among providers and forms of coverage, and the government neither requires them to enroll in an HMO nor precludes them from disenrolling. In this respect, the HMO's relationship with its Medicare-beneficiary members resembles its relationship with members who elect HMO coverage under employer-sponsored or other private health plans. Moreover, when an HMO decides whether to provide particular medical services requested by a member who has enrolled through Medicare, it does not act as an agent of the government or distribute government resources or funds. The HMO responds as it would to a similar request by a privately-enrolled member. The HMO exercises its own judgment as to whether the services are reasonable and necessary, and thus within the scope of its professional and contractual obligations. Although money is paid out of the Medicare Trust Funds to cover the flat monthly cost of the Medicare beneficiary's enrollment in the HMO, the

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and necessary," 42 U.S.C. 1395y(a) -- requires essentially medical, not legal, judgment. The complaint in this case, moreover, demonstrates that respondents seek to challenge medical judgments. One named plaintiff, for example, alleged that she was denied physical therapy because she could not follow therapeutic instructions. C.A. E.R. 10-11, ¶ 29. Another plaintiff alleged that treating physicians failed to prescribe adequate pain medication or to order physical therapy. C.A. E.R. 12-13, ¶¶ 40-41. Another plaintiff, much like the plaintiffs in Blum, alleged that the HMO erroneously concluded that skilled nursing care was not medically necessary. C.A. E.R. 13-15, ¶¶ 48-54. And yet another named plaintiff alleged that the HMO denied speech therapy services on the ground that the therapy would not be effective. C.A. E.R. 16, ¶ 62.

financial consequences of a determination by the HMO to furnish or deny particular services to that enrollee are borne by the HMO alone.[2]

Nor does an HMO exercise traditionally-governmental adjudicatory powers with respect to its members who choose to enroll through Medicare. See App. 10a-11a. The HMO's medical treatment decisions regarding such a member represent its own judgment about what is medically appropriate. A Medicare beneficiary who disputes an HMO denial may request an ALJ hearing in HHS, and the HMO then becomes a formal party, adverse to the beneficiary. See pp. , supra. The adjudication, of course, is government action, and the Secretary may order the HMO to provide the requested service, but that does not convert the HMO's otherwise-private initial determination into government conduct.[3] Indeed, the HMO's role is little different than that of a private defendant confronting potential liability in a civil suit. The defendant would always make an initial determination

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

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

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

c. Finally, there can be no argument that "the injury caused is aggravated in a unique way by the incidents of governmental authority." Edmonson, 500 U.S. at 622. This is not a case, like Edmonson, in which a dignitary injury or stigma of the sort caused by racial discrimination might be exacerbated by an appearance of governmental endorsement. See id. at 628. The government simply provides adjudicatory mechanisms through which HMO decisions may be challenged.

d. At bottom, the Ninth Circuit's decision to attribute to the federal government an HMO's medical treatment decisions about its members who have enrolled through Medicare appears to have rested primarily on the "rather vague generalization," Blum, 457 U.S. at 1010, that there was a "high degree of interdependence" and a "symbiotic relationship," App. 9a, that made the government "a joint participant in the challenged activity." Burton v. Wilmington Parking Auth., 365 U.S. 715, 725 (1961). The facts

the Ninth Circuit relied upon for that conclusion, however, are largely common to heavily regulated industries. See App. 10a; pp. , supra. Even the most intensive governmental regulation of an industry is an insufficient basis for attributing otherwise private decisions and conduct to the government "where the initiative comes from" the private party "and not from the [government]" itself. Jackson, 419 U.S. at 357; see id. at 350.

errs is to "remand to the agency").[9]

3. Government action and due process questions very similar to those raised in this case are currently before the Court in American Manufacturers Mutual Insurance Co., et al. v. Sullivan, et al., No. 97-2000 (argued Jan. 19, 1999). There, the court of appeals held that payment decisions made by workers' compensation insurers, as permitted by state law, were both attributable to the State and inconsistent with due process. See Sullivan v. Barnett, 139 F.3d 158 (3d Cir. 1998). Not only are the court of appeals decisions in Sullivan and in this case remarkably similar,[10] but the precise arguments that the Sullivan petitioners made in support of reversal there apply with equal force in this case as well.[11]

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

[10] Neither court of appeals decision examines the three state-action "principles" identified in Edmonson, 500 U.S. at 622, and traditionally relied upon by this Court, see pp. __-__, supra, and both predicate a finding of government action largely on the government's regulatory role. Compare Sullivan, 139 F.3d at 168, with App. 9a-10a.

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

Indeed, so closely related are the cases that lead counsel in this case filed an amicus brief in Sullivan, emphasizing the potential impact of the Court's decision there on the Medicare program at issue here.[12] Accordingly, we suggest that the petition be held pending the decision in Sullivan.

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

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

On August 5, 1997, however, Congress comprehensively reformed this area of law -- enacting the new Medicare Part C and establishing the new "Medicare+Choice" program. See Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275. At the time the district court ruled, the governing statute merely required that HMOs provide "meaningful procedures for hearing and resolving grievances." 42 U.S.C. 1395mm(c)(5)(A). Neither that statutory provision nor the regulations promulgated

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required); see also Lyng v. Payne, 476 U.S. 926, 942 (1986) (noting that the Court has not resolved whether "applicants for benefits, as distinct from those already receiving them, have a legitimate claim of entitlement protected by the Due Process Clause").

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

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No. DRAFT

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

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

v.

GREGORIA GRIJALVA, ET AL.

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

PETITION FOR A WRIT OF CERTIORARI

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PARTIES TO THE PROCEEDINGS

The petitioner is Donna E. Shalala, Secretary, Health and Human Services. The respondents are plaintiffs Gregoria Grijalva, Carol Knox, Mary Lea, Beatrice Bennett, and Mildred Morrell, individuals and representatives of a class of persons similarly situated, and plaintiffs-intervenors Josephine Balistreri, Fred S. Scherz, Kevin A. Driscoll, Mina Ames, Edmundo B. Cardenas, Arline T. Donoho, Patricia Sloan, Beth Robley, Goldie M. Powell, and Richard Baxter.

QUESTIONS PRESENTED

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

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

The questions presented by this case are:

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

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

3. Whether Congress's enactment of new Medicare Part C, which eliminates the Secretary's authority to contract under Section 1395mm(g) and establishes a new "Medicare+Choice" program that provides greatly enhanced procedural protections for Medicare beneficiaries enrolled in HMOs, renders the current appeal moot or otherwise warrants an order vacating the judgment below with directions to remand the matter to district court for consideration of the effect of the new statutory and regulatory scheme.

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

No.

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PETITION FOR A WRIT OF CERTIORARI

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

OPINIONS BELOW

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

JURISDICTION

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

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Relevant portions of the Medicare Act, as it existed when the district court ruled, 42 U.S.C. 1395mm, are reproduced in the Appendix to this petition, see App. 102a-109a, as are relevant

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

STATEMENT

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

a. In 1982, Congress added a provision to the Medicare Act to permit beneficiaries to obtain covered services in a fundamentally different way -- by enrolling in private healthcare plans like

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

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

enrolled in risk-sharing HMOs, i.e., HMOs that entered into contracts pursuant to 42 U.S.C. 1395mm(g).

Under 42 U.S.C. 1395mm, HMOs were required to provide "meaningful procedures for hearing and resolving grievances" between themselves and enrolled members. 42 U.S.C. 1395mm(c)(5)(A). Under the HHS regulations implementing Section 1395mm(c)(5)(A) that were before the district court, HMOs denying requests for medical services were required to notify beneficiaries of such decisions, give the reasons for the denial, and notify the beneficiaries of the right to ask the HMO to reconsider the decision. 42 C.F.R. 417.608 (1996). HMOs, however, had 60 days in which to issue such decisions, ibid., as well 60 days in which to resolve reconsideration requests, id. at § 417.620. Neither the statute nor the regulations provided an expedited decision mechanism for cases involving urgent medical needs. And neither the statute nor the regulations addressed the qualifications of HMO decisionmakers. HMO enrollees dissatisfied with adverse HMO decisions, however, could obtain reconsideration review by the HMO and the Secretary or her agents, 42 C.F.R. 417.614-417.626 (1996), and, subject to certain amount-in-controversy requirements, a hearing before an ALJ in the Department of Health and Human Services (HHS), followed by appeal to the Departmental Appeals Board (DAB) and judicial review. See 42 U.S.C. 1395mm(c)(5)(B); 42 C.F.R. 417.630-417.636 (1996). The HMO was required to be made a party to any hearing before an ALJ, and the HMO, if aggrieved by the ALJ's decision, could seek review by the DAB and then judicial review. 42 C.F.R. 417.632(c)(2), 417.623, 417.636 (1996).

2. Respondents have been certified as the named

representatives of a nationwide class of Medicare-eligible individuals who enrolled in risk-based HMOs under Section 1395mm(g). See Order of Dec. 15, 1994, C.A. E.R. 36; App. 25a n.1. They alleged that the HMOs were not providing legally adequate notice and appeal rights with respect to decisions to reduce or deny services. More effective procedures, they asserted, were required by Section 1395mm(c)(5)(A). They further claimed that initial HMO decisions constituted "state action" affecting constitutionally protected property interests, and that the processes leading to those decisions did not comport with the Due Process Clause.

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

On March 3, 1997, the district court entered a mandatory injunction that imposed detailed new notice and hearing requirements. App. 59a-64a. Among other things, the injunction commands the Secretary to require that HMOs provide (in all but "exceptional circumstances") a written notice of any decision that

denies, terminates or reduces services or treatment within "five working days" of an oral or written request for that care -- without regard to whether the beneficiary would be adversely affected if the HMO took longer to resolve the matter. Id. at 60a. If the beneficiary seeks reconsideration of the decision, and the request is urgent, the HMO must issue a reconsideration decision within three working days. Id. at 62a. (The injunction provides no deadline for resolution of non-urgent reconsideration requests.) And where "acute care services" are at issue, the order provides that the HMO must provide a hearing before denying the request; it may not discontinue such services until after the initial decision and the reconsideration process is completed. Id. at 63a. Any notice informing a beneficiary of such a decision, moreover, must be printed in 12-point type, specify the basis for the decision, and advise the beneficiary of his appeal rights. Id. at 60a-61a.

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

b. The Secretary moved the district court to stay its injunction pending appeal, and the district court granted the motion. App. 65a-69a. In seeking the stay, the Secretary pointed out that on April 30, 1997 -- just after the district court entered

its injunction -- the Secretary had issued new HMO regulations in interim final form. See 62 Fed. Reg. 23,368 (1997). The Secretary noted that those regulations made several significant changes in notice and appeal procedures. Among other things, the revised regulations provided a new procedure for expedited review in urgent cases: Although HMOs would have 60 days within which to make ordinary determinations, they would have only 72 hours to make decisions where delay could seriously jeopardize the beneficiary's life, health, or functioning. See id. at 23,370-23,371; see also id. at 23,375 (adding 42 C.F.R. 417.608, 417.609). The district court concluded that a stay was warranted, reasoning that "the hardships faced by the Plaintiffs outweigh those of the Defendant, but that the entire case may become largely moot if the Secretary's attestations regarding rule changes * * * are implemented without delay." App. 68a.

3. The Secretary appealed the district court's March 3, 1997 Order. While the appeal was pending, Congress (on August 5, 1997) overhauled Medicare's statutory structure with respect to HMOs as part of the Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275. See App. 70a-101a (reproducing relevant portions).

a. Replacing Section 1395mm(g), the BBA creates new Part C of the Medicare Act and establishes the "Medicare+Choice" program. "Medicare+Choice" is designed to offer beneficiaries a widely expanded choice of alternatives to traditional fee-for-service Medicare. Those options include participation in HMOs, other private managed-care organizations, and private fee-for-service plans at government expense, and a new medical savings account

option. See 111 Stat. 276 (Section 1851(a)(2), to be codified at 42 U.S.C. 1395w-21(a)(2)); H.R. Conf. Rep. No. 217, 105th Cong., 1st Sess. 585 (1997). The new law directs the Secretary to implement the Medicare+Choice program by establishing a process through which Medicare beneficiaries can, at their option, have the Secretary acquire coverage for them through participating private healthcare organizations in place of original fees-for-services Medicare. 111 Stat. 278 (Section 1851(c)(1), to be codified at 42 U.S.C. 1395w-21(c)(1)). HMOs may not accept Medicare beneficiaries as enrollees and may not receive payments under the program absent a valid "Medicare+Choice" contract with the Secretary. See 111 Stat. 319 (Section 1857(a), to be codified at 42 U.S.C. 1395w-27(a)).

Part C provides an enhanced statutory framework -- an entire Section entitled "Benefits and Beneficiary Protections" -- to govern such issues as quality assurance, disputes over treatment, grievances and appeals. See 111 Stat. 293 (Section 1852(g), to be codified at 42 U.S.C. 1395w-22(g)). As before, HMOs must in the first instance determine for themselves whether they believe that a requested treatment is appropriate (just as they would with respect to non-Medicare enrollees). But, as a condition of participation, HMOs must provide Medicare enrollees with a prompt, clear, and understandable statement concerning adverse decisions. 111 Stat. 293 (Section 1852(g)(1), to be codified at 42 U.S.C. 1395w-22(g)(1)). As before, an enrollee dissatisfied with such a decision may seek reconsideration. But, unlike the statute before the district court, which did not prescribe a deadline for reconsideration decisions, the new statute requires HMOs to issue

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

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

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

remaining in controversy after administrative review exceeds $1000, either the HMO or the beneficiary may (if aggrieved) seek judicial review of the agency's decision. Ibid.

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

Finally, the new law eliminates the Secretary's authority to renew risk-sharing contracts under Section 1395mm(g) -- the principal statutory provision at issue in the district court -- as of January 1, 1999. 111 Stat. 328 (amending Section 1876 by adding

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

new subsection (k)(1), to be codified at 42 U.S.C. 1395mm(k)(1)).[2] We have been informed by HHS that all risk-sharing contracts entered into under Section 1395mm(g) expired effective December 31, 1998, and that no such contracts were renewed for 1999.[3]

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

Building on new Medicare Part C's enhanced procedural protections for Medicare beneficiaries, the Secretary's regulations require participating HMOs to issue prompt and understandable initial decisions and reconsideration decisions. While the BBA provides no deadline for initial HMO decisions, and the Section 13955mm regulations before the district court allowed delays of up to 60 days, the Secretary's new regulations require HMOs to make initial decisions in non-urgent cases "as expeditiously as the [beneficiary's] health condition requires, but no later than 14

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

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

calendar days after the date the organization receives the request." 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.568(a)). While the BBA (like the regulations before the district court) sets 60 days as the maximum time limit for resolution of ordinary reconsideration requests, the Secretary's new regulations now require that such decisions be made within 30 days in non-urgent cases. Id. at 35,110 (adding 42 C.F.R. 422.590(a)(2)). Finally, all HMO notices informing enrollees of denials of requested services must, among other things, state "the specific reasons for the denial in understandable language," and inform enrollees of their reconsideration and appeal rights. Id. at 35,108 (adding 42 C.F.R. 422.568(d)(1)); see also 111 Stat. 293 (Section 1852(g)(1)(B), to be codified at 42 U.S.C. 1395w-22(g)(1)(B)). The regulations before the district court, in contrast, required a statement of reasons, but did not specifically require that it be understandable to ordinary people. 42 C.F.R. 417.608 (1996); see also App. 46a-50a (criticizing prior HMO notices).

Unlike the Section 1395mm regulations before the district court, the new regulations also address the need for expedition in particular cases. Following the BBA, the Secretary's Medicare+Choice regulations provide that, where delays may threaten the health of the beneficiary, HMOs must make initial and reconsideration decisions within 72 hours of the relevant request. See 63 Fed. Reg. at 35,108-35,109 (adding 42 C.F.R. 422.572 pertaining to initial decisions); id. at 35,110 (adding 42 C.F.R. 422.590(d) pertaining to reconsideration). Moreover, where an enrollee is receiving authorized in-patient hospital care, the Secretary's new regulations provide that the HMO may not decide

that the care is unnecessary absent concurrence of the physician responsible for the in-patient treatment. Id. at 35,112 (adding 42 C.F.R. 422.620(b)). Even then, the enrollee may seek immediate review from an independent peer review organization, and the care may not be discontinued until that organization issues its decision. Id. at 35,112-35,113 (adding 42 C.F.R. 422.622).

The new regulations also address the HMO decisional process. Among other things, they require HMOs to afford enrollees seeking reconsideration "a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing." 63 Fed. Reg. at 35,110 (adding 42 C.F.R. 422.586). And, implementing the BBA, they provide that reconsideration decisions must be made by qualified medical personnel in appropriate circumstances and by personnel other than the individuals who made the initial decision. Id. at 35,111 (adding 42 C.F.R. 422.590(g)(1) and (2)). Finally, any disputed reconsideration decision by an HMO must be referred to an independent outside review organization that acts, under contract, as an agent of the Secretary. Id. at 35,111 (adding 42 C.F.R. 422.592); 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)). An enrollee dissatisfied with the result of the outside review organization's decision may seek a hearing before an ALJ, and either the enrollee or the HMO may seek administrative review before the DAB, and judicial review, as set forth and subject to the limits provided by statute. See pp. __-__, supra.[4]

[4] The statute and regulations also provide mechanisms for monitoring and enforcing HMO compliance with grievance and appeal requirements. The statute, for example, requires HMOs to establish

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

The court of appeals held that a private HMO's decision to reduce or deny services constitutes government action. The court explained that, to establish government action, the plaintiff must show that "there is a sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself." App. 8a (quoting Blum v. Yaretsky, 457 U.S. 991, 1004 (1982)). It further noted that, while government regulation is not by itself sufficient to attribute private action to the government, "[g]overnment action exists if there is a symbiotic relationship

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and maintain provisions for monitoring and evaluating both clinical and administrative aspects of health plan operations, and the regulations make clear that such "quality assurance" programs must monitor and evaluate the grievance and appeal process. See 111 Stat. 291 (Section 1852(e), to be codified at 42 U.S.C. 1395w-22(e)); 63 Fed. Reg. at 35,082 (adding 42 C.F.R. 422.152). In addition, the Secretary may treat an HMO's failure to comply substantially with appeal and grievance provisions as a ground for terminating its contract. 63 Fed. Reg. at 35,104 (adding 42 C.F.R. 422.510).

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

with a high degree of interdependence between the private and public parties such that they are 'joint participant[s] in the challenged activity.'" Id. at 8a-9a (quoting Burton v. Wilmington Parking Author., 365 U.S. 715, 725 (1961)).

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

by the district court. App. 12a-18a.

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

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

REASONS FOR GRANTING THE PETITION

Affirming the district court's issuance of a detailed and

highly prescriptive nationwide injunction, the Ninth Circuit in this case held (1) that Health Maintenance Organizations and similar healthcare organizations (HMOs) engage in government action when they deny Medicare enrollee requests for services and (2) that the HMO procedures required by the Secretary's now statutorily-superseded regulations under 42 U.S.C. 1395mm were insufficient to meet the requirements of due process. Those rulings and their practical consequences are of broad significance in the administration of the Medicare Program and ordinarily would warrant plenary review by this Court. The legal issues presented by this case, however, are similar to those before this Court in American Manufacturers Mutual Insurance Co., et al. v. Sullivan, et al., No. 97-2000 (argued Jan. 19, 1999). Accordingly, we suggest that the petition in this case be held pending the Court's decision in that case.

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

Court vacate the judgment of the court of appeals and remand the case with directions to (1) vacate the judgment of the district court and (2) remand the case to that court for consideration of any challenges respondents might raise to the new statute and its implementing regulations in light of the decision in Sullivan.

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

1. The Fifth Amendment's prohibition against deprivations of property without due process does not apply to purely private conduct; it applies only where the actor is governmental, or the conduct can be fairly attributed to the government. NCAA v. Tarkanian, 488 U.S. 179, 191 (1988); Jackson v. Metropolitan Edison Co., 419 U.S. 345, 349 (1974). Concluding that the decisions of otherwise private HMOs to reduce or deny treatments are properly attributed to the federal government, the Ninth Circuit reasoned that the federal government and the HMOs "are essentially engaged as joint participants to provide Medicare services." App. 9a. In particular, the Ninth Circuit found "a symbiotic relationship with a high degree of interdependence," ibid., because the "Secretary extensively regulates the provision of Medicare services by HMOs"; HMOs must "comply with all federal laws and regulations"; the Secretary pays HMOs "for each enrolled Medicare beneficiary (regardless of the services provided)"; and the "federal government has created the legal framework -- the standards and enforcement mechanisms -- within which HMOs must operate, id. at 10a.

The Ninth Circuit's analysis departs from this Court's established approach to the "fair attribution" and "government action" inquiries. In determining whether otherwise private

conduct "is governmental in character," this Court normally looks to (1) "the extent to which the actor relies on governmental assistance" or the government's coercive powers in effectuating its will, (2) "whether the actor is performing a traditional governmental function," (3) and "whether the injury caused is aggravated in a unique way by the incidents of governmental authority." Edmonson v. Leesville Concrete Co., 500 U.S. 614, 621-622 (1991); see Blum v. Yaretsky, 457 U.S. 991, 1004 (1982) (government "normally can be held responsible for a private decision only when it has exercised coercive power or has provided such significant encouragement * * * that the choice must in law be deemed to be that of the [government]"); Jackson, 419 U.S. at 353 (government action may be found where a private entity exercises functions that are "traditionally the exclusive prerogative of the State."). The Ninth Circuit looked at none of those "three principles," Edmonson, 500 U.S. at 622, and none of them supports the Ninth Circuit's holding.

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

medical services are provided." 42 U.S.C. 1395.[6]

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

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

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

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

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

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

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

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

d. At bottom, the Ninth Circuit's decision to attribute HMO decisions and conduct to the federal government appears to have rested primarily on the "rather vague generalization," Blum, 457 U.S. at 1010, that there was a "high degree of interdependence" and a "symbiotic relationship," App. 9a, that made the government "a joint participant in the challenged activity." Burton v. Wilmington Parking Auth., 365 U.S. 715, 725 (1961). The facts the Ninth Circuit relied upon for that conclusion, however, are largely common to heavily regulated industries. See App. 10a (relying on the facts that the "Secretary extensively regulates," that "HMOs are required * * * to comply with all federal laws," that the Secretary is obligated to ensure that "HMOs provide * * * meaningful * * * procedures," that the "federal government has created the legal framework," and that the Secretary has adjudicatory authority with respect to HMO decisions). Even the most intensive governmental regulation of an industry is an insufficient basis for attributing otherwise private decisions and

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[8] Nor does it make a difference that the government pays the HMO a flat, monthly rate for each covered Medicare beneficiary. See Blum, 457 U.S. at 1011 (rejecting contention that decisions made by physicians and nursing homes are attributable to the State, despite "state subsidization of the operating and capital costs of the facilities" and coverage for "the medical expenses of more than 90% of the patients"). That the government pays for coverage neither encourages HMOs to deny requests for treatment, nor prevents the financial impact of HMO decisions from being visited exclusively on the HMO. If the fact that the government pays for coverage were a sufficient basis for attributing HMO conduct to the government, HMOs providing services to government employees under the Federal Employees Health Benefits Act of 1959, 5 U.S.C. 8901 et seq., would also all be government actors.

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

2. The Ninth Circuit's due process holding is also inconsistent with this Court's decisions. Rejecting the Secretary's request that her view of the appropriate and meaningful procedures be accorded substantial weight, the Ninth Circuit declared that there is "nothing in Mathews v. Eldridge or subsequent cases to suggest that such is necessary or advisable." App. 13a n.3. That was error: Mathews v. Eldridge, 424 U.S. 319, 349 (1976) expressly states that, "[i]n assessing what process is due * * * substantial weight must be given to the good-faith judgments of the individuals charged by Congress with the administration of social welfare programs that the procedures they have provided assure fair consideration."

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

errs is to "remand to the agency").[9]

3. Government action and due process questions very similar to those raised in this case are currently before the Court in American Manufacturers Mutual Insurance Co., et al. v. Sullivan, et al., No. 97-2000 (argued Jan. 19, 1999). There, the court of appeals held that payment decisions made by workers' compensation insurers, as permitted by state law, were both attributable to the State and inconsistent with due process. See Sullivan v. Barnett, 139 F.3d 158 (3d Cir. 1998). Not only are the court of appeals decisions in Sullivan and in this case remarkably similar,[10] but the precise arguments that the Sullivan petitioners made in support of reversal there apply with equal force in this case as well.[11]

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

[10] Neither court of appeals decision examines the three state-action "principles" identified in Edmonson, 500 U.S. at 622, and traditionally relied upon by this Court, see pp. __-__, supra, and both predicate a finding of government action largely on the government's regulatory role. Compare Sullivan, 139 F.3d at 168, with App. 9a-10a.

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

Indeed, so closely related are the cases that lead counsel in this case filed an amicus brief in Sullivan, emphasizing the potential impact of the Court's decision there on the Medicare program at issue here.[12] Accordingly, we suggest that the petition be held pending the decision in Sullivan.

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

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

On August 5, 1997, however, Congress comprehensively reformed this area of law -- enacting the new Medicare Part C and establishing the new "Medicare+Choice" program. See Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275. At the time the district court ruled, the governing statute merely required that HMOs provide "meaningful procedures for hearing and resolving grievances." 42 U.S.C. 1395mm(c)(5)(A). Neither that statutory provision nor the regulations promulgated

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required); see also Lyng v. Payne, 476 U.S. 926, 942 (1986) (noting that the Court has not resolved whether "applicants for benefits, as distinct from those already receiving them, have a legitimate claim of entitlement protected by the Due Process Clause").

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

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

The new statute and the Secretary's regulations promulgated thereunder, however, dramatically expand the procedural and substantive protections afforded to Medicare beneficiaries enrolled in private HMOs. Indeed, Congress gave specific attention to the sorts of procedures it considered necessary to protect beneficiary rights, enacting a section of new Medicare Part C entitled "Benefits and Beneficiary Protections." 111 Stat. 286 (Section 1852, to be codified at 42 U.S.C. 1395w-22). Consequently, the new statute and the implementing regulations it required the Secretary to promulgate now separately address the alleged deficiencies identified by the lower courts. See pp. __-__, supra. Among other things, they specifically require HMOs to issue understandable notices of decision, 111 Stat. 293 (Section 1852(g)(1), to be codified at 42 U.S.C. 1395w-22(g)(1)); 63 Fed. Reg. 35,108 (1998) (adding 42 C.F.R. 422.568(d)); they provide that medical necessity decisions must be made by qualified medical personnel, 111 Stat.

293 (Section 1852(g)(2)(B), to be codified at 42 U.S.C. 1395w-22(g)(2)(B)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.590(g)(2)); and they mandate prompt initial decisions (within 14 days) and reconsideration decisions (within 30 days) in all cases, and expedited decisions (within 72 hours) if delay could jeopardize the health of the beneficiary. 63 Fed. Reg. at 35,108-35,110 (adding 42 C.F.R. 422.568(a), 422.572, 422.590(a)-(d)); 111 Stat. 293-294 (Sections 1852(g)(2) and (3), to be codified at 42 U.S.C. 1395w-22(g)(2) and (3)).[13] Moreover, HMO determinations adverse to the enrollee are subject to automatic review by an independent, third-party acting as the Secretary's agent, 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.592)), and dissatisfied beneficiaries may obtain a hearing before an ALJ and judicial review, as provided and subject to the limits set forth in the statute. See pp. __-__, supra.[14]

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

[14] Although these new provisions address most areas covered by the district court injunction, they take a fundamentally different approach to several key issues. For example, the Secretary's expedition provisions are more favorable to beneficiaries inasmuch as they require reconsideration decisions within three calendar days, see p. __, supra, whereas the district court's order requires such decisions in three working days, App. 62a. While the district court required that detailed written notices of initial decisions be provided within five days even where the beneficiary's health is not in imminent jeopardy, and Congress specified no specific time frame in such cases, see H.R. Conf. Rep. No. 217, 105th Cong, 1st Sess. 65 (1997) (noting that Congress left that issue to the Secretary), the Secretary selected a 14-day deadline, 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.568(a)). Finally, although the

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

Under circumstances such as these, the Court has "set aside the judgment of the Court of Appeals with direction to enter a new judgment setting aside the order of the District Court and remanding to that court for such further proceedings as may be appropriate in light of the supervening event." McLeod v. General Electric, 385 U.S. 533, 535 (1967) (per curiam); see, e.g., Calhoun v. Latimer, 377 U.S. 263, 264 (1964) (per curiam) ("vacat[ing] the judgment and remand[ing] the cause to the District Court for further proceedings" to consider "the nature and effect" of a

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Secretary has required certain in-patient hospital services to continue during the pendency of an administrative appeal, she did not extend similar requirements to a broad, unspecified range of "acute care" services. Compare App. 63a, with 63 Fed. Reg. at 35,112-35,113 (adding 42 C.F.R. 422.620(b), 422.622).

supervening change in school board policy); Heckler v. Lopez, 469 U.S. 1082 (1984) (vacating judgment and remanding case "to the Court of Appeals to be remanded to the * * * District Court" for appropriate action in light of new legislation); see also United States Dep't of the Treasury v. Galioto, 477 U.S. 556, 559-560 (1986) (vacating judgment on direct appeal and remanding to district court because a new "enactment significantly alter[ed] the posture of th[e] case"). As the Court explained in Lewis v. Continental Bank Corp., 494 U.S. 472, 482 (1990), "in instances where mootness is attributable to a change in the legal framework governing the case, and the plaintiff may have some residual claim under the new framework that was understandably not asserted previously, our practice is to vacate the judgment and remand for further proceedings in which the parties may, if necessary, amend their pleadings or develop the record more fully."

In fact, it may be that the new statute renders moot not merely the appeal, but the entire case as well. Certainly the subject matter on which the district court and the Ninth Circuit focused their analysis -- the procedures imposed on HMOs under Section 1395mm(g), the Secretary's implementing regulations, and HMO conduct thereunder, see App. 35a-40a, 46a-50a (district court); id. at 3a-5a, 13a (court of appeals) -- no longer forms a legitimate basis for judicial relief. The new statute eliminates the Secretary's authority to enter into risk contracts under Section 1395mm(g), and no such contracts were renewed for 1999. See pp. __-__, & n.__, supra. As a result, the regulations and notice and appeal procedures that were before the district court are without force or effect; they protections required by the new

Medicare Part C Medicare+Choice control instead. Princeton Univ. v. Schmid, 455 U.S. 100, 103 (1982) (per curiam) (where "the regulation at issue is no longer in force" and the "lower court's opinion" does not "pass on the validity of the revised regulation," the "case has lost its character as a present, live controversy of the kind that must exist if we are to avoid advisory opinions on abstract questions of law.").[15] Moreover, the conduct that respondents challenged and the lower courts found unconstitutional (e.g., the allegedly inadequate notice and time limits) are now addressed by the new statute and regulations. See Associated General Contractors, 508 U.S. at 663 n.3 (cases moot where "the statutes at issue * * * were changed substantially, and * * * there was therefore no basis for concluding that the challenged conduct was being repeated."); Bowen v. Kizer, 485 U.S. 386, 387 (1988) (per curiam) (new legislation that provides the relief sought by

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

the plaintiffs renders lawsuit moot).[16]

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

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

CONCLUSION

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

Respectfully submitted.

SETH P. WAXMAN
Solicitor General

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

FEBRUARY 1999

Marcus

THE WHITE HOUSE

WASHINGTON

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.

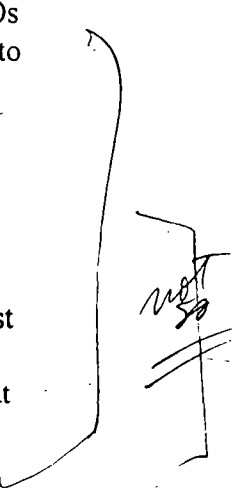
Discussion and Options

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.

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1-27-99

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 uphold 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.

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

"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 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