

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. note	re: phone number (1 page)	n.d.	P6/b(6)
002. report	re: Sullivan v. Barnett (5 pages)	n.d.	P5 <i>DMS 4/6/15</i>
003. report	re: Sullivan v. Barnett (5 pages)	02/09/1999	P5 <i>DMS 4/6/15</i>

COLLECTION:

Clinton Presidential Records
 Domestic Policy Council
 Devorah Adler
 OA/Box Number: 20469

FOLDER TITLE:

Grijalva [Folder 4]

2012-0463-S

rc766

RESTRICTION CODES

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

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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C. Closed in accordance with restrictions contained in donor's deed of gift.

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Freedom of Information Act - [5 U.S.C. 552(b)]

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- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Summary of Facts Surrounding Medicaid Managed Care

- Number of Beneficiaries in Medicaid Managed Care -- 15,068,000
- Percentage of Beneficiaries in Medicaid Managed Care -- Approximately 47%
- Of those in Managed Care, Percentage in Mandatory Managed Care -- Probably over 90%
- Only WY, AK and CT do not have either a 1915(b) or 1115 waiver.
- Through an informal survey, States provided HCFA with a preliminary answer to the question, "Does your State allow a beneficiary direct access to a State fair hearing rather than first requiring exhaustion of internal MCO grievance procedures?"
 - ▶ Of the responses to this question, approximately 60% of the States answered yes.
 - ▶ Of the States that answered yes, approximately 40% reported that the State encourages, but does not require, beneficiaries to first exhaust the MCO's internal grievance procedures.

DRAFT

One Theory of How to Think About Medicaid Notice and Appeal Rights

This document is only intended to help facilitate a general discussion on theories of notice and appeal rights. This document is not meant to convey a position on these issues.

- Recipients of certain statutorily created federal benefits, such as Medicaid benefits, have constitutionally protected property interests. Due process must be afforded to an individual at risk of being deprived of such a property interest.
- The government is constitutionally obligated to ensure that a recipient is afforded due process when s/he is threatened with deprivation of Medicaid benefits. It is not legally consequential whether the point of contact with the recipient (in this instance, the provider of Medicaid services) is a private or a state actor. Even if the point of contact with a recipient is a private actor, it is incumbent upon the government to ensure that due process is afforded. That could be achieved through regulations governing provider participation in the Medicaid program or, for example, through a contractual mandate on any private actor. The government cannot contract away or otherwise wall itself off from its constitutional obligations.
- Once it is established that due process must be afforded, the balancing test in Mathews v. Eldridge determines what process is due. In that case, the Supreme Court observed, with respect to benefits such as the cash assistance benefits at issue in Goldberg v. Kelly, that greater constitutional protections may be warranted where the interest at stake is held by recipients who are eligible for the benefit because of their low income status. Being poor (if that is not a qualification for the benefit at issue) does not entitle one to enhanced process protections. Need, perhaps "brutal need," must be a program-qualifying factor. This analysis may argue for extension of enhanced protection to Medicaid beneficiaries.
- Case law can be read to indicate that due process must be afforded once a recipient has been deemed "eligible" for the benefits at issue. Before that point, an individual has no property interest in the benefit. Thus, with respect to Medicaid benefits, if one argues by analogy from Sullivan, not only must a recipient meet Medicaid program eligibility requirements, but also the item or service in question must be deemed to be reasonable and necessary (or meet other reasonable criteria that the state imposes under 42

C.F.R. § 440.230(d)). Once a beneficiary meets all those criteria, s/he receives benefits and has a property interest in their continued receipt. Once the recipient has begun receiving benefits, a reduction or termination of those benefits is subject to due process requirements.

- The process due someone for denial of an initial application for benefits is not as recently affirmed as the process due for termination of a benefit.
- This summary begs an important question: Will courts determine that ongoing services (e.g., home health services for recipients whose medical conditions are expected to and do improve) are actually the result of a series of applications for benefits (applications measured by whether the applicant is not only still income eligible but also by whether the services are still medically necessary)? If so, what process would such courts say is required?
- It would be useful to hear your views about constitutional theories of when due process notice and hearing rights are triggered and what process is required at various stages (if process rights differ at all from point to point).

DRAFT -- INTERNAL USE ONLY -- DRAFT

(Cover Note. This would just go out under a fax cover sheet addressed to the individual.)

I appreciate your willingness to be a part of a consultative discussion on due process issues related to Medicaid, and I look forward to hearing from you on this complicated topic.

As you know, the meeting is scheduled for Friday, March 25th at 10:00am, and it will be held at the Department of Health and Human Services, 200 Independence Ave., SW. After you arrive, you will need to call my office (690-6726) from the security desk in order to be signed in as a visitor. The meeting will be held in room 505A.

Attached, please find some brief facts on Medicaid Managed Care, as well as a paper that discusses one theory of how due process rights apply to Medicaid. I hope that you will review this material and share with us other facts that may be relevant to these issues and other theories that will help inform our thinking on due process in Medicaid.

Unfortunately, I will not be able to attend the meeting on Friday as I have been requested to testify at a hearing. This request was received only yesterday, March 24th. However, in my absence, Harriet Rabb, the Department's General Council, will chair the meeting. In addition, Gary Claxton and Jane Horvath will attend from the Department along with Sally Richardson, Carol Cronin, and Bob Berenson from HCFA.

Again, thank you for agreeing to meet with us. I know that this discussion will be very helpful for us, and I hope that it will be helpful for you as well.

reasonable & necessary issue
property interest exist?

doesn't distinguish between Mcare & Medicaid?

- | | |
|----------------|-------------|
| Gordon | Bridgett |
| Tim W. | Kristen |
| Judy W. | Cindy Manh. |
| Andy Schneider | |
| Cybele | |

tomorrow at 10am
505A

DRAFT

**Summary of
Facts Surrounding Medicaid Managed Care**

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DRAFT

TEMPLATE FOR DISCUSSION: MEDICAID NOTICE & APPEAL RIGHTS

- Recipients of certain statutorily created federal benefits, such as Medicaid benefits, have constitutionally protected property interests. Due process must be afforded to an individual at risk of being deprived of such a property interest.
- The government is constitutionally obligated to ensure that a recipient is afforded due process when s/he is threatened with deprivation of Medicaid benefits. It is not legally consequential whether the point of contact with the recipient (in this instance, the provider of Medicaid services) is a private or a state actor. Even if the point of contact with a recipient is a private actor, it is incumbent upon the government to ensure that due process is afforded. That could be achieved through regulations governing provider participation in the Medicaid program or, for example, through a contractual mandate on any private actor. The government cannot contract away or otherwise wall itself off from its constitutional obligations.
- Once it is established that due process must be afforded, the balancing test in Mathews v. Eldridge determines what process is due. In that case, the Supreme Court observed, with respect to benefits such as the cash assistance benefits at issue in Goldberg v. Kelly, that greater constitutional protections may be warranted where the interest at stake is held by recipients who are eligible for the benefit because of their low income status. Being poor (if that is not a qualification for the benefit at issue) does not entitle one to enhanced process protections. Need, perhaps "brutal need," must be a program-qualifying factor. This analysis may argue for extension of enhanced protection to Medicaid beneficiaries.
- Case law indicates that due process must be afforded once a recipient has been deemed "eligible" for the benefits at issue. Before that point, an individual has no property interest in the benefit. [Thus, with respect to Medicaid benefits, not only must a recipient meet Medicaid program eligibility requirements, but also the item or service in question must be deemed to be reasonable and necessary (or meet other reasonable criteria that the state imposes under 42 C.F.R. § 440.230(d)).] *
Once a beneficiary meets all those criteria, s/he receives benefits and has a property interest in their continued receipt. Once the recipient has begun receiving benefits, a reduction or termination of those benefits is subject to due process requirements.
- The process due someone for denial of an initial application for benefits is not as

recently affirmed as the process due for termination of a benefit.

- This summary begs an important question: Will courts determine that ongoing services (e.g., home health services for recipients whose medical conditions are expected to and do improve) are actually the result of a series of applications for benefits (applications measured by whether the applicant is not only still income eligible but also by whether the services are still medically necessary)? If so, what process would such courts say is required?
- HCFA is particularly interested in hearing other constitutional theories about when due process notice and hearing rights are triggered and what process is required at various stages (if process rights differ at all from point to point).

**PHOTOCOPY
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No.

In the Supreme Court of the United States

OCTOBER TERM, 1998

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

v.

GREGORIA GRIJALVA, ET AL.

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

PETITION FOR A WRIT OF CERTIORARI

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In the Supreme Court of the United States

OCTOBER TERM, 1998

No.

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

PETITION FOR A WRIT OF CERTIORARI

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

OPINIONS BELOW

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

JURISDICTION

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

STATUTORY AND REGULATORY PROVISIONS INVOLVED

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

STATEMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

that all risk-sharing contracts entered into under Section 1395mm(g) expired effective December 31, 1998, and that no such contracts were renewed for 1999.³

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

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

after January 1, 1999, the Secretary shall not renew any such contract." 111 Stat. 828 (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.

made within 30 days in non-urgent cases. *Id.* at 35,110 (adding 42 C.F.R. 422.590(a)(2)). Finally, all HMO notices informing enrollees of denials of requested services must, among other things, state "the specific reasons for the denial in understandable language," and inform enrollees of their reconsideration and appeal rights. *Id.* at 35,108 (adding 42 C.F.R. 422.568(d)(1)); see also 111 Stat. 293 (Section 1852(g)(1) (B), to be codified at 42 U.S.C. 1395w-22(g)(1)(B)). The regulations before the district court, in contrast, required a statement of reasons, but did not specifically require that it be understandable to ordinary people. 42 C.F.R. 417.608 (1996); see also App. 46a-50a (criticizing prior HMO notices).

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

The new regulations address other aspects of the HMO decisional process as well. Among other things, they require HMOs to afford enrollees seeking reconsideration "a reasonable opportunity to present evidence and allegations of

fact or law, related to the issue in dispute, in person as well as in writing." 63 Fed. Reg. at 35,110 (adding 42 C.F.R. 422.586). And, implementing the BBA, they provide that reconsideration decisions must be made by qualified medical personnel in appropriate circumstances, and by personnel other than the individuals who made the initial decision. *Id.* at 35,111 (adding 42 C.F.R. 422.590(g)(1) and (2)).⁴

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

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

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

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

between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself." App. 8a (quoting *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982)). It further noted that, while government regulation is not by itself sufficient to attribute private action to the government, "[g]overnment action exists if there is a symbiotic relationship with a high degree of interdependence between the private and public parties such that they are 'joint participant[s] in the challenged activity.'" *Id.* at 8a-9a (quoting *Burton v. Wilmington Parking Auth.*, 365 U.S. 715, 725 (1961)).

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

Secretary's pre-April 1997 regulations was less than their constitutional due, largely for the reasons given by the district court. App. 12a-18a.

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

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

REASONS FOR GRANTING THE PETITION

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

quests for services, and (2) that the HMO procedures required by the Secretary's now statutorily-superseded regulations under 42 U.S.C. 1395mm were insufficient to meet the requirements of due process. Those rulings and their practical consequences are of broad significance in the administration of the Medicare Program and ordinarily would warrant plenary review by this Court. The legal issues presented by this case, however, are similar to those before this Court in *American Manufacturers Mutual Insurance Co., et al. v. Sullivan, et al.*, No. 97-2000 (argued Jan. 19, 1999). Accordingly, we suggest that the petition in this case be held pending the Court's decision in *Sullivan*.

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

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

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

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

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

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

Significantly here, the relationship between an HMO and its Medicare-beneficiary members is the product of a private choice by those members. Medicare beneficiaries may choose among providers and forms of coverage, and the government neither requires them to enroll in an HMO nor precludes them from 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. With respect to each, the HMO simply determines what treatment is appropriate under its professional and contractual obligations, without government participation or assistance.⁶ And although money is paid out of the Medicare

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

rights, enacting a section of new Medicare Part C entitled "Benefits and Beneficiary Protections." 111 Stat. 286 (Section 1852, to be codified at 42 U.S.C. 1395w-22). Consequently, the new statute and the implementing regulations it required the Secretary to promulgate now separately address the alleged deficiencies identified by the lower courts. See pp. 10-12, *supra*. Among other things, they specifically require HMOs to issue understandable notices of decision, 111 Stat. 293 (Section 1852(g)(1), to be codified at 42 U.S.C. 1395w-22(g)(1)); 63 Fed. Reg. 35,108 (1998) (adding 42 C.F.R. 422.568(d)); they provide that medical necessity decisions must be made by qualified medical personnel, 111 Stat. 293 (Section 1852(g)(2)(B), to be codified at 42 U.S.C. 1395w-22(g)(2)(B)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.590(g)(2)); and they mandate prompt initial decisions (within 14 days) and reconsideration decisions (within 30 days) in all cases, and expedited decisions (within 72 hours) if delay could jeopardize the health of the beneficiary. 63 Fed. Reg. at 35,108-35,110 (adding 42 C.F.R. 422.568(a), 422.572, 422.590(a)-(d)); 111 Stat. 293-294 (Section 1852(g)(2) and (3), to be codified at 42 U.S.C. 1395w-22(g)(2) and (3)).¹¹ Moreover, HMO determinations adverse to the enrollee are subject to automatic review by an independent third party acting as the Secretary's agent, 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.592), and dissatisfied beneficiaries may obtain a hearing before an ALJ

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

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

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

¹² Although these new provisions address most areas covered by the district court's injunction, they take a fundamentally different approach to several key issues. For example, the Secretary's expedition provisions are more favorable to beneficiaries inasmuch as they require reconsideration decisions within three calendar days, see p. 10, *supra*, whereas the district court's order requires such decisions in three working days, App. 62a. While the district court required that detailed written notices of initial decisions be provided within five days even where the beneficiary's health is not in imminent jeopardy, and Congress specified no specific time frame in such cases, see H.R. Conf. Rep. No. 217, 105th Cong, 1st Sess. 605 (1997) (noting that Congress left that issue to the Secretary), the Secretary selected a 14-day deadline, 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.568(a)). Finally, although the Secretary has required certain inpatient hospital services to continue during the pendency of an administrative appeal, she did not extend similar requirements to a broad, unspecified range of "acute care" services. Compare 63 Fed. Reg. at 35,112-35,118 (adding 42 C.F.R. 422.620(b), 422.622), with App. 63a.

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

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

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

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

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

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

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

CONCLUSION

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

Respectfully submitted.

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FEBRUARY 1999

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

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

Significantly here, the relationship between an HMO and its Medicare-beneficiary members is the product of a private choice by those members. Medicare beneficiaries may choose among providers and forms of coverage, and the government neither requires them to enroll in an HMO nor precludes them from disenrolling. In this respect, the HMO's relationship with its Medicare-beneficiary members resembles its relationship with members who elect HMO coverage under employer-sponsored or other

This truly sounds like a defined contribution.

private health plans. With respect to each, the HMO simply determines what treatment is appropriate under its professional and contractual obligations, without government participation or assistance.¹ And although money is paid out of the Medicare Trust Funds to cover the flat monthly rate charged for the Medicare beneficiary's enrollment in the HMO, the financial consequences of a determination by the HMO to furnish or deny particular services to that beneficiary once he has enrolled are borne by the HMO alone.²

On the merits of the due process issue, the Ninth Circuit rejected the Secretary's contention that her view of the appropriate and meaningful procedures be accorded substantial weight, declaring that there is "nothing in Mathews v. Eldridge or subsequent cases to suggest that such is necessary or

¹ Indeed, the first sentence of the Medicare statute prohibits the "exercise [of] any" governmental "supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. 1395. In Blum v. Yaretsky, the Court held that the exercise of ordinary medical judgment is not state action, even where it may affect eligibility for government benefits. 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 medical services are "reasonable and necessary," 42 U.S.C. 1395y(a) -- essentially requires an exercise of medical, not legal judgment. The complaint in this case, moreover, demonstrates that respondents seek to challenge medical judgments. C.A.E.R. 10-11 (§ 29)(physical therapy denied because patient could not file therapeutic directions), 12-13 (§§ 40-41)(failure to prescribe adequate pain medication or order physical therapy), 13-15 (§§ 48-54)(skilled nursing care found not medically necessary), 16 (§ 62)(speech therapy denied because it would not be effective).

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The arguments that the Sullivan petitioners make in support of reversal there apply with equal force in this case as well.⁴

³ 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).

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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.⁵ For the foregoing reasons, we suggest that the petition in this case be held pending the decision in Sullivan.

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 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").

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

TO: Chris Jennings

DATE: 2/10/99

DEPARTMENT/OFFICE: _____

PHONE: _____

FAX: 456-5557

FROM: HARRIET S. RABB
GENERAL COUNSEL

COMMENTS: For use as
Gary explained
but not on the
record. Melissa's
office has the
all-the-record
Qs + As

PAGES INCLUDING COVER: 2

DISCUSSION POINTS – NOT ON THE RECORD

THESE ARE NOT THE PUBLIC TALKING POINTS

Q. Why go the Supreme Court now rather than back to the District Court?

A. The answer to that question have both Medicare and Medicaid components:

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

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

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

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

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

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Lynnette Williams

Deputy Assistant Secretary for Public Affairs

Phone: (202)690-7850

Fax: (202)690-5673

To: Chris Jennings / Deborah AdlerFax: 456-5557 Phone: _____Date: 2/10/99 Total number of pages sent: 5

Comments:

The following Talking Points and Qs & As address the Grigalva filing. They are not much different from the Qs & As after Robert Bar's article.

Please call should you have any additional questions or concerns.

TALKING POINTS AND Qs and As**GRIJALVA APPEAL**

February 10, 1999

Background: *The Administration has appealed a Ninth Circuit ruling in the case of Grijalva v. Shalala to the Supreme Court. In Grijalva, a nationwide class action suit, the plaintiffs challenged a since-superseded appeals process that applied when Medicare HMOs decided not to provide or arrange for services. The Administration's appeal seeks consideration of the effect of the stronger new Medicare+Choice appeals provisions.*

Talking points:

- There is no conflict between our decision to appeal the case and our support for the Patients' Bill of Rights. The Clinton Administration has always supported the right of Medicare beneficiaries to appeal decisions by their HMOs. That's why we issued regulations to ensure that Medicare beneficiaries in managed care have fair and prompt appeal rights and called on Congress to pass a Patients' Bill of Rights to ensure that all Americans have adequate procedural protections.
- We are requesting that the Supreme Court act in this case *not* because we believe that the appeal rights of beneficiaries should be diminished, but because we think that it is critical that Congress and the Administration retain the flexibility to shape appeals procedures that are tailored to the ever-changing health care environment. We also continue to have concerns about the repercussions of a ruling that essentially finds that HMOs should be considered agents of the government.
- The original *Grijalva* case was decided based on statutes and regulations that have since been replaced by new, stronger statutory and regulatory protections. The Medicare+Choice rules include some faster and more comprehensive appeal rights than the court-ordered procedures, without the same burdens and confusion on patients and providers.

GRIJALVA QUESTIONS AND ANSWERS -- February 4, 1999

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

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

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

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Background: In October 1997, the district court ruled in favor of the plaintiffs. It held that when a Medicare HMO denies or reduces a beneficiary's services, that decision by the HMO constitutes governmental action and the beneficiary is therefore entitled to due process relating to timely notice and appeal rights. Applying those principles to the Medicare appeals rules then in effect, the court found those rules inadequate and established its own appeals process as a remedy in the case. In August 1998, the appeals court affirmed the district court's ruling. Before the court of appeals issued its decision, Congress enacted the new Medicare+Choice program containing new appeals provisions. These provisions were implemented by new HCFA regulations on June 26, 1998. The court of appeals declined to consider the effect of these new provisions.

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

A: Our new regulations implementing the new Medicare+Choice law give Medicare beneficiaries enrolled in HMOs appeal rights that are, in significant ways, superior to what the *Grijalva* court ordered. For example, the court would allow plans to take up to 60 days to make service decisions, while the new HCFA rules limit the time for decision to 14 days. Medicare beneficiaries with emergency appeals have stronger protections under the new HCFA rules -- Medicare would require these appeals to be decided as fast as the medical condition of the patient requires, but never any longer than 72 hours. Under the court's procedures, even these emergency appeals could take up to 5 days.

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

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

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

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

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

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

A: The *Grijalva* court case addresses grievance and appeals within the Medicare program. Medicaid beneficiaries continue to have full appeal rights and protections under the Medicaid statute and regulations. The Clinton Administration will continue to guarantee and improve those protections. We have proposed additional important protections in regulations implementing Medicaid managed care provisions in the Balanced Budget Act (BBA). Among other things, these regulations provide for expedited decisions and reconsiderations in time-sensitive cases.

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

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

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

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

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

ROUTING AND TRANSMITTAL SLIP		DATE	February 9, 1999
TO: (Name, office symbol, room number, Agency/Post)		Initials	Date
1. Dan Marcus (via fax) confidential attorney-client and attorney work-product communication			
REMARKS: This is bare bones. The version I sent you this morning is clearly preferable, but this would be much better than not filing a petition at all.			
<small>DO NOT use this as a RECORD of agency transactions, decisions, opinions, and similar actions.</small>			
FROM: (Name, org. symbol, Agency/Post)		Room No. - Bldg.	
Seth Waxman Solicitor General Department of Justice		5712-Main DOJ	
		Phone No.	
		202-514-2201	

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⁵ See Amici Curiae American Association of Retired Persons, The Center For Medicare Advocacy, Inc., et al., Br. at 4, 7.

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

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

Background

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

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

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

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

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

Problem

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

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

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

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



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Timothy M. Westmorland
Senior Policy Fellow
Ralph G. Neas
Visiting Professor

**CASES USING A PRIVATE CAUSE OF ACTION TO
ENFORCE FEDERAL MEDICAID GUARANTEES**

The current Medicaid program is a cooperative federal-state partnership established by Title XIX of the Social Security Act. Through this program, the federal government grants funds to participating states to provide health care services, including physician and hospital care, to low income individuals. 42 U.S.C. §1396 et seq. A state's participation in Medicaid is voluntary. However, if states choose to participate, they must comply with certain requirements imposed by the Medicaid Act and regulations promulgated by the Secretary of Health and Human Services (HHS). Under 42 U.S.C. §1396a, each state must submit a plan for medical services in compliance with these guarantees.

Under the current Medicaid program, if a state does not provide a guaranteed service or fails to interpret a policy consistent with federal law, individual beneficiaries and service providers are permitted to bring suit against a state to enforce the federal guarantee and obtain a reimbursement. This accountability mechanism -- *a private right of action* -- is not created by the Medicaid statute itself, but is found at 42 U.S.C. § 1983. This section provides in part:

Every person who, under color of any statute . . . of any State . . . subjects . . . any citizen . . . to the deprivation of any rights, privileges, or immunities secured by the constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding.

Following are several examples of cases brought by individuals (acting alone or in a class) in which this private cause of action has been used effectively to ensure that states meet federal requirements and fulfill the obligations in their state plans.

Weaver v. Reagan, 886 F.2d 194 (8th Cir. 1989): The State of Missouri attempted to deny AIDS patients, who were otherwise qualified for Medicaid services, the drug AZT by passing a statute that created an "irrebuttable presumption that AZT can never be medically necessary treatment for AIDS patients . . ." However, these AIDS patients, by utilizing a private cause of action, were able to take the state to court and eventually obtain this treatment by demonstrating "the widespread recognition by the medical community and scientific literature that AZT is the only known antiviral treatment for individuals with AIDS."

to provide prescription drug coverage to severe schizophrenics suffering from intense hallucinations. One such person who qualified for Medicaid went to court to obtain an injunction so she could receive Clozapine, a drug her physician prescribed and the FDA approved. The Court's ruling allowed her immediate relief, prevented her health from deteriorating to a point at which she would need to be institutionalized, and required the state to meet its federal obligations. The private cause of action served, in this case, as a check on Kansas' effort to deny federally guaranteed services merely to save money: "To jeopardize the life of Visser in order to preserve the public fisc under the circumstances of this case is clearly contrary to the public interest."

Harris v. James, 883 F.Supp. (M.Dist.Ala. 1995): In this case, Alabama refused to provide transportation services to Medicaid beneficiaries who needed to reach providers and receive essential medical treatment. The state denied these services despite a regulation requiring that "a state plan for medical assistance under Title XIX of the Social Security Act must . . . specify that there will be provision for assuring necessary transportation of recipients to and from providers of services . . ." A person eligible for such services brought a suit, however, and forced the state to follow this federal requirement, thus avoiding the denial of guaranteed medical services and a deterioration of his medical condition.

Miller v. Whitburn, 10 F.3d 1315 (7th Cir. 1993): In this case, there was no dispute that five-year old Tiffany Miller was entitled to Medicaid benefits. She suffered from a condition known as "short-bowel syndrome," which required that she be fed intravenously through a catheter in her stomach and which, unfortunately, resulted in liver deterioration. Without a liver transplant, Tiffany was "almost certain to die." However, the State of Wisconsin refused to pay for a transplant "for one reason and one reason only: the Department [of Health] considered the procedure 'experimental'," and thus not reimbursable. Although Wisconsin argued that this decision was solely within the discretion of the state, the court disagreed, vacated the lower court's order, and ordered the district court to reexamine the propriety of the operation.

Regardless of whether one believes the Medicaid program should continue all of the guarantees now in place, or move to a system with more state control, it is imperative to recognize the integral nature of the private right of action within such a scheme. Without an efficient, reliable enforcement mechanism such as this, any federal guarantees that Congress may choose to continue will remain subject to the fiscal, moral, and political pressures of the states highlighted above. Any effort to retain important federal guarantees to medical services must, by definition, include a corresponding attempt to retain the private right of action.



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**THE PRIVATE RIGHT OF ACTION AS MEDICAID ENFORCEMENT
MECHANISM — NOT AS SUBSTANTIVE RIGHT**

The Medicaid program establishes a system in which states agree to provide health care services to indigent persons in exchange for federal funding. Although a state's participation in Medicaid is voluntary, if it chooses to receive federal funds, the state must provide specified services and comply with requirements agreed to in the Medicaid contract, as set forth in the statute and in the regulations promulgated by the Secretary of Health and Human Services.

If a state does not provide a contractual service or fails to interpret a policy consistent with federal law, individual beneficiaries and service providers may sue a state to enforce the federal guarantee. This accountability mechanism — *a private right of action* — is not created by the Medicaid statute itself, but is found at 42 U.S.C. § 1983. This section prohibits any person acting under color of state law from depriving an individual of *any* rights guaranteed in *any* federal law.

Although § 1983 was originally intended to address the *constitutional* problems of states discriminating against African-Americans, in 1980 the Supreme Court officially recognized that § 1983 provides a cause of action against anyone who infringes upon federal *statutory* rights as well. Parties bringing § 1983 claims can go to federal or state courts and have available to them the full range of legal and equitable remedies.

Scope of § 1983 Claims

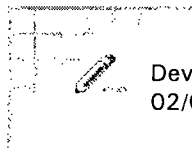
In 1990, the Supreme Court, in *Wilder v. Virginia Hospital Association*, set forth three questions for analyzing whether a statute created a clear right that could be enforced through a § 1983 action, and in 1994, Congress passed legislation codifying this approach:

- (1) Was the provision in question intended to benefit the plaintiff?
- (2) Does the provision create binding obligations on the State (or other governmental unit), rather than merely expressing a congressional preference?
- (3) Is the interest the plaintiff asserts specific enough to be enforced judicially, rather than being "vague and amorphous"?

Thus, in order to utilize the § 1983 enforcement mechanism, **Congress must have first created a substantive right.** The current Medicaid Act contains several substantive rights that can and have been enforced through a § 1983 claim:

- When the State of Kansas refused to cover under its Medicaid plan a specific drug for treating severe schizophrenia, a Medicaid patient went to court to obtain an injunction to require the state to provide the medicine. The court found in the patient's favor, based upon a Medicaid regulation prohibiting states from arbitrarily denying services due to the patient's type of illness. The court's decision allowed the patient immediate relief, preventing her health from deteriorating to a point at which she would need to be institutionalized. The private cause of action served as a check on Kansas' effort to deny federally guaranteed services merely to trim its budget. *Visser v. Taylor*, 756 F.Supp. 501 (D.Kan. 1990).
- When the State of Alabama refused to provide transportation services to Medicaid beneficiaries who needed to reach providers and receive essential medical treatment, Medicaid patients brought suit, claiming the State was in violation of a Medicaid regulation that required states to "ensure necessary transportation . . . to and from providers." By using the private right of action, the patients were able to force the state to follow this federal requirement, thus avoiding the denial of guaranteed medical services and a deterioration of their health. *Harris v. James*, 896 F.Supp. 1120 (M.Dist.Ala. 1995).
- After the U.S. Food and Drug Administration announced its approval of AZT, the State of Missouri Department of Health Services promulgated a rule that severely limited eligibility for Medicaid coverage of AZT. Medicaid patients with AIDS brought a successful § 1983 claim to challenge this rule. The court ruled in the patients' favor, citing Medicaid regulations that have been interpreted by courts as requiring state Medicaid plans to cover "medically necessary" treatments. The AZT treatments, ultimately obtained, substantially improved and prolonged lives of these patients. *Weaver v. Reagan*, 886 F.2d 194 (8th Cir. 1989).

As demonstrated above, the private right of action is **merely an enforcement mechanism, not a substantive right.** The substantive right is decided *first* by Congress. If the private right of action is *prohibited* in Medicaid reform, beneficiaries and providers will not be able to hold states accountable to comply with their federal obligations under the Medicaid program -- even if Congress mandates that Medicaid beneficiaries have these substantive rights. The complete removal of the private right of action will effectively eliminate these remaining guarantees as well.



Devorah R. Adler
02/09/99 01:57:38 PM

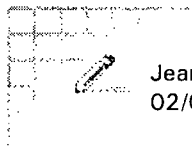
Record Type: Record

To:

cc:

Subject: response to HHS's argument about Medicaid

----- Forwarded by Devorah R. Adler/OPD/EOP on 02/09/99 01:58 PM -----



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

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Christopher C. Jennings/OPD/EOP, Devorah R. Adler/OPD/EOP

Subject: response to HHS's argument about Medicaid

From Chris as well:

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

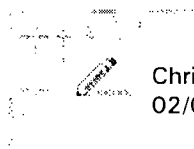
Medicaid is not that different from Medicare -- millions of Medicaid beneficiaries have a choice of managed care or fee-for-service.

- **Only 2 states have 100 percent of beneficiaries in managed care** (Tennessee and Washington). States need 1115 waivers to require Medicare-Medicaid "dual eligibles" and children with special needs to join Medicaid managed care plans. In 10 states, less than 25 percent of beneficiaries are enrolled in managed care.
- **Half (25) of states do not enroll any elderly or disabled Medicaid beneficiaries in managed care.** This, plus the choice of fee-for-service for some adults and children account for the fact that 50 percent of Medicaid beneficiaries are not enrolled in managed care.

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

managed care but not alright to take away the right of action from the healthy child.

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



Christopher C. Jennings
02/08/99 03:13:45 PM

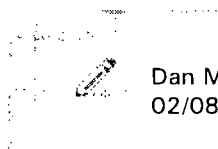
Record Type: Record

To: Devorah R. Adler/OPD/EOP

cc:

Subject: Grijalva and Medicaid

----- Forwarded by Christopher C. Jennings/OPD/EOP on 02/08/99 03:15 PM -----



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

Record Type: Record

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

cc:

Subject: Grijalva and Medicaid

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

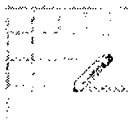


Christopher C. Jennings
02/08/99 03:13:39 PM

Record Type: Record

To: Devorah R. Adler/OPD/EOP
cc:
Subject: Re: Grijalva and Medicaid

----- Forwarded by Christopher C. Jennings/OPD/EOP on 02/08/99 03:15 PM -----



Elena Kagan
02/08/99 03:11:53 PM

Record Type: Record


To: Christopher C. Jennings/OPD/EOP
cc:
Subject: Re: Grijalva and Medicaid

----- Forwarded by Elena Kagan/OPD/EOP on 02/08/99 03:13 PM -----



Dan Marcus
02/08/99 02:51:24 PM

Record Type: Record

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

I have a call into Westmoreland. I pressed the very reluctant Mr. K re timing. Lamkin is working on it but he and Seth need to see it and the best we can do is first thing tomorrow. I will call Seth on merits of middle course. Shalala, as you point out, has come around, but only, I suspect, as an alternative to not filing at all. Certainly Rabb, whom I will talk to again, has not told Kneedler that Shalala is now convinced stripped-down is best. I may also call Seth.
Elena Kagan




Elena Kagan
02/08/99 01:14:45 PM

Record Type: Record

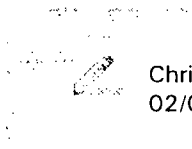
To: Dan Marcus/WHO/EOP

cc:

Subject: Re: Grijalva and Medicaid 

1. I'm not convinced. Why don't you talk with Tim Westmoreland? He's at the Georgetown legislation program -- Devorah Adler will be able to give you a number.

2. I'd like to see it by the end of the day. And I do not think that a stripped-down brief can include any explicit conclusions on the merits of the state action issue. If the SG can't write a brief without those conclusions, then we're really left with a choice between filing or not filing. And by the way, my understanding is that Shalala and Min now want a true stripped-down brief -- at least, that's what Thurm told Podesta this morning.

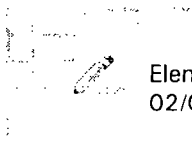


Christopher C. Jennings
02/08/99 02:51:18 PM

Record Type: Record

To: Devorah R. Adler/OPD/EOP
cc:
Subject: Re: Grijalva and Medicaid

----- Forwarded by Christopher C. Jennings/OPD/EOP on 02/08/99 02:52 PM -----



Elena Kagan
02/08/99 01:21:38 PM

Record Type: Record

To: Christopher C. Jennings/OPD/EOP
cc:
Subject: Re: Grijalva and Medicaid


I responded by asking him to call westmoreland and telling him that this was not my idea of a stripped-down brief.

----- Forwarded by Elena Kagan/OPD/EOP on 02/08/99 01:22 PM -----



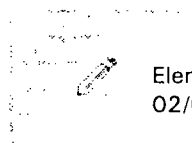
Dan Marcus
02/08/99 12:58:07 PM

Record Type: Record

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

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

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




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

Record Type: Record

To: Dan Marcus/WHO/EOP

cc:

Subject: Re: Grijalva and Medicaid 

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

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