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No.

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

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

v.

GREGORIA GRIJALVA, ET AL.

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

PETITION FOR A WRIT OF CERTIORARI

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PARTIES TO THE PROCEEDINGS

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

QUESTIONS PRESENTED

Before 42 U.S.C. 1395mm(g) was superseded, it authorized the Secretary of Health and Human Services to enter into contracts with private health maintenance organizations and similar healthcare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

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

The questions presented by this case are:

1. Whether the decision by a Section 1395mm(g) HMO to deny an enrolled Medicare beneficiary's request for health services constitutes government action subject to the requirements of the Due Process Clause of the Fifth Amendment.
2. Whether the district court properly issued an injunction, creating new procedural requirements that HMOs must follow and the Secretary must enforce through Section 1395mm(g) contracts, on due process grounds.
3. Whether Congress's enactment of new Medicare Part C, which eliminates the Secretary's authority to contract under Section 1395mm(g) and establishes a new "Medicare+Choice" program that provides greatly enhanced procedural protections for Medicare beneficiaries enrolled in HMOs, renders the current appeal moot or otherwise warrants an order vacating the judgment below with directions to remand the matter to district court for consideration of the effect of the new statutory and regulatory scheme.

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PETITION FOR A WRIT OF CERTIORARI

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

OPINIONS BELOW

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

JURISDICTION

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

STATUTORY AND REGULATORY PROVISIONS INVOLVED

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

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

STATEMENT

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

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

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

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

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

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

2. Respondents have been certified as the named

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

new subsection (k)(1), to be codified at 42 U.S.C. 1395mm(k)(1)).² We have been informed by HHS that all risk-sharing contracts entered into under Section 1395mm(g) expired effective December 31, 1998, and that no such contracts were renewed for 1999.³

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

Building on new Medicare Part C's enhanced procedural protections for Medicare beneficiaries, the Secretary's regulations require participating HMOs to issue prompt and understandable initial decisions and reconsideration decisions. While the BBA provides no deadline for initial HMO decisions, and the Section 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

REASONS FOR GRANTING THE PETITION

Affirming the district court's issuance of a detailed and

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

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

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

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

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

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

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

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

medical services are provided." 42 U.S.C. 1395.⁶

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

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

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

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

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

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

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

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

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

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

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

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

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

errs is to "remand to the agency").⁹

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the plaintiffs renders lawsuit moot).¹⁶

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

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

33

CONCLUSION

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

Respectfully submitted,

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FEBRUARY 1999

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

RUTH HEALEY, et al.,

Plaintiffs,

v.

DONNA SHALALA, Secretary of
the United States Department
of Health and Human Services,
Defendant.

CIVIL NO. 3:98CV00418(DJS)

June 17, 1999

MEMORANDUM IN SUPPORT OF
DEFENDANT'S MOTION FOR SUMMARY JUDGMENTPRELIMINARY STATEMENT

Congress contemplated a Medicare system in which eligible elderly and disabled individuals would receive medical services from private providers. As with other fee-for-service benefits, home health services are provided to Medicare beneficiaries by private home health agencies ("HHAs") and the beneficiaries are entitled to have payment made, on their behalf, for covered services. Private HHAs may make changes in patients' services for any number of reasons including physician orders, patient hospitalization, patient noncompliance with self care responsibilities, patient abuse of health care provider staff, and lack of clinical resources at the home health agency. Most important for the purposes of this action, HHAs may make changes in care because they believe that the requested services may not or may no longer be covered by Medicare. In such cases, HHAs must inform the patient of the HHA's opinion that services may not or may longer be covered. If the HHA fails to do so, it will be liable for the costs of care if it

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knew or should have known the care would not be covered. Once the patient has been informed of potential changes in coverage, under the fee-for-service system established by Congress, the patient may decide whether he wishes to obtain the services, knowing that he may be liable for the costs of the services if the Health Care Financing Administration ("HCFA") later determines that the services are not covered.

In this lawsuit, plaintiffs ask the Court to hold the Secretary responsible for the actions of the private HHAs when they make changes in care, on their own initiative, on the ground that, in the HHAs' opinion, the requested services will not be covered under the Medicare program. Even though HHAs are not obligated by their agreements with HCFA to provide specific services to specific patients, plaintiffs request the Secretary to require HHAs to implement burdensome additional procedural requirements before HHAs can take such actions. In the first instance, HHAs are not "state actors" when they take such actions and due process protections do not apply to their conduct. Under controlling Supreme Court precedent, the decisions of private entities -- even decisions relating to government sponsored public benefits programs -- do not constitute, government action unless there is a nexus between the private conduct and the government or the government has compelled, coerced or directed the private action. Although HHAs are required to inform beneficiaries when they believe that services may not or may no longer be covered, their decisions to make changes in the care that they provide are wholly private actions based on their own experience and liability assessments.

In addition, Medicare patients do not have a constitutionally protected property interest in a continuous stream of Medicare benefits. The Medicare statute and regulations place significant

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limitations on a beneficiary's entitlement to coverage. Indeed, even a doctor's prescription for home health services does not bind HCFA to cover those services. The Medicare program contemplates that coverage will be determined on a claim by claim basis. Until there has been a finding that a beneficiary meets all the criteria for coverage, no property interest attaches.

Finally, the additional procedures plaintiffs demand are not required or appropriate. Extensive, and constitutionally sufficient safeguards already are in place. HHAs are required by statute, regulation, and Medicare program rules to provide beneficiaries with notice when they believe that services may not or may no longer be covered, and HCFA is in the process of designing a new and improved notice which will be implemented soon. Moreover, HCFA has established a process under which home health beneficiaries may receive disputed services and obtain an official Medicare determination of coverage. The additional procedures plaintiffs demand will do little, if anything, to diminish the risk of erroneous deprivation of coverage, and will impose substantial burdens on the government.

In essence, plaintiffs are asserting that neither an HHA nor HCFA may make any change in their care, even in the frequency of visits by a home health aide, without first providing the patient with constitutional notice and a full hearing, as well as continuing coverage throughout the appeals process. Neither the Medicare act nor the Constitution confers any such rights. Moreover, the relief plaintiffs request is inconsistent with the very nature of the fee-for-service system established by Congress. The Court should resist plaintiffs' plea to redesign the program.

BACKGROUND

A. The Medicare Program

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The federal Medicare program, Social Security Act, title XVIII, 42 U.S.C. §§ 1395-1395xx, provides federal reimbursement for covered medical care provided to the elderly and disabled. Medicare Part A provides hospital insurance coverage for the costs incurred by eligible beneficiaries for hospital care, extended care and related home health care. See Isaacs v. Bowen, 865 F.2d 468, 470 (2d Cir. 1988) (citing 42 U.S.C. §§ 1395c to 1395i-2). Medicare Part B is a voluntary supplementary medical insurance program in which eligible beneficiaries who pay a monthly premium are entitled to reimbursement for physicians' and other medical services. Id. (citing 42 U.S.C. §§ 1395j to 1395w). The Medicare program is not a need-based program; that is, eligibility is not dependent upon a beneficiary's income or financial situation. See Kraemer v. Heckler, 737 F.2d 214 (2d Cir. 1984).

Under parts A and B of the Medicare Act, Medicare is administered like a traditional fee-for-service indemnity insurance plan.¹ HCFA evaluates the medical services after they have been rendered, according to the statutory criteria of medical "reasonableness and necessity," 42 U.S.C. § 1395y(a), and then provides reimbursement for covered medical services on a retrospective basis. Heckler v. Ringer, 466 U.S. 602, 605 (1984). In other words, a beneficiary must first received services before a coverage determination may be made.

B. The Home Health Benefit

Medicare beneficiaries are eligible to receive home health services under both parts A and

¹ Although some Medicare beneficiaries receive services, including home health services, from health maintenance organizations ("HMOs") or competitive medical plans, see 42 U.S.C. § 1395mm(g), (h), only services provided on a fee-for-service basis are at issue in this action.

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B of the Medicare program. 42 U.S.C. §§ 1395d(a)(3)(part A), 1395k(a)(2)(A)(part B). Home health services include, inter alia, items and services such as skilled nursing care, physical or occupational therapy, medical social services provided under the direction of a physician, and the services of a home health aide. See 42 U.S.C. § 1395x(m).

Under the Medicare program, a beneficiary is entitled to have payment made on his behalf for the reasonable cost of covered home health services. See 42 U.S.C. § 1395x(v). In order to be eligible for home health services, a beneficiary must establish, inter alia, that he is confined to his home, 42 U.S.C. § 1395f(a)(2)(C), requires "part-time or intermittent care," 42 U.S.C. § 1395x(m)(1) and (4), and that the care is medically "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A).

Home health services are provided under a written plan of care, prepared by the beneficiary's physician, specifying the medical treatments to be furnished and the frequency of the treatments. 42 C.F.R. § 409.43(b)(Part A); see also 42 C.F.R. § 410.80 (Part B). The plan of care must be reviewed by the physician in consultation with the HHA at least every 62 days. Id. § 409.43(e).

C. Private Home Health Agencies Provide Care

Patients receive home health services from private HHAs, which are agencies or organizations primarily engaged in providing skilled nursing services and other therapeutic services. 42 U.S.C. § 1395x(o)(1). HHAs enter into agreements with HCFA to furnish specified health care services to Medicare beneficiaries in conformity with the Medicare Act and HCFA's implementing rules. See 42 U.S.C. §§ 1395c, d & cc.

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To participate in the Medicare program, HHAs are required, inter alia, to meet "conditions of participation" specified by statute and regulation. 42 U.S.C. §§ 1395x(o); 1395bbb(a). Among other things, the conditions of participation require HHAs to "protect[] and promote[] the rights of each individual under its care * * * to be fully informed" about the care and treatment to be provided by the HHA and the Medicare coverage available for the care and treatment, as well as of any changes in service or coverage. See § 1395bbb(a).² In addition, the regulations promulgated by the Secretary include conditions of participation providing that "[t]he patient has the right to be informed in advance about the care to be furnished, and of any changes in the care to be furnished" and requiring that an HHA "must advise the patient in advance of any change in the plan of care before the change is made." 42 C.F.R. § 484.10(c)(1).

HCFA's Medicare Home Health Agency Manual, HCFA Pub. 11 (attached hereto as

² Section 1395bbb(a) provides, in pertinent part:

(1) The agency protects and promotes the rights of each individual under its care, including the following rights:

(A) The right to be fully informed in advance about the care and treatment to be provided by the agency [and] the right to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual's well-being * * *.

(E) The right to be fully informed orally and in writing (in advance of coming under the care of the agency) of --

(i) all items and services furnished by(or under arrangements with) the agency for which payment may be made under [Medicare],

(ii) the coverage available for such items and services [under the Medicare program],

(iii) any charges or items for services not covered [under the Medicare program],

(iv) any changes in the charges or items described in clauses (i), (ii), or (iii).

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exhibit __), requires HHAs to notify beneficiaries in writing if the HHA believes that services are not covered. The manual provides as follows:

Notifying Patient of Noncoverage — If you are aware that the services to be furnished to the patient are not covered, advise the patient (or his representative) in writing prior to or at the time of start of care (or at the time the type of care changes) that the care is noncovered and that no claim for Medicare reimbursement is submitted. If the beneficiary insists that you submit a claim for payment, indicate that the bill is being submitted at the beneficiary's request, and why you consider the care to be noncovered * * * *.

Establish a procedure for notifying beneficiaries and physicians promptly when a decision of noncoverage is made. The procedure should provide for written notice of noncoverage * * *.

Id. § 265.1.

In addition, HCFA's Home Health Agency Manual contains an "HHA Model Letter" for the purpose of serving as a notice to the patient that the HHA believes home health services may not or may no longer be covered. See Home Health Agency Manual § 270 (attached hereto as Exhibit __). The manual explains the model letter and identifies the information that should be included in the notice. See id.

Moreover, although the Secretary does not concede that her procedures for notice or the model letter are constitutionally insufficient, as part of a program-wide initiative to make notices more beneficiary-friendly, HCFA currently is engaged in the process of developing form notices that HHAs will be required to use when they believe that Medicare coverage may be denied from the outset, or that services will no longer be covered at all or at the same level. (Sparr Decl. ¶¶ 8-9). HCFA has drafted a proposed notice, in consultation with plaintiffs' counsel, and submitted the draft for consumer-testing. (Id. ¶ 9). Because the consumer testing revealed some potential

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problems with the notice, HCFA currently is reviewing the results of the testing and making revisions to the draft. (*Id.* ¶ 10). HCFA anticipates that the new mandatory form notice will be ready for dissemination during the summer of 1999. (*Id.*).

C. The Payment Process: Obtaining a Medicare Initial Determination

The Medicare program covers some services, when they are "medically reasonable and necessary," 42 U.S.C. § 1395y(a), and does not cover others. The Medicare statute provides that the determination of whether an individual is entitled to benefits, including home health benefits, "shall be made by the Secretary in accordance with regulations prescribed by him." 42 U.S.C. § 1395ff(a). Like other indemnity insurance plans, for beneficiaries eligible for services under Medicare's Part A and Part B, HCFA evaluates the medical services after they have been rendered, according to the statutory criteria of medical "reasonableness and necessity," 42 U.S.C. § 1395y(a), and then provides reimbursement for covered medical services on a retrospective basis. *Heckler v. Ringer*, 466 U.S. 602, 605 (1984).

Payment is typically made directly to the provider of services (here the HHA).³ See 42

³ Previously, Medicare paid HHAs based on the retrospectively-determined "reasonable costs" they incurred, up to certain limits authorized by statute, see H. Conf. Rep. No. 105-217 ("Conf. Rep."), at 806 (1997), reprinted in 1997 U.S.C.C.A.N. 176, 427; 42 U.S.C. § 1395x(v)(1)(L), provided those costs were less than prescribed per-visit limits. See 42 U.S.C. § 1395x(v)(1)(A). Responding to the dire financial condition of the Medicare trust funds and recognizing that Medicare's payments for HHA services were excessive, Congress enacted legislation to create a prospective payment system for HHAs similar to that utilized for other Medicare providers such as hospitals. See 42 U.S.C. § 1395fff. Until such a system could be developed, Congress required that HHS implement an interim payment system ("IPS"), under which HHAs are paid based on the lowest of three calculations: (1) the HHA's actual reasonable allowable costs; (2) an aggregate per-visit limit not to exceed 105% of median HHA per-visit costs; or (3) an aggregate per-beneficiary limit. See 42 U.S.C. § 1395x(v)(1)(L). Because the per-visit and per-beneficiary limits are calculated in the aggregate for each HHA, an individual

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C.F.R. § 424.51(a). In order to obtain payment, after providing services to the patient the provider submits a claim for Medicare payment to the Regional Home Health Intermediary ("RHHI"), which serves as HCFA's agent. See Kraemer v. Heckler, 737 F.2d at 216 (generally describing the role of the intermediary). To encourage providers to bill Medicare only for services that are covered under Medicare rules, providers are required to accept liability for billed noncovered services unless the providers have notified beneficiaries in advance of the provision of medical care that the provider believes the service is not covered and therefore, because Medicare is not likely to pay, the beneficiary will be liable for payment.⁴ Home Health Agency Manual § 431; Medicare Intermediary Manual, Part 3, § 3439. Thus, providers must make their own determinations whether they believe the services are covered by the Medicare program based on [the patient's condition,] their experience and the guidance on coverage from Medicare through issuances including manuals, program memoranda, and intermediary instructions. Id.

When a provider believes that a service may not or may no longer be covered by Medicare — that is, the service is not medically reasonable and necessary, or is otherwise not covered pursuant to statutory and regulatory criteria — the provider is required, as discussed above, to inform the beneficiary, in writing and prior to the service being rendered, that the provider believes that the service is not covered and that the beneficiary will be liable for

beneficiary's care or number of visits is not limited under IPS. See, e.g., 42 U.S.C. § 1395x(v)(1)(L)(ii).

⁴ Neither providers nor beneficiaries are required to accept liability when the provider did not know or have reason to know that the service was not covered. Home Health Agency Manual §§ 262.2; 268.2.

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payment if Medicare does not cover the service. 42 C.F.R. § 484.10(e). The beneficiary is then able to decide whether or not he is willing to have the service provided and a bill submitted, knowing that he will be liable for the service if the final Medicare determination is that the services are noncovered.⁵

If the beneficiary opts to have the service provided and a bill submitted to Medicare, the provider submits the bill to the RHHI as a "demand bill." A demand bill is a claim for services or items that the provider believes are not covered but which the provider must submit at the demand of the beneficiary or the beneficiary's representative. (See Giebelhaus Decl. ¶ 8). This allows the beneficiary to obtain an initial determination from the RHHI.

The initial determination is made by HCFA's contractor, the RHHI. 42 C.F.R. § 405.702. The RHHI must provide the beneficiary and, in certain cases, the provider of the services, with a notice of the initial determination in writing. Id. The notice must state in detail the basis for the determination and inform the beneficiary and, where appropriate, the provider of services, of their right to reconsideration. Id.

D. Appeal and Review Process

An individual dissatisfied with an initial determination, including a determination as to the amount of benefits, is entitled to an administrative hearing and judicial review to the extent and under the terms provided in the Social Security Act. Id. § 1395ff(b) (referencing 42 U.S.C.

⁵ For the home health benefit, the HHA may either bill the beneficiary for the disputed service after an adverse determination is received from Medicare, or the HHA may bill the beneficiary immediately and require him to pay, subsequently refunding the payment if Medicare determines that the service is covered. Intermediary Manual § 3314D.

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§§ 405(b),(g)). The Medicare regulations provide for a comprehensive administrative appeal and review process.

An individual who is a party to an initial determination may request reconsideration by HCFA by filing a request for reconsideration within 60 days after the date of receipt of the notice of initial determination. 42 C.F.R. § 405.710-11. The regulations direct HCFA to review the initial determination and the record upon which the initial determination was made, as well as any additional evidence which may be submitted or obtained. Id. § 405.715. HCFA may affirm or reverse, in whole or in part, the initial determination, and must notify the beneficiary and his representative, if any, of the reconsidered determination in writing. Id. §§ 405.715, 405.716. The notice must state the basis for the reconsidered determination and advise the party of his right to a hearing if the amount in controversy is \$100 or more. Id. § 405.716.

A party to a reconsidered determination has a right to a hearing regarding any initial determination if the amount of the controversy is \$100 or more and a request for a hearing is properly filed. 42 C.F.R. § 405.722. The hearing is held before an Administrative Law Judge. See 42 C.F.R. §§ 405.722. If the beneficiary is dissatisfied with the ALJ's decision, he or she may request review by the Departmental Appeals Board ("DAB"). Id. 405.724; 20 C.F.R. § 404.968(a)(1).

Finally, a party to a DAB decision, or an ALJ decision if the DAB does not review the ALJ decision, may seek judicial review in federal district court if the amount in controversy is \$1000 or more. 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. § 405.730. Judicial review is governed by section 205(g) of the Social Security Act, 42 U.S.C. § 405(g).

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E. Enforcement

HCFA monitors HHAs' compliance with the conditions of participation through a system of survey and certification. HCFA administers the home health survey and certification process through state survey agencies, which are usually components of state health departments. (Derville Decl. ¶ 5). The Medicare statute requires that HHAs participating in the Medicare program be surveyed not less than every 36 months. See 42 U.S.C. § 1395bbb(c)(1),(2). A survey consists of visits to the home and a review of the quality of care and services furnished by the HHA for a case-mix stratified sample of the HHAs patients. See id. § 1395(c)(2)(C); see also Derville Decl. ¶ 5. If a survey reveals deficiencies, the HHA may be subjected to an "extended survey." Id. § 1395(c)(2)(D). The Secretary has established a policy of different intervals for surveys based on [CITE] In addition to surveys conducted within the established intervals, state survey agencies may investigate beneficiary complaints, including complaints regarding the failure of an HHA to provide required notices to beneficiaries or to submit a demand bill upon request. (Derville Decl. ¶ 10).

An HHA that has failed to provide notice, use required language detailing the beneficiary's demand bill rights, or refused to submit a demand bill may be found out of compliance with the conditions of participation. (Id.) Information regarding substantiated complaints will also be forwarded to the appropriate HCFA Regional Office. (Id.). The Regional Office will then direct the HHA to take corrective action. (Id.). Providers that repeatedly fail to provide beneficiary notices or to submit demand bills when required to do so will be subject to an on-site complaint survey and possibly sanctions, including termination of

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their Medicare provider agreement, as determined appropriate by the Regional Office. (Id.). See also 42 U.S.C. §§ 1395bbb(c), 1395(f)(2)(A)(iii).

HCFA has also taken additional extraordinary steps since the implementation of IPS to ensure that beneficiaries receive adequate notice and that their demand bill rights are protected. In February, 1998, the Administrator of HCFA issued a letter informing all Medicare HHAs that any reports received concerning an HHA providing misleading information to beneficiaries regarding their coverage or inappropriately terminating beneficiaries would be considered a basis for a complaint survey that could lead to termination of the HHA from participation in the Medicare program. (Derville Decl. ¶ 6). And HCFA is in the process of developing new protocols, and will train state survey agencies, with respect to reviewing whether beneficiaries are receiving correct information regarding the extent of their liability for services not covered by Medicare and their right to have a demand bill submitted so that they may obtain a Medicare initial determination. (Id. ¶ 9).

ARGUMENT

I. PRIVATE HHAs ARE NOT STATE ACTORS.

In this lawsuit, plaintiffs ask the Court to hold the Secretary responsible for the conduct of the private HHAs that provide them with home health services. Due process principles apply only where there is "state action", not where there is merely private conduct. American Manufacturers Mutual Insurance Co. v. Sullivan, 119 S.Ct 977, 989 (1999). The government action requirement both "preserves an area of individual freedom by limiting the reach of federal law and federal judicial power" and "avoids imposing on the State, its agencies or officials

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responsibility for conduct for which they cannot fairly be blamed." Lugar v. Edmondson Oil Co., 457 U.S. 922, 936 (1982). As the Supreme Court has recognized, the distinction between private and governmental action is "well-established and easily stated," but its application in practice "frequently admits of no easy answer." Jackson v. Metropolitan Edison Co., 419 U.S. 345, 349-50 (1974). HHAs are not state actors when, on their own initiative, they make changes in care on the ground that, in the HHAs' opinion, services may not or may no longer be eligible for coverage under the Medicare program.⁶ Thus, due process protections do not attach to these actions.

A. Supreme Court Precedent Requires A Close Nexus Between Private Action and the Government Before Due Process Applies.

In Blum v. Yaretsky, 457 U.S. 534 (1982), the Supreme Court examined whether decisions initiated and made by private nursing homes to discharge or transfer Medicaid patients constituted "state action" for the purposes of due process analysis. The plaintiff class asserted that Medicaid patients were discharged or transferred from nursing homes without notice or opportunity for a hearing. Id. at 993. The Court held that the nursing homes' independent decisions to transfer beneficiaries to a lower level of care were not state action.

⁶ Of course, there are reasons other than coverage considerations why an HHA may make changes in the care it provides its patients. As the applicant for intervention in this case, the National Association for Home Care, Inc. ("NAHC"), suggests, "[c]are may be reduced or terminated for a host of reasons unrelated to Medicare coverage including: patient hospitalization or institutionalization[,] patient noncompliance with self care responsibilities, patient abuse of health care provider staff, physician orders to reduce or terminate care, lack of clinical resources at the home health agency, and change in service area." (Mem. in Support of Motion to Intervene by [NAHC], at 8). Certainly none of these changes qualifies as "state action", and we don't assume that plaintiffs argue that they do.

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The Court identified three factors that should be considered in determining whether state action exists. Id. at 1004-05. First, noting that "the mere fact that a business is subject to state regulation does not by itself convert its action into that of the state for the purposes of the Fourteenth Amendment," id. at 1004 (citation omitted), the Court asked whether there is a "sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the state itself." Id. (citation omitted). The purpose of this requirement "is to assure that constitutional standards are invoked only when it can be said that the State is responsible for the specific conduct of which the plaintiff complains." Id. The second factor is whether the state "has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State. Mere approval of or acquiescence in the initiatives of a private party is not sufficient to justify holding the state responsible". Id. at 1004-05 (citations omitted). In other words, the State must have dictated the specific decision being challenged. Third, a court must consider whether "the private entity has exercised powers that are 'traditionally the exclusive prerogative of the State'". Id. at 1005 (quoting Jackson v. Metropolitan Edison Co., 419 U.S. at 353).

In the circumstances at issue in Blum, the Court held that the nursing homes' decisions were not state action. First, the Court noted that the plaintiff class did not challenge "the adjustment of benefits", which was the role of the State, but the decision to discharge or transfer patients. "That the State responds to such actions by adjusting benefits does not render it responsible for those actions." Id. at 1005. Second, the Court rejected plaintiffs' argument that

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the State "affirmatively commands" the discharge of patients who were thought to be receiving inappropriate levels of care, even though regulations did provide that providers were required "to make all efforts possible to transfer patients to the appropriate level of care . . . indicated by the patient's medical condition or needs." Id. at 1005-09. The Court concluded that the actual decisions to discharge or transfer "ultimately turn on medical judgments made by private parties according to professional standards that are not established by the State." Id. at 1008. The Court also rejected plaintiffs' argument that regulations imposing a range of penalties for providing inappropriate levels of care in some way dictated the decisions of the private actors. Id. at 1009-10. Third, the Court found that the regulations requiring state officials to review nursing home decisions and to approve or disapprove continued payment of benefits did not support a finding of state action. Id. at 1010. Finally, the Court noted that the decisions to discharge or transfer nursing home patients are not "the kind of decisions traditionally and exclusively made by the sovereign for and on behalf of the public." Id. at 1012.

Recently, in Sullivan, the Supreme Court "clean[ed] up and rein[ed] in" its "state action" jurisprudence, 119 S.Ct at 991 (Ginsburg, J., concurring), and reaffirmed the validity of Blum. The Court strictly applied the state action requirement and concluded that an insurer's decision to withhold payment under Pennsylvania's workers' compensation scheme and seek utilization review of the reasonableness and necessity of particular medical treatment is not state action.

Under Pennsylvania's workers' compensation scheme, an employer, or its insurer, must pay for all reasonable and necessary medical treatment required by an injured employee. If an employer believes a treatment is not reasonable or necessary it may request utilization review

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and, upon filing a proper request, withhold payment for the treatment. The plaintiffs in Sullivan asserted that procedural due process requirements applied to employers who withheld medical benefits from workers' compensation beneficiaries without providing notice and an opportunity to be heard because withholding the benefits constituted state action. The Court found that the allegedly unconstitutional conduct at issue was not fairly attributable to the state.⁷

The Court began its analysis by "identifying 'the specific conduct of which the plaintiff complains.'" Id. at 985 (citing Blum, 457 U.S. at 1003). In Sullivan, the conduct at issue was the decision of a private insurer to withhold payment for disputed medical treatment, pursuant to state law, because, in the insurer's opinion, the treatment was not reasonable or necessary. See id. at 986. The Court held that whether a sufficiently "close nexus" exists to convert a private decision into state action "depends on whether the State 'has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State.'" Id. (quoting Blum, 457 U.S. at 1004). In the context of the comprehensive benefits scheme in Sullivan, the government did not exercise such power with respect to the decisions made by the private insurers to withhold payment for medical services. See id. at 986-87. "The decision to withhold payment, like the decision to transfer Medicaid patients to a lower level of care in Blum, is made by concededly private parties, and 'turns on judgments * * * made by private parties' without 'standards * * * established by the State.'" Id. at 986 (quoting Blum, 457 U.S. at 1008).

⁷ The Court also found, as discussed in Part III, infra, that workers' compensation beneficiaries did not have a protected interest in benefits.

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B. There Is Not a Sufficiently Close Nexus in this Case to Hold the Secretary Responsible for the Private Actions of HHAs.

Applying Blum and Sullivan to the facts of this case, it is clear that HHAs' decisions about whether and what services to provide home health patients are not attributable to the Secretary. Like the private nursing homes in Blum and the private insurers in Sullivan, private HHAs are not government actors when, in the exercise of their independent judgment they conclude that a patient's home health services may not or may no longer be covered by Medicare, and accordingly make changes in the care that they provide.

Although the Medicare program provides reimbursement for covered home health services received by eligible beneficiaries, as in Blum, the "decisions made in the day-to-day administration of [an HHA]" about what care is reasonable and appropriate in particular cases turn on independent judgments made by the private HHA and cannot be attributed to the federal government. See Blum, 457 U.S. at 1008, 1012; see also Kraemer v. Heckler, 737 F.2d at 224 (Pollack, J., dissenting) ("[T]here is no factual basis in the record before this Court which indicates that a URC determination is based on anything other than the professional opinions of the staff physician members of the URC." (emphasis added)). Likewise, whether and how an HHA gives its patients notice of adverse decisions and an opportunity for an internal "appeal" cannot be attributed to the Secretary. Indeed, the Medicare statute and regulations specifically require HHAs to inform Medicare beneficiaries in advance of changes in coverage or care. See supra at XXX. "[T]here is no evidence that the [HHAs'] failure to do so was compelled in any way by the Secretary." Kitchens v. Bowen, 835 F.2d 1340. Further, the statute and regulations provide beneficiaries with a mechanism through which they can obtain an official Medicare

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determination of coverage. See supra at XXX. HHAs do not make coverage determinations; only HCFA (or its agent) can do that. HHAs are merely making their own judgments, in order to assess their own liability, about whether certain services are reasonable and necessary, under Medicare program rules, and otherwise meet the criteria for Medicare coverage.

It may be true that, in making coverage assessments, HHAs interpret and apply Medicare rules established by statute and regulation, as well as guidelines set forth in manuals, program memoranda, and intermediary instructions. It does not follow, however, that the decisions made by HHAs in individual cases are the decisions of the federal government. In making such assessments about whether they may be liable for services, HHAs exercise independent judgment in each case based upon the circumstances surrounding the plan of care established by the physician, the patient's individual medical condition, its experience in treating the patient, and the HHA's own ability to provide care. Those assessments may not be strictly medical judgments, but they are not unlike the medical judgments in Blum. They are initiated by the HHAs, Blum, 457 U.S. at 1007 n.17, and they are not directed, coerced or compelled by the Secretary. Sullivan, 119 S.Ct at 986. Thus, the actions of the HHAs do not constitute government action for which the Secretary can be held responsible.

C. Pre-Sullivan Second Circuit Cases Do Not Require a Different Result.

In Catanzano v. Dowling, 60 F.3d 113 (2d Cir. 1995), the Second Circuit held that decisions by certified home health agencies ("CHHAs") to deny or reduce the amount of home

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health care prescribed for Medicaid⁸ recipients are state actions for the purposes of Fourteenth Amendment due process analysis. Although a patient's treating physician prescribes the home health services, CHHAs make determinations regarding the medical necessity and economies of home health care, as required by state law. Specifically, they must determine whether the prescribed care is reasonably necessary and can be provided safely in the home, and whether there are less expensive alternatives available. Id. at 115-116. If the HHA determines as a result of these inquiries that a patient should receive no home health care, the decision is final and is implemented without administrative review or a hearing. Id. at 116; N.Y. Pub. Health Law § 367-j(1)(j).⁹

At issue in Catanzano was whether determinations by CHHAs that home health care was not medically necessary or that a less expensive alternative was available, from which no review was available, constituted state action and therefore required the application of due process procedural protections. Id. at 117. The Second Circuit concluded that the HHA decisions at issue were state action. The court found it significant that, the state delegated its authority for

⁸ The Medicaid program provides federal financial assistance to states to reimburse certain medical costs incurred by the poor. 42 U.S.C. §§ 1396-1396p. In contrast to Medicare, Medicaid is a means-tested program.

⁹ Under the New York system in effect at the time, if a Medicaid beneficiary's prescribed care is expected to last for more than 60 days, and if it is determined that home health care is medically necessary and appropriate, additional analysis is required. Specifically, the CHHA must determine whether the cost of home health care will exceed 90 percent of the cost of institutionalization and whether the beneficiary meets one of several enumerated exceptions that would allow him or her to avoid mandatory institutionalization. Catanzano, 60 F.3d at 116; N.Y. Pub. Health Law § 367-j(1)(a), (e). If an adverse decision is made during these latter steps, beneficiaries are entitled to administrative review. Catanzano, 60 F.3d at 116; N.Y. Pub. Health Law § 367-j(1)(j).

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prior approval of benefits to the CHHAs, thus allowing the private agencies to "assume[] the 'responsibility for [the State's] mandated health care duties.'" Id. at 119-20 (quoting J.K. v. Dillenberg, 836 F. Supp. 694, 697-98 (D. Ariz. 1993)). The court also found that the state had effectively delegated its power to deny services to the CHHA because the statute required the CHHA to deny the prescribed treatment if the evaluation results in a determination that the prescribed care is not appropriate. Id. at 117. Finally, "unlike in Blum, the decisions made by the CHHA are not purely medical judgments made according to professional standards," but also require the CHHA "to determine whether the health and safety of the recipient can be maintained as defined by the department of health in regulation." Id. (internal quotation marks and citation to New York Public Health Law omitted).

In the first instance, Catanzano must be examined in light of the Supreme Court's recent decision in Sullivan. The Second Circuit attempted to distinguish Blum on the grounds that the CHHAs were "deeply integrated into the regulatory scheme." Catanzano, 60 F.3d at 119. That analysis does not withstand scrutiny after Sullivan. The Supreme Court reiterated its holding in Blum that even "extensive" regulation is insufficient to impose responsibility on the government for private action. Sullivan, 119 S.Ct. at 986. As the Court explained, "[f]aithful application of the state-action requirement in these cases ensures that the prerogative of regulating private business remains with the States and the representative branches, not the courts." Id.¹⁰

¹⁰ Plaintiffs may rely on Grijalva v. Shalala, 152 F. 3d 1115 (9th Cir. 1998), for their claim that the private conduct of HHAs constitutes state action. In that case, the district court and Ninth Circuit found that HMO denials of medical services to Medicare beneficiaries constitute state action for due process purposes. The Supreme Court, however, recently vacated the judgment in Grijalva and remanded the appellate court decision for further consideration in

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Second, several critical factual distinctions exist between Catanzano and the present case. In Catanzano, the health care provider decisions at issue were final and unreviewable. First, in Catanzano, the court found that the State had delegated authority to the CHHAs to grant prior approval for benefits, 60 F.3d at 119, and to deny services. Id. at 117. HCFA has not done so. Indeed, reimbursement for benefits under the Medicare program are expressly conditioned on a later finding, by HCFA or its agent, that they are reasonable and necessary, and otherwise within the program criteria. [CITE] Second, under state law, no administrative review or hearing was available to patients denied home health care services. See Catanzano, 60 F.3d at 117. By contrast, in the Medicare home health care context, a beneficiary may obtain an official Medicare determination by obtaining the disputed services and requesting the HHA to submit a demand bill to HCFA's representative. See supra at XXX. Under the facts at issue in Catanzano, the decisions being challenged were effectively the final decision of the State. That is simply not the situation here.

Nor is the Second Circuit's decision in Kraemer v. Heckler controlling. Kraemer was a class action challenging termination of hospital and skilled nursing facility benefits under Medicare Part A as a result of URC determinations. The court vacated the district court's order entering summary judgment and remanded the case to resolve factual issues with respect to whether there was state action. The Second Circuit distinguished Blum because the Supreme Court, it believed, had "ruled only with respect to 'transfers initiated by the patients' attending

light of Sullivan. Shalala v. Grijalva, 119 S.Ct 1573 (1999).

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physicians or the nursing home administrators themselves.'" Kraemer, 737 F.2d at 219. The court found that the URCs' decisions were effectively initial determinations by the Secretary because HCFA directed the intermediary to accept an adverse URC decision unless there is a clear deficiency in the committee's decision or the committee failed to follow appropriate procedures. Thus, the required nexus between the challenged action and the agency decision was present. Kraemer, 737 F.2d at 220. The situation in the instant case, however, is closer to Blum than to Kraemer. Here the decisions at issue are initiated by the provider, as in Blum, and no such deference is given to the opinions of HHAs that services are not covered. [CITE]

The Kraemer court also found that a question of fact existed as to the extent to which URC decisionmaking was controlled by HCFA's own standards. Kraemer, 737 F.2d at 220. As explained above, supra at XX, even though HHAs make coverage assessments with reference to program rules established by statute, regulation and program issuances, HHA decisions in individual cases involve the exercise of the HHAs' independent judgment and their own liability assessments. Just as the nursing homes in Blum determined whether to discharge or transfer patients, and as the employers in Sullivan decided whether to dispute medical claims, so too the HHAs here make determinations that are not controlled or directed by the government.

II. HOME HEALTH PATIENTS DO NOT HAVE A PROPERTY INTEREST IN A CONTINUOUS STREAM OF MEDICARE BENEFITS.

Even if the private decisions of HHAs are considered federal action, plaintiffs are not entitled to due process protections when HHAs make changes in services because Medicare beneficiaries do not have a protected property interest in continuous Medicare coverage for their home health services. As the Supreme Court recently stated in Sullivan, "[t]he first inquiry in

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every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.' Only after finding the deprivation of a protected interest do we look to see if the State's procedures comport with due process." 119 S.Ct. at 989 (citations to U.S. Const. Amend. XIV and Mathews v. Eldridge omitted); see also Logan v. Zimmerman Brush Co., 455 U.S. 422, 428 (1982) ("[W]e are faced with what has become a familiar two-part inquiry: we must determine whether Logan was deprived of a protected interest, and, if so, what process was his due."). To determine whether the plaintiff has a protected property interest deserving procedural protection we look at the substantive law underlying the asserted interest. "Property interests flow * * * from 'existing rules or understandings that stem from an independent source such as state [or, in this case, federal] law.'" Kelly Kare, Ltd. v. O'Rourke, 930 F.2d 170 (2d Cir.) (quoting Board of Regents v. Roth, 408 U.S. 564, 577 (1972)), cert. denied, 502 U.S. 907 (1991).

A. Sullivan, Mathews v. Eldridge, and Goldberg v. Kelly

In Sullivan, the plaintiffs argued that the workers' compensation benefits were a state-created entitlement because state law obligated the employer to pay the benefits once the employer's liability is established for a particular work-related injury. See 119 S.Ct. at 990. The Court noted, however, that the Pennsylvania workers' compensation statute did not entitle an employee to payment for all medical treatment once the employer's initial liability is established, but only for medical treatment that is reasonable and necessary with respect to the specific injury for which the employer was found liable. Id. Thus, "disputes over the reasonableness and necessity of particular treatment must be resolved before an employer's obligation to pay — and

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an employee's entitlement to benefits — arise." Id.

The Court contrasted the Sullivan scenario with Goldberg v. Kelly, 397 U.S. 254 (1970), and Mathews v. Eldridge, in which "an individual's entitlement to benefits had been established, and the question presented was whether predeprivation notice and a hearing were required before the individual's interest in continued payment of benefits could be terminated." Sullivan, 119 S.Ct. at 990 (citing Goldberg, 397 U.S. at 261-63, and Mathews, 424 U.S. at 332). The Pennsylvania worker's compensation claimant's property interest "parallels" that of the welfare assistance beneficiary in Goldberg and the disability benefits recipient in Mathews only after he establishes both that his employer is liable for a work-related injury and that "the particular medical treatment at issue is reasonable and necessary." Sullivan, 119 S.Ct. at 990.

B. A Property Interest in Medicare Benefits Does Not Attach Until
An Initial Coverage Determination is Made.

In determining whether a property interest exists, the court must look to "the relevant statute, regulation, or contract establishing eligibility for the government benefit at issue." Plaza Health Laboratories, Inc. v. Perales, 878 F.2d 577, 581 (2d Cir. 1989). Under the Medicare statute and regulations, beneficiaries do not have a property interest in continuous Medicare benefits prior to an initial determination by the Secretary's agent, the RHHI. Moreover, an initial determination that a beneficiary may be eligible for some home health services does not carry with it the expectation or entitlement that all future services will be covered.

The Medicare statute and regulations place several significant limitations on a beneficiary's entitlement to services. First, the beneficiary must be "homebound" [CITE] and must require part-time or intermittent skilled services. [CITE] In addition, like the Pennsylvania

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worker's compensation scheme at issue in Sullivan, the Medicare statute excludes coverage for services that are not "reasonable and necessary." See 42 U.S.C. § 1395y(a)(1)(A). Furthermore, although chronic cases may require long-term care, each home health patient's plan of care must be reviewed at least every 62 days. [CITE] Thus, the Medicare program contemplates that each patient's condition must be reviewed continuously to determine whether additional benefits are "reasonable and necessary" and otherwise appropriate.¹¹

In his concurrence in Sullivan, Justice Breyer suggested that "there may be individual circumstances in which the receipt of earlier payments leads a[] * * * person reasonably to expect their continuation, in which case that person may well possess a constitutionally protected 'property interest.'" Sullivan, 119 S.Ct. at 991 (Breyer, J., concurring). Given the expressly qualified nature of the home health benefit and the requirement of bi-monthly review, this is not such a case. Indeed, even a doctor's prescription, in a plan of care, that certain services are required, does not create an expectation that the services will be covered. See Bodnar v. Sec. of Health and Human Serv., 903 F.2d 122, 125-26 (2d Cir. 1990) ("dual certification" of an admitting physician and a URC do not bind Secretary to provide Medicare coverage). Under the fee-for-service structure of the Medicare program, coverage is determined on a claim by claim basis; beneficiaries are not entitled to a continuous stream of benefits. A home health patient must satisfy establish specific statutory and regulatory requirements to receive payments under

¹¹ Plaintiffs may attempt to rely on several cases in which the courts assumed or decided that a protected property interest exists in Medicare benefits. See Kramer v. Heckler, 737 F.2d 214; Grey Panthers v. Schweiker, 652 F.2d 146 (D.C. Cir. 1980); Martinez v. Richardson, 472 F.2d 1121 (10th Cir. 1973). Each of these cases was decided without the benefit of the Supreme Court's decision in Sullivan, and they must be considered in light of that opinion.

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the Medicare program. Until he does so, his property interest in Medicare benefits for home health services does not "attach." See Sullivan, 119 S.Ct. at 990.

III. HCFA' CURRENT PROCEDURES REQUIRING HHAs TO NOTIFY BENEFICIARIES OF POTENTIAL CHANGES IN COVERAGE AND FOR OBTAINING AN OFFICIAL MEDICARE DETERMINATION SATISFY DUE PROCESS.

If the Court finds that private HHAs are government actors and that a protected property interest exists in Medicare benefits prior to an official coverage determination, it must turn to the due process claims raised in counts two, three and four of the amended complaint. As discussed in more detail below, plaintiffs ask the Court to grant declaratory and injunctive relief requiring the Secretary to (1) require HHAs to provide notice with certain characteristics, (2) "establish an effective process for allowing home health beneficiaries to demand that their providers submit bills needed to initiate appeals of adverse coverage decisions", and (3) "establish a pretermination or contemporaneous review process for home health denials so that needed services are not terminated pending appeals." (Am. Compl. at 25). Moreover, plaintiffs contend that these review procedures should be conducted within 10 days. (Pls. Resp. to Interrog. 11). The Secretary's current procedures are consistent with the Medicare statute and are more than sufficient to satisfy the strictures of due process.

A. HCFA's Current Notice Requirement Permits Beneficiaries to Protect their Interests, and an Improved Notice is Forthcoming.

The Medicare statute, the conditions of participation, and the Home Health Agency and Intermediary Manuals all require HHAs to notify patients when the HHA believes that services may not or may no longer be covered. Nonetheless, plaintiffs assert that home health

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beneficiaries do not receive sufficient notice of changes in their care.¹² Plaintiffs' request that the Court order the Secretary to require that HHAs give beneficiaries written notice when coverage is denied, reduced or terminated, and that the notice contain (1) a written statement of the reasons why services were denied, reduced or terminated, (2) an explanation of the beneficiary's right to have a demand bill submitted, and (3) a description of the procedure for pursuing an appeal. (Am. Compl. at 25).

Although the Secretary does not concede that notice is constitutionally required when HHAs make changes in the care that they provide based on their own determinations that the services may not be covered, HCFA has at all times required HHAs to give patients notice before making changes in the services that the HHAs provide. The notice required by the statute, regulatory conditions of participation, and program manuals is more than sufficient to satisfy the basic requirements for such notices under the due process clause.

"A primary purpose of the notice required by the Due Process Clause is to ensure that the opportunity for a hearing is meaningful." City of West Covina v. Perkins, 119 S.Ct. 678, 681 (1999); Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306, 314 (1950) (notice must be "of such nature as reasonably to convey the required information, and it must afford a reasonable time for those interested to make their appearance." (citations omitted)). "There is 'no rigid formula as to the kind of notice that must be given; notice required will vary with circumstances and conditions.'" Baker v. Latham Sparrowbush Associates, 72 F.3d 246, 254 (2d Cir. 1995)

¹² Plaintiffs do not appear to assert that the requirements for notice during the actual review and appeal process, see supra at XXX, are insufficient.

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(quoting Walker v. City of Hutchinson, 352 U.S. 112, 115 (1956)). Due process does not require, as a general rule, "that notice of remedies and procedures" be provided. City of West Covina, 119 S.Ct at 682. Rather, the notice must merely be sufficient to inform the person that his interest may be in jeopardy and that he should consider taking additional steps to protect that interest. See id. at 681-82.

The Medicare conditions of participation for HHAs provide that "[t]he patient has the right to be informed in advance about the care to be furnished, and of any changes in the care to be furnished" and require that an HHA "must advise the patient in advance of any change in the plan of care before the change is made." 42 C.F.R. § 484.10(c)(1). As quoted, *supra* at XX, HCFA's Medicare Home Health Agency Manual, requires HHAs to notify beneficiaries in writing if services are not covered and provides a model letter which the HHAs may follow. (See exhibit ____). The manual explains the model letter and identifies the information that should be included in the notice. See id. The notice requires the HHA to identify the services that are at issue and to provide indicate why the HHA believes the services are not covered. (See id. at § HHA 270.1.A.5, B). The notice also indicates that the beneficiary may request the HHA to file a claim (i.e. a "demand bill") with the intermediary so that the patient may receive an initial determination. (See id. (model letter)).

Under the circumstances, the current requirement is more than sufficient to satisfy both the needs of Medicare beneficiaries and the requirements of the due process clause. The notice informs patients that they are in danger of losing their Medicare coverage, advises them succinctly of the reasons, and provides them with basic information on how to seek a Medicare

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determination. No more is required. See City of West Covina, supra. Moreover, if, in some isolated instances, the notices provided by HHAs have not met even these requirements, the Secretary is not responsible for the failure of the HHAs.

Nonetheless, in order to ensure that Medicare beneficiaries are provided the most effective notice possible, the Secretary is in the process of developing and implementing a mandatory form notice which will require HHAs to provide beneficiaries with the type of information that plaintiffs insist is required as a constitutional mandate. See supra at XX. As Ms. Sparr's declaration indicates, HCFA has taken affirmative steps to implement the proposed notice and a draft is available for the Court's review. The new form notice will require a specific description of the basis for the HHA's opinion that services may not or may no longer be covered, explain how the patient may continue to obtain the services, and describe the process for seeking and official Medicare termination. Plaintiffs request no more. The Court should allow HCFA to conclude its own internal processes and issue the new form notice requirement.

B. Plaintiffs Are Not Entitled to Relief With Respect to their Request
that the Court Redesign the Medicare Review and Appeal
Procedure and Allow Benefits to Continue Pending Review.

Plaintiffs not only take issue with the current form of notice, they also seek to reform the entire process for payment and review of Medicare claims. Plaintiffs ask the Court to redesign the demand bill process and to provide them with benefits pending administrative review.

1. The Demand Bill Process is Essential to the
Fee-For-Service System Established by Congress
And Does Not Violate Due Process.

Contending that "[t]he Medicare appeals process is useless for most beneficiaries," (Pls.'

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Resp. to Interrog. 8), plaintiffs ask the court to order the Secretary to "devise specific plans" for "establishing an effective process for allowing home health beneficiaries to demand that their providers submit bills needed to initiate appeals of adverse coverage decisions." (Compl. at 25). Plaintiffs assert that the current process is "useless" because beneficiaries cannot enter the appeals process unless they continue to receive the services that are in dispute. (Pls.' Resp. to Interrog. 8). Plaintiffs further contend that HHAs "will not provide such services unless the beneficiaries pay privately for them, which most cannot afford to do. Some home health agencies will not provide such services even if the beneficiaries offer to pay privately." (Id.) Finally, plaintiffs contend that the home health appeals process is too slow. (Id.)

The first of these contentions -- plaintiffs apparent demand that the Court permit them to obtain prior determinations of coverage -- is fundamentally at odds with the retrospective nature of the Medicare program. The Medicare statute requires beneficiaries to first obtain services before seeking reimbursement. As the Supreme Court held in Heckler v. Ringer, 466 U.S. at 621, a claim for Medicare benefits "c[an] be filed * * * only after the medical service for which payment is sought has been furnished." Allowing members of the plaintiff class to obtain "declarations of entitlement" prior to the receipt of health care services would "ignore[] the scheme which Congress has created and do[] nothing less than change the whole character of the Medicare system." Id. at 625.

More recently, in Rizzi v. Shalala, No. 5:88CV00360 (D. Conn.), a class of home health beneficiaries asserted that they were entitled, as a matter of constitutional due process, to "declarations of entitlement" for future home health services. Relying on the Supreme Court's

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decision in Ringer, this court held that "a claimant has no right to obtain a decision from the intermediary pertaining to services which he or she intends to receive in the future." Rizzi v. Shalala, 1994 WL686630, at *6. As this Court recognized in Rizzi, due process does not require that plaintiffs be provided with prior determinations of coverage.

If home health patients believe that they are entitled to coverage despite an HHA's opinion to the contrary and wish to receive the disputed services and have a demand bill submitted,¹³ they are free to pay privately for the services or to request the services from another HHA. Although some beneficiaries may have difficulty paying for the services, Medicare is not a need-based program and the retrospective payment system is fundamental to the fee-for-service nature of the program. Moreover, there is no indication that HHAs routinely demand that patients pay upon receiving services, rather than billing them after a final Medicare determination. See footnote 5, supra.

Plaintiffs assert, solely on the basis of the isolated allegations of several home health beneficiaries, that HHAs will not provide such services unless the beneficiaries pay privately for them, and that some home health agencies refuse to provide services even if the beneficiaries offer to pay privately. Nothing in the statute or regulations requires HHAs to provide services on a private-pay basis.¹⁴ There is nothing to indicate, however, that HHAs routinely refuse to

¹³ The demand bill process is not unique to the home health benefit. Demand bills are also used to obtain official Medicare determinations with respect to coverage of nursing home benefits. [CITE for nursing homes. Any other benefits??].

¹⁴ Medicare beneficiaries may be able to take independent action on other grounds to enforce their rights against HHAs who have wrongfully denied them services. In two recent opinions, district courts have held that home health beneficiaries have viable claims under

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provide services to patients on a private-pay basis. On the contrary, HCFA's data show that in 1997 alone, more than 80,000 demand bills relating to home health services were processed by the RHHIs. (Giebelhaus Decl. ¶ 8). Of these, 43.6 % resulted in full or partial reversals, meaning that coverage ultimately was approved with respect to at least some of the disputed services. [CITE: Bates No. 8-9 (attach to Giebelhaus decl.?)].

Because plaintiffs do not explain exactly what it is they seek in this arena, it is virtually impossible to assess the value of additional procedural safeguards. It is noteworthy, however, that the draft form notice that HCFA is preparing explains the demand bill process in great detail. (See Sparr Decl., Exhibit 1). As Ms. Sparr explains, HCFA is endeavoring to ensure that its notices are beneficiary-friendly throughout the Medicare program. (*Id.* ¶ 8). The new notice will certainly enhance home health patients' understanding and access to the demand bill process. The Court should refrain from interfering with HCFA's ongoing efforts to improve the demand bill system.

Plaintiffs also contend that the Secretary's procedure for obtaining review of coverage determinations imposes delays because the fiscal intermediary initial determination and reconsideration steps are required before beneficiary may obtain an ALJ hearing. (See Pls.' Response to Interrog. 10; see also Pls.' Resp. to Interrog. 8). Note that plaintiffs assume that the due process requirement for a hearing requires a formal ALJ hearing and that beneficiaries have

section 504 of the Rehabilitation Act and various state law causes of action against HHAs who terminate them because they are "heavy care" patients. See Winkler v. Interim Services, Inc., 36 F. Supp.2d 1026 (W.D. Tenn. 1999); Morris v. North Hawaii Comm. Hosp., 37 F. Supp.2d 1181 (D. Hawaii 1999).

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not been provided with process until such a hearing has occurred. However, a hearing is simply "any confrontation, oral or otherwise, between an affected individual and an agency decision-maker sufficient to allow the individual to present his case in a meaningful manner," Grey Panthers, 652 F.2d at 148 n.3, and may be formal or informal, oral or on paper. See id. Beneficiaries are provided an opportunity to confront the decision-maker in writing as early as the reconsideration stage. Moreover, in Isaacs the Second Circuit rejected the contention, set forth by several of the same attorneys who represent plaintiffs here, that initial administrative review procedures, similar to the initial and reconsideration procedures at issue here, constitute "a meaningless procedural hurdle" that causes unreasonably delay. 865 F.2d at 476. As the court recognized, such procedures are faster and less expensive than full-blown ALJ review and serve the government's "real and substantial" interest in "speed and efficiency" Id. at 477. "Regrettably, delay is a natural concomitant of our administrative bureaucracy." Isaacs, 865 F.2d at 477 (holding that estimated 19 months from claim initiation to completion of ALJ review was not remarkable" and was not inordinately long" so as to violate due process).

2. Due Process Does Not Require That Home Health
Beneficiaries Continue to Receive Disputed
Benefits Pending An Official Coverage
Determination.

As part and parcel of their effort to change the very nature of the Medicare fee-for-service program, plaintiffs request the Court to order the Secretary "to establish[] a pretermination or contemporaneous review process for home health denials so that needed services are not terminated pending appeals." (Am. Compl. at 25). Plaintiffs further contend that "an expedited appeals process is required by Due Process for home health services that are urgently needed * *

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*. An internal review process by the home health agency should be completed within 3 days and an independent review agency process should be completed within 10 days. In each case the beneficiary should have a meaningful opportunity to obtain and submit evidence in support of her claim." (Pls.' Resp. to Interrog. 11)

In Mathews v. Eldridge, the Supreme Court established a three-factor balancing test to determine "what process is due" in a particular situation. The court is to consider:

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest including the function involved and the fiscal and administrative burdens that additional or substitute procedural requirements would entail.

424 U.S. at 335. Mathews involved the process due Social Security disability recipients before their benefits could be terminated. Under the procedures at issue there, the state agency reviewing continuing eligibility for disability benefits notified beneficiaries whose benefits were proposed to be terminated, giving them an option to respond in writing if they disagreed with the determination. 424 U.S. 337-38. If the state agency's final determination was accepted by the Social Security Administration, "as is usually the case," benefits were terminated. Id. Only after termination, and after seeking reconsideration by the state agency, was the beneficiary given an evidentiary hearing by someone outside the state agency — namely an SSA administrative law judge. Id. at 339.

The Court weighed the three factors it had enumerated in its decision. Regarding the private interest factor, the Court acknowledged that "the hardship imposed upon the erroneously

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terminated disability [benefits] recipient may be significant," particularly given the potentially lengthy delay before a final decision after a hearing might be made. Id. at 342. As to the probable value of additional procedures, the Court noted that "the decision whether to discontinue disability benefits will turn, in most cases, upon 'routine, standard, and unbiased medical reports by physician specialists,'" and thus is "a more sharply focused and easily documented decision than the typical determination of a welfare entitlement." Id. at 343-45 (citation omitted). The final factor, the public interest, was explained as being "the cost resulting from the increased number of hearings and the expense of providing benefits to ineligible recipients pending decision." Id. at 347. The Court balanced these factors as follows:

At some point the benefit of an additional safeguard to the individual affected by the administrative action and to society in terms of increased assurance that the action is just, may be outweighed by the cost. Significantly, if the cost of protecting those whom the preliminary administrative process has identified as likely to be found undeserving may in the end come out of the pockets of the deserving since resources available for any particular program of social welfare are not unlimited.

Id. at 348.¹⁵ The Court concluded that "an evidentiary hearing is not required prior to the termination of disability benefits and that the present administrative procedures fully comport with due process." Id. at 349.

In the present case, Mathews is controlling. Analyzing the issues under the Mathews formula, it is evident that home health beneficiaries receive sufficient process to protect their

¹⁵ The Court also noted that, "[i]n assessing what process is due in this case, substantial weight must be given to the good faith judgments of the individuals charged by Congress with the administration of the social welfare programs that the procedures they have provided assure fair consideration of the entitlement claims of individuals." Id. at 349.

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putative interest.

The private interest at issue in this case is the interest of the plaintiff class in receiving or continuing to receive Medicare coverage for specific home health services. In other words, the interest is in the payments for the services, not in the provision of the services themselves. See Isaacs v. Bowen, 865 F.2d at 476 (2d Cir. 1989) (Medicare beneficiaries' "private interest lies in the prompt and fair reimbursement of medical expenses"); Califano v. Himmler, 611 F.2d 137, 145 (6th Cir. 1979) ("The Medicare program gives eligible individuals the benefit of [p]ayment for medical services already rendered; it does not directly provide any entitlement to the medical services themselves."). It is certainly true that medical expenses may sometimes be significant, particularly to individuals on a fixed income. See Kraemer v. Heckler, 737 F.2d at 222. Nonetheless, since Medicare benefits are not based on financial need, the private interest in receiving payment for medical treatment under Medicare is not "overwhelming." Isaacs v. Bowen, 865 F.2d at 476 (citing McClure, 456 U.S. at 194).

In Isaacs, the Second Circuit stated that Medicare beneficiaries' interest in reimbursement of medical expenses "may be 'considerable,' but they are hardly as significant, for example as an individual's right to receive welfare." Id. (referring to Goldberg v. Kelly). Certainly this interest is no greater than an individual's interest in continued employment, Cleveland Board of Ed. v. Loudermill, 470 U.S. 532 (1985), or in continued disability benefits, Mathews v. Eldridge, neither of which the Supreme Court considered compelling enough to require pretermination review.

There is no indication that the risk of erroneous deprivation is significant. Nothing

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prohibits patients from paying privately or seeking care elsewhere. Moreover, as the Sixth Circuit recognized in Himmeler, "deprivation * * * is only temporary, for full payment for medical services rendered will be made if the services are finally determined to be covered by Medicare." 611 F.2d at 147. And as HCFA's data show, more than half of demand bills are denied, indicating that in most cases in which patients disagree with an HHA's assessment of coverage, coverage is found, at least initially, to be unavailable under Medicare rules. This is not surprising, given the fact that patients' decisions to file demand bills generally are based on their own subjective judgments, as opposed to HHA coverage opinions which are informed by their accumulated experience and judgment.

Moreover, the value of the additional procedures sought by plaintiffs is questionable. As in Mathews, Medicare coverage determinations are not based on credibility determinations and may typically be based on the patient's medical and clinical records. And here again, HCFA's forthcoming revision of its notice requirements will enhance beneficiaries' ability to protect their interests.

Finally, it cannot be denied that requiring Medicare to conduct more expeditious determinations or to continue to pay for home health services pending a coverage determination, whether by the RHHI or by an ALJ, would impose a great burden on the government and the Medicare trust fund. Requiring HCFA or its RHHIs to conduct determinations within ten days, as plaintiffs request, would require the deployment of additional personnel at a substantial cost. (See Giebelhaus Decl. ¶ 19). And since plaintiffs appear to contemplate that these procedures would adhere any time any change in coverage or services is considered (including changes in

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the frequency or duration of home health visits), the number of determinations potentially required could increase dramatically.

In addition, the government would incur significant costs in paying for beneficiaries' claims later found to be without merit. As the Court recognized in Mathews, "the theoretical right of the Secretary to recover undeserved benefits" would not likely result "as a practical matter, in any substantial offset to the added outlay of public funds." 424 U.S. at 347. The dire fiscal condition of the Medicare trust fund has been well-publicized and was considered by Congress when it legislated changes in the Medicare program, including the home health benefit, in the Balanced Budget Act of 1997.¹⁶ Ultimately, the costs of pretermination review and expedited hearings demanded by plaintiffs would be paid by the government and would be passed on to other beneficiaries. See Mathews, 424 U.S. at 348.

IV. HCFA's ENFORCEMENT DECISIONS ARE NOT SUBJECT TO JUDICIAL REVIEW.

In addition to their challenges to the sufficiency of the notice and review processes applicable to the home health benefit, plaintiffs claim (count one) that the Secretary has failed to enforce her regulations and program rules. In Heckler v. Chaney, 470 U.S. 821, 832 (1985), the

¹⁶ Congress' principal concern in enacting the Balanced Budget Act of 1997 was preservation, in the face of extreme financial drain, of the fiscal integrity of the Medicare trust funds. See H. Rep. No. 105-149 (1997), reprinted in 1997 WL 353017 at 2514-15. Congress observed that Medicare costs were growing at a rate totally out of proportion to the growth rate in the private health care markets, see id. at 1332; that home health care was one of the fastest growing components of the Medicare program, id. at 2708; and that much of its growth "was fueled by relatively generous payments, coverage policies, and little agency oversight." Id. See also Medicare Home Health Care: Hearing Before the Subcomm. on Health and Env't of the House Comm. on Commerce, 105th Cong. 43-44 (1997) ("Hearing"), attached as Exh. ____.

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Supreme Court held that agency enforcement actions are generally unsuitable for review because they involve "complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." For example, the agency must assess whether a violation has occurred, the best use of limited agency resources, the agency's likelihood of success in an enforcement action, and the agency's overall policies. Id.; Andrews v. Consolidated Rail Corp., 831 F.2d 678, 685 (7th Cir. 1987).

Accordingly, an agency's decision not to take enforcement action is presumptively unreviewable because the Court lacks a meaningful standard against which to judge the agency's exercise of discretion. Lincoln v. Vigil, 508 U.S. 182, 191 (1993); Heckler v. Chaney, 470 U.S. at 832. This presumption may be rebutted where the statute or the agency's regulations have "provided guidelines for the agency to follow in exercising its enforcement powers." Heckler v. Chaney, 470 U.S. at 833 (footnote omitted). If such guidelines exist, it is possible for the court to determine whether an agency's failure to take enforcement action breached those guidelines or was otherwise an abuse of discretion. Id. at 834-35. If, however, the statute or regulations do not provide meaningful standards for defining the limits of the agency's enforcement discretion, there is "no law to apply" and "an agency refusal to institute proceedings is a decision 'committed to agency discretion by law.'" Id.

The Secretary's enforcement of federal requirements with respect to the Medicare home health benefit is presumptively unreviewable. Neither the Medicare statute nor the regulations implementing the home health benefit set forth any "law to apply." It is not enough that the statute or regulations provide guidelines that are used to determine * * * compliance once the

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Secretary goes forward with an enforcement action and may be used by a court to review the Secretary's decision." Sierra Club v. Larson, 882 F.ed 128, 132 (4th Cir. 1989) (emphasis added). Instead, the statute or regulations must "provide standards for ascertaining when [the agency] should recommend that formal enforcement proceedings be commenced or when the Secretary is required to make a determination of compliance or non-compliance or to institute an enforcement action." Id. (emphasis in original); accord Arnow v. U.S. Nuclear Regulatory Comm'n, 868 F.2d 223, 231 (7th Cir.), cert. denied, 493 U.S. 813 (1989) (enforcement decision not reviewable where regulations did not define how the agency's decision must be reached or mandate what particular action agency must take if it finds a violation); Singh v. Moyer, 867 F.2d 1035, 1039 (7th Cir. 1989) (agency decision unreviewable where statute contained no criteria by which "to judge how the Director determines the content of his inquiry or the nature of his recommendation").

Nor can plaintiffs evade the holding of Heckler v. Chaney by cloaking their enforcement cause of action in the regalia of a due process claim. Plaintiffs have no independent constitutionally protected interest in enforcement of Medicare program requirements. "No due process right is implicated here because [plaintiffs] have no right to demand that [HCFA] enforce" federal requirements with respect to the home health benefit. Gagliardi v. Village of Pawling, 18 F.3d 188, 192 (2d Cir. 1994).

Finally, plaintiffs may argue, based on a footnote in Chaney, that "the agency has 'consciously and expressly adopted a policy' that is so extreme as to amount to an abdication of its responsibilities." Chaney, 470 U.S. at 833 n.4 (citing Adams v. Richardson, 480 F.2d 1159

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(D.C. Cir. 1973)). The Court expressly declined to decide whether such an extreme abdication would be reviewable. *Id.* In the first instance, plaintiffs' contentions appear to concern merely the level of enforcement, and not the abdication of enforcement responsibility. In any event, it is clear from the Derville declaration that HCFA has a comprehensive enforcement program in place. See supra at XX-XX.

Dated: June 17, 1999

Respectfully submitted,

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BACKGROUND

A. The Medicare Program

The federal Medicare program, Social Security Act, title XVIII, 42 U.S.C. §§ 1395-1395xx, provides federal reimbursement for covered medical care provided to the elderly and disabled. See Kraemer v. Heckler, 737 F.2d 214, 215 (2d Cir. 1984). Medicare Part A provides hospital insurance coverage for the costs incurred by eligible beneficiaries for hospital care, extended care and home health care. [Duggan v. Bowen, 691 F. Supp. 1487, (D.D.C. 1988) (citing 42 U.S.C. §§ 1395c to 1395i-2).] Medicare Part B is a voluntary supplementary medical insurance program in which eligible beneficiaries who pay a monthly premium are entitled to reimbursement for physicians' and other medical services. [Id. (citing 42 U.S.C. §§ 1395j to 1395w).] The Medicare program is not a need-based program; that is, eligibility is not dependent upon a beneficiary's income or financial situation. See Kraemer, 737 F.2d at 214; Califano v. Himmler, 611 F.2d 137, 146 (6th Cir. 1979).

B. The Home Health Benefit

Medicare beneficiaries are eligible to receive home health services under both parts A and B of the Medicare program. 42 U.S.C. §§ 1395d(a)(3)(part A), 1395k(a)(2)(A)(part B). Home health services include, inter alia, items and services such as nursing care, physical or occupational therapy, medical social services provided under the direction of a physician, and the services of a home health aide. See 42 U.S.C. § 1395x(m).

Under the Medicare program, a beneficiary is entitled to have payment made on his

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behalf for the reasonable cost of home health services. See 42 U.S.C. § 1395x(v).¹⁷ In order to be eligible for home health services, a beneficiary must establish, *inter alia*, that he is confined to his home, [42 U.S.C. § 1395f(a)(2)(C)], requires "part-time or intermittent care," [42 U.S.C. § 1395x(m)(1) and (4)], and that the care is medically "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A).

Home health services are provided under a written plan of care, prepared by the beneficiary's physician, specifying the medical treatments to be furnished and the frequency of the treatments. 42 C.F.R. § 409.43(b)(Part A); see also 42 C.F.R. § 410.80 (Part B). The plan of care must be reviewed by the physician in consultation with the HHA at least every 62 days. *Id.* § 409.43(e).

Patients receive home health services from third party HHAs, which are agencies or organizations primarily engaged in providing skilled nursing services and other therapeutic services. 42 U.S.C. § 1395x(o)(1). HHAs enter into agreements with HCFA to furnish specified

¹⁷ Previously, Medicare paid HHAs based on the retrospectively-determined "reasonable costs" they incurred, up to certain limits authorized by statute, see H. Conf. Rep. No. 105-217 ("Conf. Rep."), at 806 (1997), reprinted in 1997 U.S.C.C.A.N. 176, 427; 42 U.S.C. § 1395x(v)(1)(L), provided those costs were less than prescribed per-visit limits. See 42 U.S.C. § 1395x(v)(1)(A). Responding to the dire financial condition of the Medicare trust funds and recognizing that Medicare's payments for HHA services were excessive, Congress enacted legislation to create a prospective payment system for HHAs similar to that utilized for other Medicare providers such as hospitals. See 42 U.S.C. § 1395fff. Until such a system could be developed, Congress required that HHS implement an interim payment system ("IPS"), under which HHAs are paid based on the lowest of three calculations: (1) the HHA's actual reasonable allowable costs; (2) an aggregate per-visit limit not to exceed 105% of median per-visit costs; or (3) an aggregate per-beneficiary limit. See 42 U.S.C. § 1395x(v)(1)(L). Because the per-visit and per-beneficiary limits are calculated in the aggregate for each HHA, an individual beneficiary's care or number of visits is not limited under IPS. See, e.g., 42 U.S.C. § 1395x(v)(1)(L)(ii).

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health care services to Medicare beneficiaries in conformity with the Medicare Act and HCFA's implementing rules. See 42 U.S.C. §§ 1395c, d & cc. To participate in the Medicare program, HHAs are required, *inter alia*, to meet "conditions of participation" specified by statute and regulation. 42 U.S.C. §§ 1395x(o); 1395bbb(a). Among other things, the conditions of participation require HHAs to "protect[] and promote[] the rights of each individual under its care * * * to be fully informed" about the care and treatment to be provided by the HHA and the Medicare coverage available for the care and treatment, as well as of any changes. See § 1395bbb(a).² In addition, the regulations promulgated by the Secretary include conditions of participation providing that "[t]he patient has the right to be informed in advance about the care to be furnished, and of any changes in the care to be furnished" and requiring that an HHA "must advise the patient in advance of any change in the plan of care before the change is made." 42

² Section 1395bbb(a) provides, in pertinent part:

(1) The agency protects and promotes the rights of each individual under its care, including the following rights:

(A) The right to be fully informed in advance about the care and treatment to be provided by the agency [and] the right to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual's well-being * * *.

(E) The right to be fully informed orally and in writing (in advance of coming under the care of the agency) of --

(i) all items and services furnished by (or under arrangements with) the agency for which payment may be made under [Medicare],

(ii) the coverage available for such items and services [under the Medicare program],

(iii) any charges or items for services not covered [under the Medicare program],

(iv) any changes in the charges or items described in clauses (i), (ii), or (iii).

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C.F.R. § 484.10(c)(1).

HCFA's Medicare Home Health Agency Manual, HCFA Pub. 11 (attached hereto as exhibit __), requires HHAs to notify beneficiaries in writing if services are not covered. The manual provides as follows:

Notifying Patient of Noncoverage — If you are aware that the services to be furnished to the patient are not covered, advise the patient (or his representative) in writing prior to or at the time of start of care (or at the time the type of care changes) that the care is noncovered and that no claim for Medicare reimbursement is submitted. If the beneficiary insists that you submit a claim for payment, indicate that the bill is being submitted at the beneficiary's request, and why you consider the care to be noncovered * * * *.

Establish a procedure for notifying beneficiaries and physicians promptly when a decision of noncoverage is made. The procedure should provide for written notice of noncoverage * * *.

Id. § 265.1.

In addition, HCFA's Intermediary Manual currently contains an "HHA Model Letter" for the purpose of serving as a notice to the beneficiary of noncovered home health services. See Intermediary Manual § 3730.2 (attached hereto as Exhibit __). The Intermediary Manual explains the model letter and identifies the information that should be included in the notice. See id. Moreover, although the Secretary does not concede that her procedures for notice or the model letter are constitutionally insufficient, HCFA currently is engaged in the process of revising its notice requirements and manual instructions with respect to notice. [DESCRIBE PROCESS].³

³ The parties to this action engaged in extensive settlement discussions intended to design and implement a new notice. Although the negotiations broke down with respect to procedural

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C. The Payment Process: Obtaining a Medicare Initial Determination

Under parts A and B of the Medicare Act, Medicare administers its insurance benefit like a traditional indemnity insurance plan. Like other indemnity insurance plans, the Medicare program covers some services, when they are "medically reasonable and necessary" 42 U.S.C. § 1395y(a), and does not cover others. The Medicare statute provides that the determination of whether an individual is entitled to benefits, including home health benefits, "shall be made by the Secretary in accordance with regulations prescribed by him." 42 U.S.C. § 1395ff(a). For beneficiaries eligible for services under Medicare's Part A and Part B, Medicare evaluates the medical services after they have been rendered, according to the statutory criteria of medical "reasonableness and necessity," 42 U.S.C. § 1395y(a), and then provides reimbursement for covered medical services on a retrospective basis. Heckler v. Ringer, 466 U.S. 602, 605 (1984).

The Medicare statute provides that payment will be made on the beneficiary's behalf for covered services. 42 U.S.C. §§ 1395d(a), 1395k(a)(2). Payment is typically made by Medicare directly to the provider of services (here the HHA). See 42 C.F.R. § 424.51(a). Medicare informs providers certified to participate in its program of the services covered, through issuances including manuals, program memoranda, and intermediary instructions. To encourage providers to bill Medicare only for services that are covered under Medicare rules, Medicare requires providers to accept liability for billed noncovered services unless the providers have

matters, the parties exchanged numerous drafts of a revised, improved notice. The notice that resulted from the parties' settlement discussions is the notice that is currently being revised for further focus testing.

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notified beneficiaries in advance of the provision of medical care that the provider believes the service is not covered and therefore, because Medicare is not likely to pay, the beneficiary will be liable for payment.⁴ Home Health Agency Manual § 431; Medicare Intermediary Manual, Part 3, § 3439. Thus, providers determine, based on their experience and the guidance on coverage from Medicare, whether they believe the services are covered by the Medicare program. *Id.*

When a provider believes that a service or services will not be covered by Medicare, that is, the service is not medically reasonable and necessary, or is otherwise not covered pursuant to statutory and regulatory criteria, the provider is required to inform the beneficiary, in writing and prior to the service being rendered, that the provider believes that the service is not covered and that the beneficiary will be liable for payment if Medicare does not cover the service. 42 C.F.R. § 484.10(e). The beneficiary is then able to decide whether or not he is willing to have the service provided and a bill submitted, knowing that he will be liable for the service if the final Medicare determination is that the services are noncovered.⁵ If the beneficiary opts to have the service provided and a bill submitted to Medicare, the provider submits the bill to Medicare, coded as a demand bill. A demand bill is a claim for services or items that the provider believes are not covered but which the provider must submit at the demand of the beneficiary or the

⁴ Neither providers nor beneficiaries are required to accept liability when the provider did not know or have reason to know that the service was not covered. Home Health Agency Manual §§ 262.2; 268.2.

⁵ For the home health benefit, the HHA may either bill the beneficiary immediately and require him to pay, subsequently refunding the payment if Medicare determines that the service is covered, or the HHA may bill the beneficiary after an adverse determination is received from Medicare. Intermediary Manual § 3314D.

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beneficiary's representative. This allows the beneficiary to obtain an initial determination from Medicare.⁴

The initial determination is made by HCFA's contractor, the Regional Home Health Intermediary (RHHI). 42 C.F.R. § 405.702. The RHHI must provide the beneficiary and, in certain cases, the provider of the services, with a notice of the initial determination in writing. *Id.* The notice must state in detail the basis for the determination and inform the beneficiary and, where appropriate, the provider of services, of their right to reconsideration. *Id.*

D. Appeal and Review Process

An individual dissatisfied with the Secretary's initial determination, including a determination as to the amount of benefits, is entitled to an administrative hearing and judicial review to the extent and under the terms provided in the Social Security Act. *Id.* § 1395ff(b) (referencing 42 U.S.C. §§ 405(b),(g)). The Medicare regulations provide for a comprehensive administrative appeal and review process.

An individual who is a party to an initial determination may request reconsideration by HCFA by filing a request for reconsideration within 60 days after the date of receipt of the notice of initial determination. 42 C.F.R. § 405.710-11. The regulations direct HCFA to review the initial determination and the record upon which the initial determination was made, as well as any additional evidence which may be submitted or obtained. *Id.* § 405.715. HCFA may affirm

⁴ Intermediaries process claims through a system of edits, which allows them to pay claims which are "clean" and do not require further investigation, and then develop further claims which do not pass the pre-pay edits. Medicare Intermediary Manual, Part 3, Claims Processing, § 3600.1. [need assistance from HCFA on this, declaration]

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or reverse, in whole or in part, the initial determination, and must notify the parties and their representatives of the reconsidered determination in writing. Id. §§ 405.715, 405.716. The notice must state the basis for the reconsidered determination and advise the parties of their right to a hearing if the amount in controversy is \$100 or more. Id. § 405.716.

A party to a reconsidered determination has a right to a hearing regarding any initial determination if the amount of the controversy is \$100 or more and a request for a hearing is properly filed. 42 C.F.R. § 405.722. The hearing is held before an Administrative Law Judge. See 42 C.F.R. §§ 405.722. [If the beneficiary is dissatisfied with the ALJ's decision, he or she may request review by the Departmental Appeals Board ("DAB"). Id. 405.724; 20 C.F.R. § 404.968(a)(1).]

Finally, a party to a DAB decision, or an ALJ decision if the DAB does not review the ALJ decision, may seek judicial review in federal district court if the amount in controversy is \$1000 or more. 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. § 405.730. Judicial review is governed by section 205(g) of the Social Security Act, 42 U.S.C. § 405(g).

E. Enforcement

The Medicare statute requires that HHAs participating in the Medicare program be "surveyed" not less than every 36 months. See 42 U.S.C. § 1395bbb(c)(1),(2). A survey consists of visits to the homes of a case-mix stratified sample of the HHAs patients and a review of the quality of care and services furnished by the HHA. See id. § 1395(c)(2)(C). If a survey reveals deficiencies, the HHA may be subjected to an "extended survey." Id. § 1395(c)(2)(D). The Secretary has established a policy of different intervals for surveys based on [CITE]

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The Medicare Act also provides the Secretary with enforcement authority to correct deficiencies in an HHA's performance of conditions of participation. Specifically, the Act provides that, in cases where the deficiencies involved immediately jeopardize the health and safety of beneficiaries, the Secretary "shall take immediate action to remove the jeopardy" by appointing a temporary manager for the HHA or terminating the certification of the HHA. *Id.* § 1395bbb(c)(1) (emphasis added); see also § 1395(f)(2)(A)(iii). In cases where the deficiencies do not immediately jeopardize the health and safety of beneficiaries, the Secretary may impose certain intermediate sanctions for a period of six months, in lieu of terminating the HHA's certification. *Id.* § 1395bbb(e)(2). If intermediate sanctions are ineffective to cure the deficiency, the Secretary must terminate the HHA. *Id.*

ARGUMENT

A. No State Action

In this lawsuit, plaintiffs ask the Court to hold the Secretary responsible for the conduct of the private HHAs that provide them with home health services. Due process principles apply only where there is "state action", not where there is merely private conduct. Blum v. Yaretsky, 457 U.S. at 1003; Catanzano, 60 F.3d at 117. The government action requirement both "preserves an area of individual freedom by limiting the reach of federal law and federal judicial power" and "avoids imposing on the State, its agencies or officials responsibility for conduct for which they cannot fairly be blamed." Lugar v. Edmondson Oil Co., 457 U.S. 922, 936 (1982). As the Supreme Court has recognized, the distinction between private and governmental action is

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"well-established and easily stated," but its application in practice "frequently admits of no easy answer." Jackson v. Metropolitan Edison Co., 419 U.S. 345, 349-50 (1974). HHAs are not state actors when they deny, reduce or terminate home health services on the ground that, in the HHAs' opinion, the requested services are not eligible for coverage under the Medicare program.

1. **Blum and Sullivan**

In Blum v. Yaretsky, 457 U.S. 534 (1982), the Supreme Court examined whether decisions initiated and made by private nursing homes to discharge or transfer Medicaid patients constituted "state action" for the purposes of due process analysis. The plaintiff class asserted that Medicaid patients were discharged or transferred from nursing homes without notice or opportunity for a hearing. Id. at 993. The Court held that the nursing homes' independent decisions to transfer beneficiaries to a lower level of care were not state action.

The Court identified three factors that should be considered in determining whether state action exists. Id. at 1004-05. First, noting that "the mere fact that a business is subject to state regulation does not by itself convert its action into that of the state for the purposes of the Fourteenth Amendment," id. at 1004 (citation omitted), the Court asked whether there is a "sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the state itself." Id. (citation omitted). The purpose of this requirement "is to assure that constitutional standards are invoked only when it can be said that the State is responsible for the specific conduct of which the plaintiff complains." Id. The second factor is whether the state "has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be

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deemed to be that of the State." Id. In other words, "[m]ere approval of or acquiescence in the initiatives of a private party is not sufficient to justify holding the state responsible". Id. at 1004-05. Third, a court must consider whether "the private entity has exercised powers that are 'traditionally the exclusive prerogative of the State'". Id. at 1005 (quoting Jackson v. Metropolitan Edison Co., 419 U.S. 345, 353 (1974)).

In the circumstances at issue in Blum, the Court held that the decisions at issue were not state action. First, the Court noted that the plaintiff class did not challenge the adjustment of benefits, which was the role of the State, but the decision to discharge or transfer patients. "That the State responds to such actions by adjusting benefits does not render it responsible for those actions." Id. at 1005. Second, the Court rejected (at 1005-09) plaintiffs' argument that the state "affirmatively commands" the discharge of patients who were thought to be receiving inappropriate levels of care, even though regulations did provide that providers were required "to make all efforts possible to transfer patients to the appropriate level of care . . . indicated by the patient's medical condition or needs." The Court concluded that the actual decisions to discharge or transfer "ultimately turn on medical judgments made by private parties according to professional standards that are not established by the State." Id. at 1008. The Court also rejected plaintiffs' argument that regulations imposing a range of penalties for providing inappropriate levels of care in some way dictated the decisions of the private actors. (at 1009-10) Third, the Court found that the regulations requiring State officials to review nursing home decisions did not authorize the officials to approve or disapprove decisions to transfer or discharge, and so didn't support a finding of state action. (at 1010) Finally, the Court noted that

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the decisions to discharge or transfer nursing home patients are not "the kind of decisions traditionally and exclusively made by the sovereign for and on behalf of the public." (at 1012).

Recently, the Supreme Court "clean[ed] up and rein[ed] in" its "state action" jurisprudence in American Manufacturers Mutual Insurance Co. v. Sullivan, 119 S.Ct 977, 991 (1999) (Ginsburg, J., concurring). The Court strictly applied the state action requirement and concluded that an insurer's decision to withhold payment under Pennsylvania's workers' compensation scheme and seek utilization review of the reasonableness and necessity of particular medical treatment is not state action.

Under Pennsylvania's workers' compensation scheme, an employer, or its insurer, must pay for all reasonable and necessary medical treatment required by an injured employee. If an employer believes a treatment is not reasonable or necessary it may request utilization review and, upon filing a proper request, withhold payment for the treatment. The plaintiffs in Sullivan asserted that procedural due process requirements applied to employers who withheld workers' compensation benefits without providing notice and an opportunity to be heard because withholding the benefits constituted state action. The Court found that the allegedly unconstitutional conduct at issue was not fairly attributable to the state.

The Court began its analysis by "identifying 'the specific conduct of which the plaintiff complains.'" Id. at 985 (citing Blum, 457 U.S. at 1003). In Sullivan, the conduct at issue was the decision of a private insurer, pursuant to state law, to withhold payment for disputed medical treatment because, in the insurer's opinion, the treatment was not reasonable or necessary. See id. at 986. The Court held that whether a sufficiently "close nexus" exists to convert a private

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decision into state action "depends on whether the State has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State." Id. (quoting Blum, 457 U.S. at 1004). In the context of the comprehensive benefits scheme in Sullivan, government did not exercise such power with respect to the decisions made by the private insurers to withhold payment pursuant to state law. See id. at 986-87. "The decision to withhold payment, like the decision to transfer Medicaid patients to a lower level of care in Blum, is made by concededly private parties, and 'turns on judgments * * * made by private parties' without 'standards * * * established by the State.'" Id. at 986 (quoting Blum, 457 U.S. at 1008).

2. Application to Healey

Applying Blum and Sullivan to the facts of this case, it is clear that HHAs' decisions about whether and what services to provide home health patients are not attributable to the Secretary. Like the private nursing homes in Blum and the private insurers in Sullivan, HHAs are not government actors when they exercise their independent judgment to deny, reduce or terminate a patient's home health services.

Although the Medicare program may provide reimbursement for covered home health services received by eligible beneficiaries, as in Blum, the "decisions made in the day-to-day administration of [an HHA]" about what care is reasonable and appropriate in particular cases turn on independent judgments made by the private HHA and cannot be attributed to the federal government. See Blum, 457 U.S. at 1008, 1012. Likewise, whether and how an HHA gives its patients notice of adverse decisions and an opportunity to "appeal" cannot be attributed to the

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Secretary. Indeed, the Medicare statute and regulations specifically require HHAs to inform Medicare beneficiaries of changes in coverage or care. See supra at XXX. "[T]here is no evidence that the [HHAs'] failure to do so was compelled in any way by the Secretary." Kitchens v. Bowen, 835 F.2d 1340. Moreover, HHAs do not make coverage determinations. Only HCFA (or its agent) can do that. HHAs are merely making their own judgments about whether certain services are reasonable and necessary and otherwise meet the criteria for Medicare coverage.

It may be true that, in making determinations whether to deny, reduce or terminate care, HHAs interpret and apply Medicare rules established by statute and regulation. It does not follow, however, that the decisions made by HHAs in individual cases are the decisions of the federal government. In making such decisions, HHAs exercise independent judgment in each case based upon the circumstances surrounding the patient's individual medical condition and requirements. The HHA must take into account the plan of care established by the physician, see supra at XXX, as well as its experience in treating the patient. Those judgments are like the medical judgments in Blum. They are not coerced or compelled by the Secretary. Sullivan, 119 S.Ct at 986). Moreover, it is important to keep in mind that Medicare beneficiaries can obtain an official Medicare determination from HCFA's agent by pursuing the administrative procedure described in section XX, supra. Thus, the actions of the HHAs do not constitute government action for which the Secretary can be held responsible.

3. Catanzano is not controlling (and Kraemer v. Heckler)

In Catanzano v. Dowling, 60 F.3d 113 (2d Cir. 1995), the Second Circuit held that decisions by certified home health agencies ("CHHAs") to deny or reduce the amount of home

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health care prescribed for Medicaid recipients are state actions for the purposes of Fourteenth Amendment due process analysis. Under Medicaid, participating States must offer home health services as part of the program. Although a patient's treating physician prescribes the home health services, CHHAs make determinations regarding the medical necessity and economies of home health care, as required by state law. Specifically, they must determine whether the prescribed care is reasonably necessary and can be provided safely in the home, and whether there are less expensive alternatives available. *Id.* at 115-116. If the HHA determines as a result of these inquiries that a patient should receive no health care, the decision is final and is implemented without administrative review or a hearing. *Id.* at 116; N.Y. Pub. Health Law § 367-j(1)(j).²

At issue in Catanzano was whether determinations by CHHAs that home health care was not medically necessary or that a less expensive alternative was available, from which no review was available, constituted state action and therefore required the application of due process procedural protections. *Id.* at 117. Applying the Blum v. Yaretsky factors, the Second Circuit concluded that the HHA decisions at issue were state action. According to the Second Circuit,

² Under the New York system in effect at the time, if a Medicaid beneficiary's prescribed care is expected to last for more than 60 days, and if it is determined that home health care is medically necessary and appropriate, additional analysis is required. Specifically, the CHHA must determine whether the cost of home health care will exceed 90 percent of the cost of institutionalization and whether the beneficiary meets one of several enumerated exceptions that would allow him or her to avoid mandatory institutionalization. Catanzano, 60 F.3d at 116; N.Y. Pub. Health Law § 367-j(1)(a), (e). If an adverse decision is made during these steps, beneficiaries are entitled to administrative review. Catanzano, 60 F.3d at 116; N.Y. Pub. Health Law § 367-j(1)(j).

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CHHAs "are not simply regulated by the state; rather they are deeply integrated into the regulatory scheme". Id. at 119. The court found it significant that, "unlike in Blum, the decisions made by the CHHA are not purely medical judgments made according to professional standards," but also require the CHHA "to determine whether the health and safety of the recipient can be maintained as defined by the department of health in regulation." Id. (internal quotation marks and citation to New York Public Health Law omitted). The court also found that the state had effectively delegated its power to deny services to the CHHA because the statute required the CHHA to deny the prescribed treatment if the evaluation results in a determination that the prescribed care is not appropriate. Id. Finally, the state delegated its authority for prior approval of benefits to the CHHAs, thus allowing the private agencies to "assume[] the 'responsibility for [the State's] mandated health care duties.'" Id. at 119-20 (quoting Dillenberg, 836 F. Supp. at 697-98).

In the first instance, Catanzano must be examined in light of the Supreme Court's recent decision in Sullivan. The Second Circuit attempted to distinguish Blum on the grounds that the CHHAs were "deeply integrated into the regulatory scheme," and that the state had "delegated its power to deny services to the CHHAs." Id. at 119. That analysis does not withstand scrutiny after Sullivan. The Supreme Court made clear that even "extensive" regulation is insufficient to impose responsibility on the government for private action. Sullivan, 119 S.Ct. at 986. As the Court explained, "[f]aithful application of the state-action requirement in these cases ensures that the prerogative of regulating private business remains with the States and the representative

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branches, not the courts." Id.⁸

Second, an important — perhaps critical — factual distinction exists between Catanzano and the present case. In Catanzano, the health care provider decisions at issue were final and unreviewable. Under state law, no administrative review or hearing was available to patients denied home health care services. See Catanzano, 60 F.3d at 117. By contrast, in the Medicare home health care context, a beneficiary may obtain an official Medicare determination by obtaining the disputed services and requesting the HHA to submit a demand bill to HCFA's representative. See supra at XXX. Thus, HCFA has not delegated its power to deny services to the HHA in the Medicare context, as the court found that New York had done in the Medicaid context. See Catanzano, 60 F.3d at 119.

B. No Protected Interest

Even if the private decisions of HHAs are considered federal action, plaintiffs are not entitled to due process protections at this level because they do not have a protected property interest in continuous Medicare coverage for their home health services. As the Supreme Court recently stated in Sullivan, "[t]he first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.' Only after finding the

⁸ Subsequent to its decision in Sullivan, the Supreme Court vacated and remanded the appellate court decision in Grijalva for further consideration in light of Sullivan. [Brief description of Grijalva] The Ninth Circuit relied on a similar analysis in finding state action in Grijalva. Similarly, J.K. v. Dillenberg [CITE] and Perry v. Chen [CITE] must be re-examined in light of Sullivan.

In any event, [distinguish Grijalva]

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deprivation of a protected interest do we look to see if the State's procedures comport with due process." 119 S.Ct. at 989 (citations to U.S. Const. Amend. XIV and Mathews v. Eldridge omitted); see also Logan v. Zimmerman Brush Co., 455 U.S. 422, 428 (1982) ("[W]e are faced with what has become a familiar two-part inquiry: we must determine whether Logan was deprived of a protected interest, and, if so, what process was his due."). To determine whether the plaintiff has a protected property interest deserving procedural protection we look at the substantive law underlying the asserted interest. "Property interests flow * * * from 'existing rules or understandings that stem from an independent source such as state [or, in this case, federal] law.'" Kelly Kare, Ltd. v. O'Rourke, 930 F.2d 170 (2d Cir.) (quoting Board of Regents v. Roth, 408 U.S. 564, 577 (1972)), cert. denied, 502 U.S. 907 (1991).

1. Sullivan, Mathews v. Eldridge, and Goldberg v. Kelly

In Sullivan, the plaintiffs argued that the workers' compensation benefits were a state-created entitlement because state law obligated the employer to pay the benefits once the employer's liability is established for a particular work-related injury. See 119 S.Ct. at 990. The Court noted, however, that the Pennsylvania workers' compensation statute did not entitle an employee to payment for all medical treatment once the employer's initial liability is established, but only for medical treatment that is reasonable and necessary. Id. Thus, "disputes over the reasonableness and necessity of particular treatment must be resolved before an employer's obligation to pay — and an employee's entitlement to benefits — arise." Id.

The Court contrasted the Sullivan scenario with Goldberg v. Kelly and Mathews v. Eldridge, in which "an individual's entitlement to benefits had been established, and the question

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presented was whether predeprivation notice and a hearing were required before the individual's interest in continued payment of benefits could be terminated." Sullivan, 119 S.Ct. at 990 (citing Goldberg, 397 U.S. at 261-63, and Mathews, 424 U.S. at 332). The Pennsylvania worker's compensation claimant's property interest "parallels" that of the welfare assistance beneficiary in Goldberg and the disability benefits recipient in Mathews only after he establishes both that his employer is liable for a work-related injury and that "the particular medical treatment at issue is reasonable and necessary." Sullivan, 119 S.Ct. at 990.

2. No Property Interest in Continuous Medicare Benefits

In determining whether a property interest exists, attention must be given to "the relevant statute, regulation, or contract establishing eligibility for the government benefit at issue." Plaza Health Laboratories, Inc. v. Perales, 878 F.2d 577, 581 (2d Cir. 1989). Under the Medicare statute and regulations, beneficiaries do not have a property interest in continuous Medicare benefits prior to an initial determination by the Secretary's agent, the RHHI. Moreover, an initial determination that a beneficiary may be eligible for some home health services does not carry with it the expectation or entitlement that all future services will be covered.

The Medicare statute and regulations place several significant limitations on a beneficiary's entitlement to services. First, the beneficiary must be "homebound" [CITE] and must require part-time or intermittent skilled services. [CITE] In addition, like the Pennsylvania worker's compensation scheme at issue in Sullivan, the Medicare statute excludes coverage for services that are not "reasonable and necessary." See 42 U.S.C. § 1395y(a)(1)(A). Furthermore, although chronic cases may require long-term care, each home health patient's plan of care must

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be reviewed at least every 62 days. [CITE] Thus, the Medicare program contemplates that each patient's condition must be reviewed continuously to determine whether additional benefits are "reasonable and necessary" and otherwise appropriate.²

In his concurrence in Sullivan, Justice Breyer suggested that "there may be individual circumstances in which the receipt of earlier payments leads a[] * * * person reasonably to expect their continuation, in which case that person may well possess a constitutionally protected 'property interest.'" Sullivan, 119 S.Ct. at 991 (Breyer, J., concurring). Given the expressly qualified nature of the home health benefit and the requirement of bi-monthly review, this is not such a case. As in Sullivan, a home health patient beneficiaries must satisfy establish specific statutory and regulatory requirements to receive payments under the Medicare program. Until he does so, his property interest in Medicare benefits for home health services does not "attach." See Sullivan, 119 S.Ct. at 990.

Nor are plaintiffs deprived of a property interest in their claims for benefits, as opposed to the benefits themselves. See Sullivan, 119 S.Ct. at 990 n.13 (dictum). In Logan v. Zimmerman Brush Co., 455 U.S. 422, 434 (1982), the Court stated that "the State may not finally destroy a

² [address plaintiffs' assertion {see Grijalva briefs} that certain cases establish protected interest exists in Medicare benefits (sec n. 4 of our Reply Brief in Support of Petition for Cert., citing Plaintiffs' Cert Opp. at 5, 6, 9, 17, 20, in turn citing cases:

Schweiker v. McClure 456 U.S. 188, 198 (1982)
Kramer v. Heckler, 737 F.2d 214 (2d Cir. 1984)
Grey Panthers v. Schweiker, 652 F.2d 146 (D.C. Cir. 1980)
Martinez v. Richardson, 472 F.2d 1121 (10th Cir. 1973)]

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property interest without first giving the putative owner an opportunity to present his claim of entitlement." HHA decisions denying, reducing or terminating home health services, however, do not cut off plaintiffs' rights to seek an official Medicare determination with respect to their entitlement to benefits. Compare Logan, 455 U.S. at 430-31 (holding that an alleged victim of discrimination had a protected property interest in his discrimination claim under his state's fair employment statute); see also Schvartsman v. Apfel, 138 F.2d 1196, 1198-99 (7th Cir. 1998) (no protected property interest in food stamp recertification procedures where there was not property interest in underlying benefits). Home health beneficiaries still may seek redress for alleged improper decisions through the administrative mechanism set up by the Medicare statute and the regulations.

III. Due Process Analysis: Application of Mathews v. Eldridge

A. Review Mathews

In Mathews v. Eldridge, the Supreme Court established a three-factor balancing test to determine "what process is due" in a particular situation. The court is to consider:

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest including the function involved and the fiscal and administrative burdens that additional or substitute procedural requirements would entail.

424 U.S. at 335.

B. Application to Healey

1. Importance of Interest

- Discuss Goldberg/Mathews distinction
- address Kramer v. Heckler, compare Califano v. Himmeler (see also Issacs v. Bowen, 865 F.2d 468, 476 (2d Cir. 1989)):
 Plaintiffs' private interest is in receiving or continuing to receive Medicare coverage for specific home health services

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pending an official Medicare determination.¹⁹ In other words, the interest is in the payments for the services, not the services themselves. [From Grijalva: The seriousness of this interest varies with the patient, his or her condition, and the nature of the services at issue. In some cases, the need for services may be urgent or critical. In other cases the need may be less dire.] However, since Medicare benefits are not based on financial need, the private interest in receiving payment for medical treatment under Medicare is not "overwhelming." Issacs v. Bowen, 865 F.2d 468, 476 (2d Cir. 1989) (citing McClure, 456 U.S. at 194). In Issacs, the Second Circuit stated that Medicare beneficiaries interest "may be 'considerable,' but they are hardly as significant, for example as an individual's right to receive welfare." *Id.*

The Second Circuit has not been entirely consistent about the significance of Medicare beneficiaries' interest. In Kraemer, the court stated that "the interest at stake should be weighed more heavily than in Eldridge because of the astronomical nature of medical costs." 737 F.2d at 222. Contrasts case with Eldridge.

Need to look at the degree of the deprivation that may be created.

2. Risk of Erroneous Deprivation (and Add'l Safeguards)
 - no evidence of substantial risk of erroneous deprivation
 - safeguards in place: statutes and regs provide for extensive review process
3. (Value of Additional Safeguards and) Burden on Government
 - note fiscal health of Medicare trust fund
 - a. Notice
 - discussion of implementation of new notice

In order to provide due process, notice must be "of such nature as reasonably to convey the required information, and it must afford a reasonable time for those interested to make their appearance." Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306, 314 (1950) (citations omitted). Whether notice is reasonable in a given case must be determined by reference to the Mathews factors. Perales v. Reno, 48 F.3d 1305, 1313 (2d Cir. 1995); "There is 'no rigid formula as to the kind of notice that must be given; notice required will vary with circumstances and conditions.'" Baker v. Latham Sparrowbush Associates, 72 F.3d 246, 254 (2d Cir. 1995) (quoting

¹⁹ [What is interest with respect to notice? Is it different?]

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Walker v. City of Hutchinson, 352 U.S. 112, 115 (1956)).

"A primary purpose of the notice required by the Due Process Clause is to ensure that the opportunity for a hearing is meaningful." City of West Covina v. Perkins, 119 S.Ct. 678, 681 (1999). Moreover, it is not typically the court's role to design the notice that an agency must give. [CITE]

"Due process requires notice that gives an agency's reason for its action in sufficient detail that the affected party can prepare a responsive defense." Barnes v. Healey, 980 F.2d 572, 579 (9th Cir. 1992).

The due process clause requires a form of notice "reasonably certain to inform those affected ... or, where conditions do not reasonably permit such notice, that the form chosen is not substantially less likely to bring home notice than other of the feasible and customary substitutes." > Mullane, 339 U.S. at 315, 70 S.Ct. at 658.
 948 F.2d 1327

----- Excerpt from page 948 F.2d 1327, *1334, 292 U.S.App.D.C. 219, **226

"[t]he precise form of notice ... depends upon a balancing of the competing public and private interests involved, as defined by the now familiar > Mathews factors." > Proper, 948 F.2d at 1332.

164 F.3d 37

----- Excerpt from page 164 F.3d 37, *46

Plaintiffs' request that the Court order the Secretary to require that HHAs give beneficiaries written notice when coverage is denied, reduced or terminated, and that the notice contain (1) a written statement of the reasons why services were denied, reduced or terminated, (2) an explanation of the beneficiary's right to have a demand bill submitted, and (3) a description of the procedure for pursuing an appeal. Am. Compl. at 25.

Due process does not require, as a general rule, "that notice of remedies and procedures" be provided. City of West Covina, 119 S.Ct. at 682. Rather, the notice must merely be sufficient to inform the person that his interest may be in jeopardy and that he should consider taking additional steps to protect that interest. See id. at 681-82. W

While it may be true that in some isolated instances the notices provided by HHAs have not met even this basic requirement, it is clear that the Secretary, through the conditions of participation and the Home Health Agency and Intermediary Manuals, has at all times required HHAs to do so. See supra at XX. Moreover, the Secretary is in the process of developing and implementing a mandatory form notice which will require HHAs to provide beneficiaries with the type of information that plaintiffs insist is required as a constitutional mandate. [Court should avoid ordering what we have committed to doing].

b. Demand Bills

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Plaintiffs contend that "[t]he Medicare appeals process is useless for most beneficiaries because they cannot enter the appeals process unless they continue to receive the services that are in dispute. Home health agencies will not provide such services unless the beneficiaries pay privately for them, which most cannot afford to do. Some home health agencies will not provide such services even if the beneficiaries offer to pay privately. Finally, if an appeal could be taken without prior receipt of services, the home health appeals process is so slow that urgently needed services would no longer be useful by the time a decision was obtained." (Pls.' Resp. to Interrog. 8).

Plaintiffs also contend that the Secretary's procedure for obtaining review of home health agency services determinations imposes delays because the fiscal intermediary initial determination and reconsideration steps are required before beneficiary may obtain an ALJ hearing. (See Pls.' Response to Interrog. 10).

c. Pretermination Review

Plaintiffs request the Court to order the Secretary to establish[] a pretermination or contemporaneous review process for home health denials so that needed services are not terminated pending appeals." (Complaint at 25).

Plaintiffs contend that "an expedited appeals process is required by Due Process for home health services that are urgently needed * * *. An internal review process by the home health agency should be completed within 3 days and an independent review agency process should be completed within 10 days. In each case the beneficiary should have a meaningful opportunity to obtain and submit evidence in support of her claim." (Pls.' Resp. to Interrog. 11).

"Regrettably, delay is a natural concomitant of our administrative bureaucracy." Issacs, 865 F.2d at 477 (holding that estimated 19 months from claim initiation to completion of ALJ review was not remarkable" and was not inordinately long" so as to violate due process)

IV. Enforcement Claim

- A. Not Reviewable - Heckler v. Chaney
- B. No Judicial Supervision of Medicare Program
 - Seafarer's, Council for the Blind