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UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

FILED

SEP 21 2 51 PM '01

RUTH HEALEY, ET AL
Plaintiffs

V.

CASE NO. 3:98cv418(DJS)

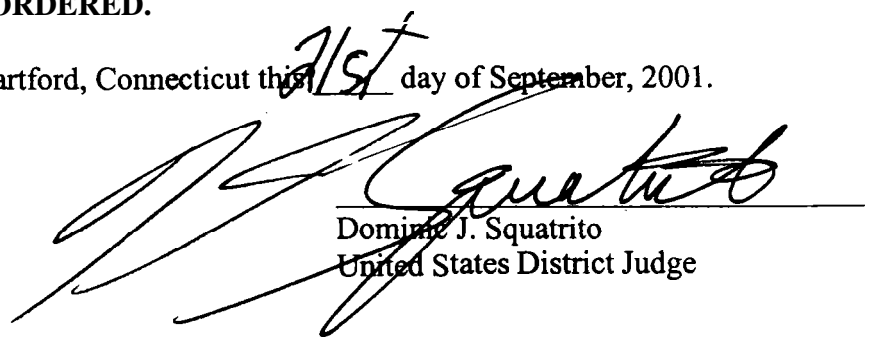
TOMMY G. THOMPSON, SECRETARY
OF THE UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES
Defendant

ORDER

Upon review and pursuant to 28 U.S.C. § 636(b)(1)(B) and Rule 2 of the Local Rules for United States Magistrate Judges (D. Conn.), Magistrate Judge Thomas P. Smith's Recommended Ruling (Doc. #140), is APPROVED and ADOPTED as the Ruling of this Court, over objection.

IT IS SO ORDERED.

Dated at Hartford, Connecticut this 21st day of September, 2001.



Dominic J. Squatrito
United States District Judge

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UNITED STATES DISTRICT COURT FILED

DISTRICT OF CONNECTICUT Aug 8 2 44 PM '01

U.S. DISTRICT COURT
HARTFORD, CT

RUTH HEALEY; MARCIA LUTWIN; LINDA WIERDA; JANE KOZLOWSKI; MARGARET A. WALZ; ROGER AUDETTE; MARION MORGAN, by her next friend, DOROTHY M. HILTZ; JULIA M. CULVER, by her next friend, THE REVEREND HORACE MITCHELL; and BERTHA CHIPLIN, by her next friend, ALFRED J. CHIPLIN, SR.; MADALYN ROVNER; ROLAND COTE; FLORENTINA CALDERON, by her next friend, EVA MORENO; HELEN BAGWELL; MAXINE MARMOR; and KATHERINE WATTS, individually and on behalf of all others similarly situated,
-Plaintiffs

v.

NO. 3:98 CV 418 (DJS) (TPS)

TOMMY G. THOMPSON, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

-Defendant

RECOMMENDED RULING ON CROSS MOTIONS FOR SUMMARY JUDGMENT

This case is a nation-wide class action brought on behalf of recipients of home health care benefits from Medicare seeking "meaningful notice and appeal rights when their home health benefits are reduced or terminated," (Compl., ¶1), in the form of injunctive relief against the Department of Health and Human Services. On February 11, 2000, the court partially granted plaintiffs' first motion for summary judgment in part, issued a

declaratory judgment, and afforded plaintiffs the opportunity to seek further relief. Plaintiffs have now come forth in search of such relief by way of a second motion for summary judgment (**docket no. 114**), which defendant opposes by way of his own motion for summary judgment (**docket no. 123**). For the reasons set forth below, plaintiffs' motion is DENIED, and defendant's motion is GRANTED. In light of the considerations discussed herein, this court's prior ruling addressing the circumstances in which home health agencies ("HHAs") are required to give written notice of decisions regarding **Medicare** coverage and the procedure to appeal such **decisions** should not be expanded upon.

I. BACKGROUND

This is a provisionally certified class action, see Fed. R. Civ. Pro. 23(c)(1), brought by named plaintiffs who reside across the country on behalf of "persons entitled to Medicare benefits who need and/or have received home health services which have been or will be denied, reduced or terminated." (Compl. ¶ 10). Familiarity with this court's prior ruling, ~~Healey v. Shalala~~, No. 3:98cv418 (DJS), 2000 WL 303439 (D. Conn. Feb. 11, 2000), which sets forth much of the necessary background information, is presumed, and therefore only the pertinent changes in the landscape of this litigation are discussed herein.

The plaintiffs are either aged 65 and over, or have been found to be disabled; are eligible for Medicare; and have been receiving

home health care services¹ from private home health agencies, which

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"Home health services" are defined as:

the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual's home-

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical or occupational therapy or speech-language pathology services;

(3) medical social services under the direction of a physician;

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary;

(5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk) of this section), but excluding other drugs and **biologicals**) and durable medical equipment while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or **resident-in-training** of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b) of this section; and

(7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations,

contract with the defendant to be reimbursed for the services covered by the Medicare program. (See Pls.' Local Rule 9(c) (1), Dkt. # 116, ¶¶ 1-2 (hereinafter "Pls.' 9(c) (1)")).² Generally

and--

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A),

but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) of this section if furnished to an inpatient of a hospital. For purposes of paragraphs (1) and (4), the term "part-time or intermittent services" means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1395f(a) (2) (C) and 1395n(a) (2) (A) of this title, "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

42 U.S.C. § 1395x(m); see also 42 C.F.R. § 409.42 (listing the necessary qualifications for eligibility for home health services).

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Pursuant to Rule 9(c) of the Local Rules of Civil Procedure for the District of Connecticut, the parties have submitted statements of the material facts as to which the parties contend there is no genuine issue to be tried, and the appropriate supporting materials and responses thereto. As such, all

speaking, home health care is, in appropriate cases, a less expensive and more comfortable alternative to hospital or skilled nursing facility care. Each of these named plaintiffs has experienced an actual or proposed reduction or termination of home health services resulting from a determination of the home health agency administering care. (See id., ¶ 6). Briefly stated, they all challenge the adequacy of the notice provided to them upon a change in care and the sufficiency of the appeals process available to them.

After this lawsuit was filed, the payment system for the home health services program within the Medicare scheme has undergone fundamental changes that have a significant impact upon this litigation. On July 3, 2000, the Health Care Financing Administration ("HCFA") published the final rule implementing the Home Health Prospective Payment System "HH PPS" effective October 1, 2000, as required by the Balanced Budget Act of 1997. See Medicare Program: Prospective Payment System for Home Health Agencies, 65 Fed. Reg. 41128 (Jul. 3, 2000) (codified at 42 C.F.R. 409, 410, 411, 413, 424, and 484); see also 42 U.S.C. § 1395fff(a); 42 C.F.R. 484.200. The new rule "establishes requirements for the new prospective payment system for home health agencies," which include "the implementation of a prospective payment system for

statements taken from these documents are admitted unless an objection is noted. See D. Conn L. Civ. R. 9(c)(1).

home health agencies, consolidated billing requirements, and a number of other related changes." Id. at 41128.

The linchpin of the HH PPS is the sixty-day episode of care. See 42 C.F.R. § 484.205(a). When a patient eligible for Medicare coverage requires home health care services, the physician, in conjunction with the provider, devises a plan of care for the patient for the next sixty days that includes, among other things, a diagnosis and prognosis, description of the types of services required, the frequency of the services, and the provider of the services. See 42 C.F.R. § 484.18(a). This plan of care must then be certified in order to obtain final payment. 42 U.S.C. § 1395f(a)(2)(C).³

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This section reads, in pertinent part, as follows:

Payment for services furnished an individual may be made only to providers of services which are eligible **therefor** under section 1395cc of this title and only if-

(2) a physician . . . certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations . . .) **that-**

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely veinpuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a

In addition, the HHA must conduct a comprehensive assessment of the patient as follows:

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and the time of the comprehensive assessment.

42 C.F.R. § 484.55. This assessment must incorporate the Outcomes and Assessment Information Set ("OASIS"), which is "a standardized assessment tool that provides a detailed examination of the patient's physical and mental condition, as well as other information pertinent to the patient's care, such as the patient's health history, living arrangements, and activities of daily living." (Hoyer Dec., Dkt # 90, ¶ 5). At a minimum an OASIS review must be conducted every sixty days, and a new physician certified plan of care must be issued at the same increment of time. 42 C.F.R. § 484.55(d).

Upon evaluation of the patient and formulation of a plan of care, the HHA then submits a request for anticipated payment. This

plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; and such services are or were furnished while under the care of a physician. . . .

42 U.S.C. § 1395f(a)(2)(C).

request is based upon a nationally uniform price figure that is modified through the application of two adjustments: the case-mix adjustment and the wage adjustment. In determining the case-mix adjustment, the patient is assigned to one of eighty home health resource groups, which is done by assigning three different variables pursuant to the data from the OASIS evaluation, including clinical severity factors, functional severity factors, and services utilization factors. (See Wardwell Dec., Dkt # 127, Ex. c, ¶ 5). The wage adjustment takes into account the geographic variation in wages. These adjustments represent the HCFA's standardized valuation of the services the HHAs intend to provide, taking into account the beneficiary's condition and needs, during the sixty-day episode of care.

Upon submission of a properly supported request for anticipated payment, the HHA will then receive 60% (50% for subsequent episodes) of the total payment from the fiscal intermediary, and the remaining 40% upon submission of a final claim, detailing the actual services provided, along with a physician certified plan of care. See 42 C.F.R. § 484.205(b). This final request is considered the actual Medicare claim; the fiscal intermediary reserves the right to cancel and recover the initial payment in situations when "protecting Medicare integrity warrants this action," and when the final claim is not submitted beyond the greater of sixty days from the end of the episode or sixty days from the issuance of the request for anticipated

payment. 42 C.F.R. § 409.43(c)(2).

In addition to the change in the payment system, the Secretary has also required that HHAs provide a mandatory notice to beneficiaries in certain situations. As of March 1, 2001, HHAs must provide Home Health Advance Beneficiary Notices ("HHABNs") when a physician orders services under the following circumstances:

Provision of Home Health Advance Beneficiary Notices (HHABNs)-- Provide a HHABN to beneficiaries, according to the following instructions, whenever Medicare payment denial is expected on any one of the following statutory bases: not medically necessary and reasonable (under § 1862(a) (1) of the Act); custodial care exclusion (under § 1862(a) (9) of the Act); and failure to meet the HHA services homebound and intermittent care requirements (under § 1879(g)(1) of the Act). Do not pre-select any option on the form.

a. Providing HHABNs at Initiation of Services-- In the situation in which you advise a beneficiary that you will not accept the beneficiary as a Medicare patient because you expect that Medicare will not pay for the services, for one of the reasons listed above, provide a HHABN to the beneficiary before you furnish home health services to the beneficiary. Check the first block ("We expect Medicare will not pay for any home health services for you") on the first page [of the HI-IABN].

b. Providing HHABNs at Reduction of Services-- In the situation in which you propose to reduce a beneficiary's home health services because you expect that Medicare will not pay for a subset of home health services, or for any services at the current level and/or frequency of care, for one of the reasons listed above, provide an HHABN to the beneficiary before you reduce services to the beneficiary. Check the second block ("We expect Medicare will stop paying for some of your home health services") on the first page [of the HHABN].

c. Providing HHABNs at Termination of Services-- In the situation in which you propose to stop furnishing all home health services to a beneficiary, because you expect that Medicare will not continue to pay for the services, for one of the reasons listed above, provide a HHABN to

the beneficiary before you terminate such home health services. Check the third block ("We expect Medicare will stop paying for all home health services for you") on the first page [of the HHABN].

Health Care Financing Administration, Transmittal A-01-05 at 6-7 (Jan. 16, 2001) (Advance Beneficiary Notices Must Be Given To Beneficiaries and Demand Bills Must be Submitted By Home Health Agencies (HHAs)-ACTION). The Secretary emphasizes that "Medicare never pays for home health care that is not ordered by a physician," and therefore his instructions to provide a HHABN do not

apply to situations where care is reduced or terminated in accordance with a physician's order; that is, where the services at issue are not ordered by a physician or where the physician agrees with your assessment that the services are not or are no longer reasonable and necessary.

Id. at 9. When the physician concurs, the HHA is obliged to document the concurrence in writing in the patient's records, and provide notice in accordance with the conditions of participation. See 42 U.S.C. § 1395bbb(a)(1); 42 C.F.R. § 484.10.

The HHABN is written in plain language and purports to serve the dual purpose of providing written notification of an HHA's adverse coverage determination, as well as apprizing the beneficiary of the appeals process. Specifically, the notice provides a reason why the HHA does not believe the services ordered by a physician are covered under Medicare, the cost of the services, and the conditions precedent to initiating the appeals process. The HHABN whittles this information down into three

options for the beneficiary:

A. I want to receive the specified home health services and obtain a Medicare official decision. Please submit a claim, with any supporting evidence that I include, to Medicare for its official decision. Please bill my other health insurance (_____) if necessary. I understand that, if I have no insurance other than Medicare, I might have to pay for these services while Medicare is making its decision. If Medicare or another insurer does decide to pay and I have made any payments, I will be refunded any amounts that I am due. I agree to be fully and personally responsible for payment of any amount for which Medicare and my other insurance will not pay.

B. I do not want to receive the specified home health services.

C. I want to receive the specified home health services. I do not want you to submit a claim or any health information to Medicare for an official decision. I know that I will be fully responsible for payment.

Health Care Financing Administration, Transmittal A-01-05 (Jan. 16, 2001) (Advance Beneficiary Notices Must Be Given To Beneficiaries and Demand Bills Must be Submitted By Home Health Agencies (HHAs)-ACTION). If the beneficiary chooses option "A," the HHA becomes obligated to submit a demand bill to the Regional Home Health Intermediary ("RHHI") for an initial determination, thus commencing the appeals process.

Due to the change in the payment system, the demand bill process is somewhat different than it was at the time of this court's prior ruling. Because the final request for payment at the end of a sixty-day episode of care is considered the Medicare "claim," and only one claim may be submitted per episode, a demand bill can only be submitted after the sixty-day episode has

occurred:

The meaning of "prompt" submission under HHA PPS, specifically, is as follows: Under HHA PPS, you may submit only one claim for payment at the end of each episode of care. See 65 F.R. 41,128 (July 3, 2000) (Medicare Program: Prospective Payment System for Home Health Agencies, Final Rule). Thus, under HHA PPS, "prompt submission" of a claim with the demand bill code requires that the claim (i.e., the demand bill) be submitted at the end of the episode in question, at the time you submit your claim for final payment for the episode. See 65 F.R. at 41,141. Pursuant to the HHA PPS Final Rule, where you have received a "request for anticipated payment" (RAP) for an episode, the RAP will be canceled and recovered unless the claim for the episode (with the condition code 20 to indicate that the claim is a demand bill when requested by the beneficiary in the circumstances described in this PM [Program Memorandum]) is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the anticipated payment.

Health Care Financing Administration, Transmittal A-01-05 (Jan. 16, 2001) (Advance Beneficiary Notices Must Be Given To Beneficiaries and Demand Bills Must be Submitted By Home Health Agencies (HHAs)-ACTION). Although at present there is no time limitation⁴ on the processing of the demand bills once they reach the RHHIs, beginning October 1, 2002 RHHIs will have to initially process "clean" (or sufficiently documented) claims within forty-five days of receiving them. See An Act Making Consolidated Appropriations for the Fiscal Year Ending September 30, 2001, and for Other Purposes, Pub. L. 106-554, 114 Stat. 2763, 2763A-534 (2000) (amending 42 U.S.C. §

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Prior to the implementation of HHA PPS, RHHIs took approximately four months to issue an initial determination. (Pls.' 9(c) (1), ¶ 16).

1395ff effective October 1, 2002). If the HHA fails to promulgate this notice it could be forced to accept liability for billed non-covered services. (Def.,s 9(c) (1), ¶ 4).

Plaintiffs originally alleged that the Secretary had committed four violations of the Medicare statutes and the Due Process Clause of the Fifth Amendment by: (1) failing to provide written notice when home health agencies deny, reduce, or terminate home health services; (2) failing to provide a statement of the rationale for the change in benefits, a notice that the beneficiary may contest the change, and an explanation of how to use the appeal process; (3) neglecting to establish an effective demand bill procedure; and (4) refusing to provide for a pre-deprivation review process during the appeal.

In a prior ruling, the court issued a declaratory judgment stating that:

the plaintiffs have a legal right to a written: (1) **pre-**deprivation statement why the HHA believes Medicare may not or may no longer cover their services; (2) explanation of the circumstances in which a beneficiary has the right to have a demand bill submitted, and (3) disclosure of information regarding a patient's right to appeal

Healey, 2000 WL 303439, at *1 (quoting Dkt. # 46). Because the HHAs are engaged in "making coverage decisions, without fair notice, under the mantle of the Secretary's authority, and in circumstances where their actions are fairly attributable to [him]," id. at *8, the defendant

has a statutory obligation to provide Medicare home

health benefits to eligible individuals, . . . and to assure that HHAs comply with the conditions of participation as Medicare providers, including the duty to provide fair notice to beneficiaries when services are reduced or terminated.

Id. at *9. As such, the court refused to allow defendant "to sidestep legal responsibility by delegating to HHAs the power to summarily reduce, or extinguish without notice and an opportunity to be heard, crucial and often life-sustaining benefits that have already been awarded., , Id.

Due to the court's prior decision, as well as recent developments discussed above, many of plaintiffs' claims have been addressed, to some degree, by the defendant.⁵ However, plaintiffs persist in claiming that, although some changes in the system are a step in the right direction, the procedures in place fall short of meeting the statutory requirements and affording them sufficient due process of law to protect their property interest in Medicare coverage.

II. DISCUSSION

Plaintiffs seek two forms of additional relief. First, plaintiffs' claim that the defendant's HHABN procedure violates both the Medicare statute's requirements and minimal constitutional protections in that it fails, by design, to provide adequate notice to beneficiaries in a host of situations. Second, plaintiffs claim

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For example, plaintiffs do not contest the sufficiency of the HHABN itself.

that due process mandates a pre-deprivation review of their demand bills.

A. STANDARD

When cross-motions for summary judgment are pending, "[e]ach individual summary judgment motion must be evaluated independently to determine whether there exists a genuine dispute of material fact and whether movant is entitled to judgment as a matter of law." 11 Moore's Federal Practice § 56.10(6) (Matthew Bender 3d ed. 1999) (citing A. Brod, Inc. v. SK&I Co., LLC, 998 F. Supp. 314, 320 (S.D.N.Y. 1998)). Thus, in order to prevail, each party must sustain his or her burden under Rule 56.

A motion for summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions of file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. Pro. 56(c). The Supreme Court has stated that "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery upon motions, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

However, "[i]f there is any evidence in the record from which

a reasonable inference [can] be drawn in favor of the non-moving party on a material issue of fact, summary judgment is improper." Tomka v. The Seiler Corporation, 66 F.3d 1295, 1304 (2d Cir. 1995) (citing Chambers v. TRM Copy Centers Corp., 43 F.3d 29, 37 (2d Cir. 1994)). An issue of fact must be both genuine and material; "[w]hile genuineness runs to whether disputed factual issues can 'reasonably be resolved in favor of either party,' . . . materiality runs to whether the dispute matters, i.e., whether it concerns facts that can affect the outcome under the applicable substantive law. . . . A reasonably disputed, legally essential issue is both genuine and material and must be resolved at trial." Graham v. Henderson, 89 F.3d 75, 79 (2d Cir. 1996); see Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-250 (1986). The "mere existence of factual issues-- where those issues are not material to the claims before the court-- will not suffice to defeat a motion for summary judgment." Quarles v. General Motors Corp. (Motor Holding Div.), 758 F.2d 839, 840 (2d Cir. 1985).

B. HHABN NOTICES

Plaintiffs contend that the both the Medicare statute and the Due Process Clause of the Fifth Amendment require that the HHA send the HHABN notice to the beneficiary when it makes any adverse determination, rather than just an adverse determination regarding Medicare coverage. Practically speaking, plaintiffs seek the court

to force HHAs to provide written notice whenever it reduces or terminates services rendered to a Medicare beneficiary, irrespective of the reason for the action. Defendant claims that statutory and constitutional protections do not apply to HHAs when they are not making Medicare coverage determinations, and, even if such requirements were applicable, defendant has satisfied its obligations.

The court has previously determined that an HHA's failure to provide both the notice of action contemplated by the Medicare statute, 42 U.S.C. § 1395bbb(b),⁶ as well as notice of the appeal mechanism, 42 U.S.C. § 1395ff(a),⁷ is fairly attributable to the

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This provision reads as follows:

It is the duty and responsibility of the Secretary to assure that the conditions of participation and requirements specified in or pursuant to section 1395x(o) of this title and subsection (a) of this section and the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency and to promote the effective and efficient use of public moneys.

42 U.S.C. § 1395bbb(b) .

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The Secretary's obligation in this respect is the following:

The determination of whether an individual is entitled to benefits under part A or part B of this subchapter, and the determination of the amount of benefits under part A or part B of this subchapter and any other determination with respect to a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchapter shall be made by the Secretary in accordance with regulations prescribed by him.

Secretary, in that the HHAs' actions can be considered those of the Secretary. Healey, 2000 WL 303439, at *9. Thus, in order to determine the contours of the HHAs' obligations to Medicare beneficiaries, the court must focus on the language of the statute itself:

The conditions of participation that a home health agency is required to meet under this subsection are as follows:

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

(A) The right to be fully informed in advance about the care and treatment to be provided by the agency, 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, and (except with respect to an individual adjudged incompetent) to participate in planning care and treatment or changes in care or treatment.

(B) The right to voice grievances with respect to treatment or care that is (or fails to be) furnished without discrimination or reprisal for voicing grievances.

* * * *

(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 this subchapter,

(ii) the coverage available for such items and services under this subchapter, subchapter XIX of this chapter, and any other Federal program of which the agency is reasonably aware,

42 U.S.C. § 1395ff(a).

(iii) any charges for items and services not covered under this subchapter and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and

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

(F) The right to be fully informed in writing (in advance of coming under the care of the agency) of the individual's rights and obligations under this subchapter.

42 U.S.C. § 1395bbb(a) (1).

The plain language of the statute does not require written notice of a reduction or termination of services initiated by the treating physician or the HHA that do not involve Medicare coverage. Subsection (A), which covers such situations, confers "the right to be fully informed in advance," whereas subsection (E), which explicitly covers HHA decisions relating to Medicare coverage, specifically confers "the right to be fully informed orally and in writing." Id. This disparity in use of language has a purpose, see Bates v. U.S., 522 U.S. 23, 29-30 (1997) (stating that "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion," internal quotation marks omitted), and "the court's role is not to 'correct' the text so that it better serves the statute's purposes, for it is the function of the political branches not only to define the goals but also to choose the means for reaching them," Enaine Mfr.'s Ass'n

v. U.S. Env'tl. Protection Agency, 88 F.3d 1075, 1089 (D.C. Cir. 1996). A court may not "avoid the Congressional intent clearly expressed in the text simply by asserting that its preferred approach would be better policy." Id.

Plaintiffs advance two alternative theories through which they claim the HHAs are obliged to provide written notice in a greater number of instances than required by the Secretary in his transmittal. &Health Care Financing Administration, Transmittal A-01-05 at 6-7 (Jan. 16, 2001) (Advance Beneficiary Notices Must Be Given To Beneficiaries and Demand Bills Must be Submitted By Home Health Agencies (HHAs)-ACTION).

First, plaintiffs argue that certain decisions not deemed "coverage" decisions by the Secretary should fall under the mantle of coverage decisions within the meaning of the statute, thus triggering the protections afforded by such statute and previously addressed by the court. Specifically, plaintiffs argue that "an HHA's decision to reduce or terminate care which is allegedly based upon changes in the physician's orders to the care plan is a coverage decision" within the meaning of 42 U.S.C. § 1395bbb(a)(1)(E) because one "[o]f the several criteria for eligibility for Medicare home health coverage . . . is that the services must be ordered by a physician" under 42 U.S.C. § 1395x(m). (Pl.'s Mem. Supp. Sum. J., Dkt. # 115, at 14). Defendant justifies his position by stating that

[n]on-coverage based decisions in care do not involve the Medicare statute's promise of payment for services rendered. Rather, a change in care consistent with a doctor's order, regardless of whether the change is initiated by the doctor or the HHA with the doctor's concurrence, is a function of the treatment relationship between the doctor, the home health care provider, and the patient- a relationship in which the government is not a participant.

(Def.'s Mem. Supp. Summ. J., Dkt # 128, at 15). Thus, plaintiffs claim that when an HHA refuses to provide care on the grounds that the care has not been ordered by a physician there is no practical basis to distinguish this situation from others in which the HHA makes a factual determination as required by the Medicare statutory scheme, which necessitate procedural protections.

The question to be decided is whether the Secretary's interpretation of the statute is legally permissible. When determining if an agency's construction of a statute is legally permissible, the analysis is governed by the Supreme Court's decision in Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). Pursuant to this framework, the reviewing court asks two questions. See id. at 842. First "is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id. at 842-43. If this first question is answered in the negative, then "the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. at 843. The

agency's interpretation is "given controlling weight unless [it is] arbitrary, capricious, or manifestly contrary to the statute." Id at 844.

The governing statute, 42 U.S.C. § 1395bbb(a)(1)(E), contains specific terms indicative of congressional intent, and does not require interpretation under Chevron. The statute lists four pieces of information that must be conveyed to the beneficiary in writing. First, written notice must be provided detailing "all items and services furnished by (or under arrangements with) the agency for which payment may be made under this subchapter." 42 U.S.C. § 1395bbb(a)(1)(E)(i). Second, the HHA must give written notice of "the coverage available for such items and services under this subchapter, subchapter XIX of this chapter, and any other Federal program of which the agency is reasonably aware." 42 U.S.C. § 1395bbb(a)(1)(E)(ii). Third, written appraisal of "any charges for items and services not covered under this subchapter and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency" is necessary. 42 U.S.C. § 1395bbb(a)(1)(E)(iii). The fourth section merely states that any changes in the preceding three pieces of information must also be in writing. See 42 U.S.C. § 1395bbb(a)(1)(E)(iv).

Each of these subsections requires the written transmittal of information concerning payment for and not the provision of home health services. Defendant is correct in observing that, in the

absence of a practitioner's orders, whether it be an independent physician or an HHA professional, services are not provided. Therefore, logic dictates that, if services are not provided, there is simply no information regarding any payment decision of the type specifically contemplated by 42 U.S.C. § 1395bbb(a)(1)(E). Congress has unambiguously spoken: beneficiaries are entitled to know what services are covered by Medicare and how much will be paid by Medicare. If there are no services in the first place, then the language in 42 U.S.C. § 1395bbb(a)(1)(E) simply does not apply.

Second, plaintiffs invoke the Due Process Clause, and argue that, in order to protect their property interest, the Secretary, through the HHAs, must be compelled to provide written notice of a reduction or termination of benefits regardless of the reason therefor. Plaintiffs assert that the basis for the HHA's decision to terminate or reduce benefits does not often fit neatly into one of the categories set forth in the transmittal, and therefore, in order to completely preserve plaintiffs' right to receive written notice of the actions set forth in the statute, written notice in all circumstances should be required, regardless of the ability to access the appeal process.⁸

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Plaintiffs do not claim that there should be access to the demand bill and appeal process when the basis for the action is a physician's order or a HHA business decision, only written notice of the reason.

Plaintiffs' argument ignores a fundamental distinction. Under the Medicare scheme, HHAs perform two functions, which, from the plaintiffs' perspective, are often viewed as one. First, the HHA must administer the Medicare program to the beneficiary, a task that includes determining the beneficiary's eligibility for Medicare benefits. In this capacity, the Secretary, who has delegated his responsibility to administer the Medicare program to the HHAs, reviews the HHAs' decision through the RHHIs. Second, HHAs provide, in conjunction with the beneficiary's treating physician, the care paid for by the Medicare program. In contrast to the first function, the HHA does not perform its responsibilities as a delegate of the Secretary; here the HHA functions as a health care provider and is held to the prevailing standard of care in the community. Thus, the distinction is that, when an HHA acts as an agent of the Secretary when administering the Medicare program, its actions are subject to the constitutional protections of the Fifth Amendment, but, when it acts as a health care provider, its actions are not subject to constitutional scrutiny.

Courts have recognized this dichotomy in a similar context, namely when construing the effect of the provisions of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§ 1001 et seq., upon modern private health care enterprises such as Health Maintenance Organizations ("HMOs"). ERISA is a comprehensive statutory scheme designed to ensure the competent and faithful

administration of employee benefit plans, including health insurance plans, and mandates that any claim to enforce rights under a plan, regardless of how it is presented, be presented in federal court. Therefore, when determining if a claim against an HMO (or physician acting as an agent of an HMO) is completely preempted by ERISA, and therefore subject to removal to district court from state court, courts endeavor to determine whether the claim alleges faulty administration of an employee benefit plan, and thereby should be construed as a claim brought pursuant to ERISA, see 29 U.S.C. § 1132(a) (1) (B), or negligent provision of care, which should be considered a state law malpractice claim. See Prvzbowski v. U.S. Healthcare, Inc., 245 F.3d 266, 273 (3d Cir. 2001) (holding that claims against an HMO based upon a delay in approving benefits were addressed to the HMO as a plan administrator, and therefore were both completely and expressly preempted); In re U.S. Healthcare, Inc., 193 F.3d 151, 162-65 (3d Cir. 1999) (holding that claims challenging the propriety of the HMO's policy of discharging mother and newborn from the hospital 24 hours after birth concerned the HMO's role as provider of care and therefore were not completely preempted); Jass v. Prudential Health Care Plan, Inc., 88 F.3d 1482, 1489 (7th Cir. 1996) (holding that claims directed to a registered nurse acting in a capacity as a utilization reviewer for an HMO plan were completely preempted); Dukes v. U.S. Healthcare, Inc., 57 F.3d 350, (3d Cir. 1995) (holding that claims alleged defects in the quality of care

received, not a failure to provide benefits, and therefore were not completely preempted); Corcoran v. United Healthcare, Inc., 965 F.2d 1321, 1332 (5th Cir. 1992) (holding that the claims directed to a utilization review agency, which determined what the HMO should pay for under its benefit plan, were completely preempted).

In addition, the Supreme Court has acknowledged this dichotomy during the course of determining whether, under a certain set of facts, an HMO could be considered a fiduciary within the meaning of ERISA. See Pegram v. Herdrich, 530 U.S. 211 (2000). In Pegram, the plaintiff alleged that the HMO breached a fiduciary duty, imposed by ERISA, when its physicians, who own the HMO and receive a portion of the total profits earned each year, made medical necessity determinations while standing to profit from under-utilization of services. Id. at 216. The Court held that

[i]n every case charging a breach of ERISA fiduciary duty, then, the threshold question is not whether the actions of some person employed to provide services under a plan adversely affected a plan beneficiary's interest, but whether that person was acting as a fiduciary (that is, was performing a fiduciary function) when taking the action subject to complaint.

Id. at 226. The Court then focused on the precise nature of the functions alleged to be unlawful in this case:

It will help to keep two sorts of arguably administrative acts in mind. Cf. Dukes v. U.S. Healthcare, Inc., 57 F.3d 350, 361 (C.A.3 1995) (discussing dual medical/administrative roles of HMOs). What we will call pure "eligibility decisions" turn on the plan's coverage of a particular condition or medical procedure for its treatment. "Treatment decisions," by contrast, are choices about how to go about diagnosing and treating a

patient's condition: given a patient's constellation of symptoms, what is the appropriate medical response?
These decisions are often practically inextricable from one another, as *amici* on both sides agree. See Brief for Washington Legal Foundation as *Amicus Curiae* 12; Brief of Health Law, Policy, and Ethics Scholars as *Amici Curiae* 10. This is so not merely because, under a scheme like [the HMO's], treatment and eligibility decisions are made by the same person, the treating physician. It is so because a great many and possibly most coverage questions are not simple yes-or-no questions, like whether appendicitis is a covered condition (when there is no dispute that a patient has appendicitis), or whether acupuncture is a covered procedure for pain relief (when the claim of pain is unchallenged). The more common coverage question is a when-and-how question. Although coverage for many conditions will be clear and various treatment options will be indisputably compensable, physicians still must decide what to do in particular cases. The issue may be, say, whether one treatment option is so superior to another under the circumstances, and needed so promptly, that a decision to proceed with it would meet the medical necessity requirement that conditions the HMO's obligation to provide or pay for that particular procedure at that time in that case. The Government in its brief alludes to a similar example when it discusses an HMO's refusal to pay for emergency care on the ground that the situation giving rise to the need for care was not an emergency, Brief for United States as *Amicus Curiae* 20-21. In practical terms, these eligibility decisions cannot be untangled from physicians' judgments about reasonable medical treatment. . . .

Id. at 227-229. Finally, the Court found that the decisions challenged by the plaintiff fell into the category of "mixed eligibility decisions," and that such decisions were not fiduciary decisions under ERISA. Id. at 237.

These cases stand for the prevailing view that, in the modern landscape of the health care industry, one entity can perform two traditionally distinct functions: the administration of a health

insurance plan and the provision of medical care, and the performance of each function can incur different consequences. This concept, discussed in some detail by federal courts as applied to the private sector, carries equal force when applied to Medicare, which is essentially a government insurance program for qualified individuals.⁹ When an HHA makes "eligibility decisions,,, it can be considered an agent of the Secretary because it functions as the "plan administrator,, of Medicare, and therefore the Secretary can fairly be charged with ensuring that the administration of Medicare passes constitutional muster. However, when an HHA makes "treatment decisions,,, or "mixed eligibility and treatment decisions,,, the HHA is not administering the provisions of the Medicare statute, and therefore cannot be considered an agent of the Secretary. As such, the Secretary cannot be held responsible for these decisions.

This principle, as borrowed from the law governing private administration of health care benefit plans, squares with controlling precedent" addressing federally funded health care

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Through Medicare and Medicaid, the federal government is essentially the largest health insurance provider in the United States.

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Although the judgment of the court in that case has been vacated, and the matter has been settled, the principles discussed in this opinion are also consistent with the reported opinions in the Griialva case, which attributed coverage determinations made by an HMO to the Secretary. See Griialva v. Shalala, 946 F. Supp. 747 (D. Ariz. 1996), aff'd, 152 F.3d 1115 (9th Cir. 1998), vacated, 526

benefit plans.¹¹ In Kraemer v. Heckler, 737 F.2d 214 (2d Cir. 1984), the Second Circuit held that utilization review to determine future eligibility for Medicare benefits, conducted by a private entity at the behest of the Medicare scheme, could fairly be imputed to the Secretary. Similarly, in Catanzano v. Dowling, 60 F.3d 113 (2d Cir. 1995) and Catanzano v. Wing, 103 F.3d 223 (2d Cir. 1996), the Second Circuit found that Community Home Health Agencies, determinations of the necessity and appropriateness of the medical services ordered by a physician under New York's comprehensive Medicaid regulatory scheme were state actions under the Fourteenth Amendment.* By contrast to the Second Circuit

U.S. 1096 (1999).

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The court does not draw this analogy lightly. The private sector cases are concerned with selecting an appropriate forum for litigating causes of action, while, in this case, the applicability of fundamental constitutional protections hinges upon this distinction. However, both the private sector cases construing ERISA, and the government benefit cases do square with one another. But see Jennifer L. Wright, Unconstitutional or Impossible: The Irreconcilable Gap Between Managed Care and Due Process in Medicaid and Medicare, 17 J. Contemp. Health L. & Pol'y 135, 138 (2000) (arguing that, "in a managed care context, every decision made by a doctor as to medical treatment of a Medicare or Medicaid beneficiary becomes subject to the notice and hearing requirements required by federal statutes and regulations for coverage decisions,, because of the want of an unbiased decision-maker).

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In Catanzano, the Second Circuit rejected the state's attempt to bifurcate the first step of the prior approval for benefits decision, which is governed by state regulation, at issue in that case into an "eligibility,, component and "medical judgment,, component. Catanzano, 103 F.3d at 228-29. However, taken in its proper context, this language does not detract from the analysis in this case because the Second Circuit was responding to New York's

decisions, the Supreme Court has held that decisions to transfer or discharge a patient from a skilled nursing facility, which are initiated by the professionals in the facility, cannot be attributed to the state despite the fact that the decision results in a change in Medicaid benefits. Blum v. Yaretsky, 457 U.S. 991 (1982). The distinctions set forth in the foregoing discussion comport with these established precedents.

The Secretary's position on this issue is consistent with the prevailing view. Essentially, plaintiffs seek written notice of a group of decisions for which the Secretary cannot, under the Due Process Clause of the Fifth Amendment, be fairly held accountable. Ascertaining the precise content of the treating physician's orders, determining the appropriate level and course of treatment within such orders, and proposing changes in the level of treatment in response to a change in circumstances are the types of treatment decisions that undoubtedly impact the level of Medicare benefits, but nevertheless cannot be imputed to the Secretary.

argument that, although a hearing to review the Community Home Health Agency's ("CHHA's") Medicaid "eligibility" component of the prior approval decision was necessary, the court could not compel the CHHA to actually provide the services in the event the hearing resulted in a reversal of their initial determination because the "professional medical judgment" portion of the prior approval decision was not state action. Id. The Second Circuit rejected this argument and held that, to accept the state's argument that "although the decision is in part state action requiring due process rights, it is also in part private action such that mandated due process rights cannot in fact affect the final decision," would "flout[]" its prior holding that the CHHAs' prior approval for Medicaid benefits decisions are that of the state. Id. No such interests are implicated here.

In light of the foregoing, the court should adhere to the prior decision in this case and should not impose any additional requirements upon the Secretary. The governing statute does not require the HHAs to provide written notice in the situations set forth in plaintiffs' most recent submission, and the Due Process Clause of the Fifth Amendment does not reach the HHAs' conduct at issue in this case.

However, nothing should detract from the force of this court's prior holding; this most recent foray into the niceties of state action in the Medicare arena does not change the fact that, under the current "non-system" in place to render eligibility determinations, the Secretary has delegated his authority to determine eligibility for Medicare home health benefits exclusively to the HHAs. Just because the Secretary may not be held accountable for every decision to reduce or terminate benefits, he remains ultimately responsible for all eligibility decisions rendered by the HHAs.

As a matter of law, plaintiffs have not demonstrated that they are entitled to written HHABN notices in every situation where benefits are reduced or terminated. Defendant's motion for summary judgment on this issue is therefore GRANTED. Therefore, an injunction should not issue compelling the Secretary to provide written notice in all situations, but rather a declaratory judgment, in the form proposed in this court's prior opinion,

should issue as such: "the plaintiffs have a legal right to a written: (1) pre-deprivation statement why the HHA believes Medicare may not or may no longer cover their services; (2) explanation of the circumstances in which a beneficiary has the right to have a demand bill submitted, and (3) disclosure of information regarding a patient's right to appeal"

C. PRE-DEPRIVATION DETERMINATIONS

Plaintiffs claim that pre-deprivation determinations of coverage are compulsory under the Due Process Clause of the Fifth Amendment. Because the property interest at issue is the prompt reimbursement of the costs of home health medical care for qualified individuals, which is not a need based program, in that "coverage is not related to financial need," Healey, 2000 WL 303439, at *1, the court's analysis is governed by Mathews v. Eldridge, 424 U.S. 319 (1976), and its progeny. Kraemer v. Heckler, 737 F.2d 214, 221-22 (2d Cir. 1984). Thus, in order to protect the "fundamental requirement of due process[:]" . . . the opportunity to be heard at a meaningful time and in a meaningful manner," the court must consider "the private interest that will be affected by the official action;" "the risk of erroneous deprivation of such interest through the procedures used, and the probable value, if any of additional or substitute procedural safeguards;" and "the Government's interest, including the function involved and the fiscal and administrative burdens that additional

or substitute procedural requirement would entail." Mathews, 424 U.S. at 333, 335.

After careful consideration of these components, plaintiffs' interest in additional process, combined with the risk of erroneous deprivation, does not outweigh the public interest. Although plaintiffs do have a substantial interest in continued receipt of Medicare benefits, the balance does not tip in favor of the court's intervention in plaintiffs' favor.

The private interest affected in this case is the plaintiffs' substantially uninterrupted receipt of Medicare home health care benefits pending an initial determination by the Secretary of an adverse coverage decision rendered by an HHA, which is an important interest, and thereby weighs in favor of granting additional process to plaintiffs." Being eligible for Medicare, the

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The Supreme Court's holding in American Manufacturers Mutual Insurance Co. v. Sullivan, 526 U.S. 40 (1999), does not preclude plaintiffs from asserting a viable property interest in continued receipt of benefits. The Court distinguished the factual scenario before it from Goldbera v. Kelly, 397 U.S. 254 (1970), and Mathews by noting that in those cases, eligibility for benefits had already been determined, whereas in Sullivan, the propriety of benefits had not yet been established. See American Mfrs. Mut. Ins. Co., 526 U.S. at 57-58; see also id. at 62-63 (Breyer, J., concurring in part and concurring in the judgment) ('I would add, however, that there may be individual circumstances in which the receipt of earlier payments leads an injured person reasonably to expect their continuation, in which case that person may well possess a constitutionally protected 'property' interest."). In contrast to Sullivan, the plaintiffs here have previously received Medicare benefits under similar circumstances to those upon termination or reduction, and therefore enjoy a reasonable expectation of continued receipt of similar benefits. See Board of Regents of State Colleges v. Roth, 408 U.S. 564, 577 (1972). A hypertechnical

plaintiffs are either over sixty-five years of age, or have received Title II Social Security Disability benefits for a period of over two years. Indeed, "[t]he defendant has recognized that, compared to all Medicare beneficiaries, Medicare home health patients are more likely to be female, to be older, to live alone, to be poor, and to be in worse health or have more disabilities.,, (Pls.' Rule 9(c)(1), Dkt # 116, ¶ 5). This combination of conditions "places them in a profoundly inferior position in relationship to a government bureaucracy.,, Ford v. Shalala, 87 F. Supp. 2d 163, 177 (E.D.N.Y. 1999) (internal quotation marks omitted); see Grav Panthers v. Schweiker, 652 F.2d 146, 166 (D.C. Cir. 1980) ("Nor can we ignore in any evaluation of the 'interest at stake, the significant percentage of Medicare claimants disadvantaged by disability, illness and poverty, a substantially higher figure than is true of the population at large. Indeed it was because of the special coincidence of medical needs and financial problems among elderly people that the Medicare program

application of Sullivan's holding as applied to Medicare, where any reimbursement for services is predicated upon the services being deemed reasonable and necessary, would be a substantial departure from the Supreme Court's prior decisions, a result not contemplated by Sullivan. See, e.g., Mathews, 424 U.S. at 336 (holding that plaintiff had a property interest in receipt of disability benefits even though he had a continuing burden of demonstrating disability); cf. American Mfrs. Mut. Ins. Co., 526 U.S. at 58 ("[W]e believe the court fundamentally misapprehended the nature of respondents, property interest at stake in this case. . ."). Because of the key factual differences between Sullivan and the case before the court, the Court's prior decision in Board of Regents v. Roth, 408 U.S. 564 (1972), controls the analysis, and compels a finding that a property interest exists.

was established in the first place.,,). "It is not disputed that the named plaintiffs need, or needed, home health care to live independently, or to live at all.,, Healey, 2000 WL 303439, at *2. Should the HHA decide that services are no longer covered, the beneficiary must pay for the services in order to initiate the review process; the HHA has no obligation to provide the services free of charge pending review of its decision. The combined effect of these facts is that, once the HHA determines that Medicare will no longer pay for services, home health care benefits are effectively terminated if the beneficiary cannot pay for the services pending review.

The cumulative effect of a loss of home health benefits is difficult to quantify, but unmistakably difficult to bear. An unescapable consequence of a premature termination of care is deterioration of the beneficiary's condition, due to both the lack of care and the emotional stress associated with the loss of care. The evidence in this case reveals that plaintiffs suffer from conditions (or a combination thereof) requiring anything from simple, yet vital, hygiene maintenance to physical therapy, and that they have (or had) been receiving services for a period of more than two months.¹⁴ An inability to maintain the care regimen

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Although Medicare's home health benefit program was "[o]riginally conceived as a short-term, post-acute initiative . . . intended primarily to help beneficiaries recover after hospital stays," Brooks E. Allen, Note, The Price of Reform: Cost-Sharing Proposals for the Medicare Home Health Benefit, Yale J. on Reg.

obviously impacts plaintiffs, health for the worse. In addition, as stated in the declarations submitted in support of plaintiffs' motion, the effects of a loss of home health care are often borne not only by the **infirmed** beneficiary, but by the **families** of the beneficiary, upon whom the responsibility of providing care inevitably falls by default.

Defendant does not necessarily dispute the importance of a loss of home health care benefits to a beneficiary; rather, defendant emphasizes that the interest at stake is not provision of the benefits themselves, but "the prompt and fair reimbursement of medical expenses,, contemplated by Medicare. (Def.'s Mem. Supp. Summ. J., Dkt #128, at 24 (quoting Isaacs v. Bowen, 865 F.2d 468, 476 (2d Cir. 1989)). He further argues that, to force Medicare to pay for services pending an initial determination, would be to effectively undermine the fundamental principle behind Medicare's fee-for-services reimbursement system. (Id. at 25). The effect of this argument, if accepted, is to break the causal chain between termination of Medicare coverage and termination of the home health care benefits themselves.

The Secretary's position does not preclude consideration of

137, 149 (2000)' "the program has moved beyond its previous **short-term, post-acute** focus to encompass long-term, chronic **care**. For example, one 1996 study revealed that 61% of home health **visits** in a given sample were to enrollees receiving six or more months of home health care, whereas only 4% received care for a month or less,, id. at 152-53. The declarations submitted in this case support these observations.

the effect upon plaintiffs of a deprivation of home health care because, in certain cases, practical considerations supply the necessary link between the coverage and the benefits. The Supreme Court has clearly stated that "the degree of potential deprivation that may be created by a particular decision is a factor to be considered in assessing the validity of any administrative decisionmaking process.,, Mathews, 424 U.S. at 341. For some beneficiaries, a denial in coverage amounts to a denial of services, because they may not have the means to pay for the services, or the wherewithal to secure substitute coverage," rendering them unable to access the appeals process. See, e.g., Mathews, 424 U.S. at 341 (holding that the bleak possibility that a disabled employee can find temporary employment to lessen the effect of a denial of benefits supports the importance of the interest at stake); Kraemer v. Heckler, 737 F.2d 214, 222 (2d Cir.

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The Secretary notes that 13% of all Medicare beneficiaries are "dual eligibles,,, meaning that they qualify for both Medicare and Medicaid, and therefore some of the more indigent beneficiaries can secure Medicaid coverage for their home health care. (Witt Dec., Dkt #127, Ex. B, ¶ 5). To be sure, this mitigates the effects of deprivation to some degree, but does not significantly detract from the importance of the interest at stake to those who do not qualify for Medicaid.

In addition, as evidenced by plaintiffs' declarations, some of the beneficiaries are teetering on the boundary of needing more intensive residential treatment. (See, e.g., Weirda Dec., Dkt #119, Ex. B; Katz Dec., Dkt #119, Ex. N; Grannis Dec., Dkt #119, Ex. Q; Martin Dec., Dkt #119, Ex. X; Bailey Dec., Dkt #133). Although it is not the preferred choice of treatment, some beneficiaries may be eligible to receive residential medical care benefits under Medicare.

1984) (considering that the costs of medical care "diminishes the probability that a patient could choose to continue receiving medical care,, while awaiting review); Fox v. Bowen, 656 F. Supp. 1236, 1249-50 (D. Conn. 1986) (citing Kraemer and noting that patients often forgo medical care in the absence of coverage because they cannot afford it).

The period of time that passes between notice of denial of coverage is not insignificant. See Mathews, 424 U.S. at 341 ("[T]he possible length of wrongful deprivation of . . . benefits also is an important factor in assessing the impact of official action on the private interests.,,). Historically, the time period for obtaining an initial determination has been about four months, and is likely to be comparable to this when the 45 day time limit for deciding claims goes into effect in October of 2002, see An Act Making Consolidated Appropriations for the Fiscal Year Ending September 30, 2001, and for Other Purposes, Pub. L. 106-554, 114 Stat. 2763, 2763A-534 (2000) (amending 42 U.S.C. § 1395ff effective October 1, 2002), because a demand bill can only be submitted at the conclusion of the sixty-day episode of care. Given the costs of healthcare, and the meager financial resources of many Medicare beneficiaries, a period of four months without benefits is not insignificant.

Plaintiffs therefore have an important interest in the continued receipt of home health care benefits given the fact that Medicare is sometimes their only source of funds to sustain medical

care for a period as long as four months, and this medical care could be necessary for basic health maintenance. Although important, the risk of being erroneously deprived of this interest must also be evaluated.

"Central to the evaluation of any administrative process is the nature of the relevant inquiry.,, Mathews, 424 U.S. at 343. Here, the nature of the inquiry is determining whether certain medical services are covered under the home health benefits provisions of Medicare. Thus, as the Secretary points out, the basic tenet of the "fee-for-service,, system is the initial provision of care, and the subsequent determination of coverage, based upon whether the care was reasonable, and whether coverage was warranted under the **circumstances**.¹⁶ As currently constructed, the process contemplates a retrospective analysis of eligibility, and, therefore plaintiffs' proposed action would constitute a significant change in the system.

This proposed change would not necessarily improve the accuracy of the eligibility determination. The current system allows for a decision based upon evidence of the circumstances as

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The new payment system does not alter this underlying principle. Despite the fact that the HHA submits an initial claim prior to the provision of care, to which the Secretary applies the case-mix formula to arrive at a reasonable cost for the proposed services, the final Medicare 'claim" is the bill for services submitted at the conclusion of the sixty-day episode of care because the Secretary reserves the right to modify or even cancel the initial claim.

they actually existed, and does not deal in predictions or hypothetical scenarios, thereby eliminating the risk of erroneous predictions. Unlike some other medical coverage determinations, such as hospital services, which are quickly reviewed by a peer review organization, the system in place for reviewing home health benefits coverage decisions favors accuracy over expediency. Therefore, plaintiffs' proposed modification would allow for speedy reversal of a patently incorrect coverage determination, but would not necessarily improve the accuracy of the vast majority of coverage decisions.

Furthermore, the existing procedure, although subject to some doubt in the past, has undergone important changes that have bolstered the overall reliability of the process. As the plaintiffs' declarations demonstrate,* and as the court previously found, the HHAs were not always forthcoming with information concerning appeal rights, or with a genuine reason for the adverse

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Plaintiffs urge the court to consider what they believe to be an underlying incentive for HHAs to deny care under the new PPS. Defendant responds to this argument by noting the more forgiving "outlier" provisions, designed to provide increased funding for special cases, and the 500% difference between the lowest and highest case-mix figure. Although the court takes note of these arguments, they do not add to the analysis in a meaningful way. The court will not impute a sinister motive to the HHAs, nor will it assume that the new PPS provisions will eliminate the HHAs desire to keep costs at a minimum; the focus of this inquiry is appropriately placed on the evidence submitted.

coverage decision.** Failure to give proper notice, or provision of conclusive justification for the action, worked to the detriment of the beneficiary; the only circumstance that was clear was that services were no longer being provided, and the beneficiary was effectively left without a remedy. Access to the demand bill procedure is important to the beneficiary because, as defendant's own data demonstrate, beneficiaries who gain access to the appeals process "are very likely to be successful in overturning the HHAs' denials." (Pls.' Mem Supp. Summ. J., Dkt #115, at 25). The raw statistical data show the following:

[Twenty-four thousand two-hundred and thirty-eight] demand bills relating to home health services were processed in calendar year 1998. The number of demand bills processed for calendar year 1999 was 33,116. For the first nine months of calendar year 2000, the number of demand bills processed was 49,437. In calendar year 1998, demand bills represented 0.2% of all home health claims processed. In calendar year 1999, demand bills increased to 0.3% of all home health claims processed. During the first nine months of calendar year 2000, demand bills rose to 0.6% of all home healths claims processed. The percentage of full/partial reversals for 1998 was 41.5%. In calendar year 1999, the percentage of full/partial reversals was 52.4%. The number of full/partial reversals for the first nine months of calendar year 2000 was 22.4%.

(Robinson Dec., Dkt #127, Ex. A, ¶ 7). When combined with the data submitted to the court previously, Healey, 2000 WL 303439, at *4,

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The Secretary correctly points out that logic dictates the proposition that "[i]ndiscriminate reductions in care are actually contrary to the interests of HHAs." (Def.'s Mem. Supp. Summ. J., Dkt #128, at 30). Although this is true in the abstract, the evidence submitted by plaintiffs of some HHAs' past practices belies this proposition.

these statistics show, on the average, that the **HHAs** coverage decisions have been reversed just under one-half (45.7%) of the time between 1994 through the first nine months of **2000**. Past experience therefore reveals that, once a demand bill has been submitted, there is a real chance that the **HHA's** decision could be reversed, which underscores the importance of access to the process.¹⁹

The Secretary's recent decision to require **HHAs** to submit a form HHABN notice to beneficiaries when the HHA makes a Medicare coverage decision improves communication between the beneficiary and the HHA, and therefore improves the overall reliability of the system. By clearly setting forth the **HHA's** reason for its actions, as well as the beneficiaries' options by way of a response, the new requirements are aimed at facilitating access to the demand bill procedure by improving notice to the beneficiary. Therefore, the risk of erroneous deprivation of benefits has decreased in light of the new procedures because there is much less of a chance that a beneficiary could be deprived of his or her rights altogether.

Although, as previously discussed, failure to secure Medicare coverage may serve as a disincentive to obtain medical care at all, improved notice of an adverse coverage decision provides the beneficiary with knowledge to make an informed decision as to the next step. Unfortunately, sometimes the only choice will be to

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The court does not draw any other inferences from these data.

forgo home health care services, but, when evaluating the risk of erroneous deprivation and the fairness of the process as a whole, the court must bear in mind that "procedural due process rules are shaped by the risk of error inherent in the truthfinding process as applied to the generality of cases, not the rare exceptions.,, Mathews, 424 U.S. at 344.

When considering the public interest, the court must assess "the administrative burden and other societal costs that would be associated with requiring, as a matter of constitutional right,,, the additional safeguards. Mathews, 424 U.S. at 347. Plaintiffs have shown that they have a significant interest in the continued receipt of benefits. They have also pointed out serious impediments to fair notice inherent in the system as it existed prior to March of this year. However, these combined weight of these factors is not greater than the public interest.

Any change in the Medicare scheme would require a massive re-allocation of both financial and administrative resources. As counsel for the government states, any kind of pre-deprivation determination or expedited determination would require modification to the existing billing computer software,²⁰ re-allocation of both

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Specifically, the Secretary states that

[u]nder a court-ordered process, such as that requested by Plaintiffs, requests for review would have to be received and processed by RHHIs at any time during an episode [of care], even before a claim is submitted for an episode in question. Thus the RHHIs will have to

personnel and financial resources, which would, of course, ultimately come from the taxpayers. In addition, the Secretary notes that pre-deprivation review in other Medicare contexts is only available for a discharge or termination of care, and is not available for changes in the "frequency, duration and mix of disciplines. . . ." (Sparr Dec., Dkt #127 Ex. D, ¶ 5). Thus the Secretary fears that the RHHIs would be inundated with requests to review changes in care that may be considered trivial. Further, the court takes notice of the beleaguered state of the Medicare trust fund, which, as of late, has invited serious political attention.

The administrative and fiscal burdens standing alone, however formidable, are not assigned "controlling weight in determining whether due process requires a particular procedural safeguard prior to some administrative decision,, however "the Government's interest, and hence that of the public, in conserving scarce fiscal and administrative resources is a factor that must be weighed.,, Mathews, 424 U.S. at 348. In this case, the public interest is not so limited. "Judging the constitutionality of an Act of Congress is properly considered the gravest and most delicate duty

develop a new system to track review requests (apart from claims) and to associate results of these reviews with claims that are later submitted. The design, development and training for such a new system would be extremely time-consuming and expensive.

(Sparr Dec., Dkt #127, Ex. D, ¶ 6).

that this Court is called upon to perform," and the court's analysis must reflect some measure of deference 'to the duly enacted and carefully considered decision of a coequal and representative branch of our Government." Walters v. Nat'l Ass'n of Radiation Survivors, 473 U.S. 305, 319 (1985). This principle rings especially true when the other branches of government have already begun to address the shortcomings in the administrative scheme.

As detailed earlier in this memorandum, the Medicare home health benefits system has undergone fundamental changes since the filing of this lawsuit. Specifically, the Secretary has implemented a prospective payment system, Congress has directed a shift in coverage from Part A to Part B, and the Secretary has mandated the use of HHABN notices when an HHA makes a coverage decision adverse to the beneficiary. In the face of this changing landscape, a court should be loathe intervene and usurp the reform process already running its course. Cf. Richardson v. Wright, 405 U.S. 208, 209 (1972) (vacating judgment of the district court and remanding to the Secretary for further proceedings because "[i]n the context of a comprehensive complex administrative program, the administrative process must have a reasonable opportunity to evolve procedures to meet needs as they arise.").

Plaintiffs have not met their burden of justifying judicial intervention of this order. Fair notice is at the core of due process, for a right without notice thereof is of no use. See

Mathews, 424 U.S. at 348 ("The essence of due process is the requirement that a person in jeopardy of a serious loss be given notice of the case against him and opportunity to meet it."); Goss v. Lopez, 419 U.S. 565, 579 (1975) ("The fundamental requisite of due process of law is the opportunity to be heard, . . . a right that has little reality or worth unless one is informed that the matter is pending and can choose himself whether to contest," internal quotation marks and citations omitted). When the government bestows a right upon an individual, the government must provide adequate and meaningful notice before terminating that right. Due process does not mean that the government must implement the specific procedure that affords the recipient the optimal opportunity to preserve the right; due process contemplates what is fair and proportional to the right asserted.

The importance of fair notice in evaluating the overall fairness of a government benefits scheme cannot be understated. Fair notice is at the core of many of the decisions cited by plaintiffs, and is often the catalyst for judicial intervention. See, e.g., Kraemer v. Heckler, 737 F.2d 214, 222 (2d Cir. 1984) (focusing on the lack of notice to the beneficiary of the utilization review committee's meeting); Grav Panthers v. Schweiker, 652 F.2d 146, 172 (D.C. Cir. 1980) ("We believe, at a minimum, the claimant should be informed of or have access to the evidence on which the carrier relied in reaching its initial decision to deny the claim. . ."); Ford v. Shalala, 87 F. Supp.

2d 163, 175-185 (E.D.N.Y. 1999) (holding that notice to Supplemental Security Income benefit recipients was constitutionally deficient); Fox v. Bowen, 656 F. Supp. 1236, 1250 (D. Conn. 1986) (holding that Secretary's use of "arbitrary and inflexible presumptions" in lieu of the individual determinations mandated by the statute and regulations violated due process).

Despite the fact that plaintiffs have shown that they have an important interest in continued receipt of benefits, they have not shown that pre-deprivation review is constitutionally mandated. As the evidence shows, some beneficiaries may face a significant deprivation should the HHA decide that Medicare no longer covers the services they have been receiving. However, given the improved notice to the beneficiary, as well as the recent overhaul of key components of the home health benefits program, the potential for a significant deprivation of the degree noted in Goldberg is not present, and the public interest strongly favors maintenance of status quo. The Supreme Court has consistently held that "the timing and content of the notice and the nature of the hearing will depend on appropriate accommodation of the competing interests involved." Goss v. Lopez, 419 U.S. 565, 579 (1975). Here, the "appropriate accommodation" of the competing interests is to take no further action.

III. CONCLUSION

For the reasons discussed herein, the undersigned recommends

that the court issue a declaratory judgment in the following form:

Plaintiffs have a legal right to a written:

A. Pre-deprivation statement why the HHA believes Medicare may not or may no longer cover their services;

B. Explanation of the circumstances in which a beneficiary has the right to have a demand bill submitted; and

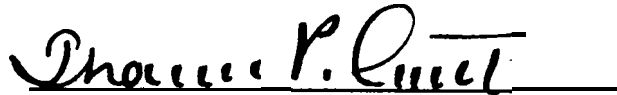
C. Disclosure of information regarding a patient's right to appeal.

See 28 U.S.C. § 2201 ("In a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."). This declaratory judgment should be in the form of a final judgment, Fed. R. Civ. Pro. 54(a), and the case should be closed. 28 U.S.C. § 2201 ("Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.").

Either party may seek review of this report and recommendation as provided in 28 U.S.C. § 636(b). 28 U.S.C. § 636(b) (written objections to recommended ruling must be filed within ten days of service of the same); see also Fed. R. Civ. Pro. 6(a), 6(e), & 72; and Rule 2 of the Local Rules for United State Magistrate Judges (D. Conn.). **Failure to object in a timely manner may preclude further review. See Small v. Secretary of Health and Human Servs.,**

892 F.2d 15, 16 (2d Cir. 1989).

Dated at Hartford, Connecticut, this 8th day of August,
2001.



Thomas P. Smith

United States Magistrate Judge