UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

CAROLYN HULL, PEGGY KNOX, ROSANN STENGER, and ERMA THOMPSON, on behalf of themselves and all others similarly situated,	)	Civil Action No.
Plaintiffs,	)	COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF
v.	)	
KATHLEEN SEBELIUS, Secretary of Health and Human Services,	)	CLASS ACTION
Defendant.	)	

I. PRELIMINARY STATEMENT

1. This is an action for declaratory, injunctive, and mandamus relief against the Secretary of Health and Human Services (the Secretary) as the official responsible for implementing and enforcing the Medicare program. The plaintiffs are Medicare beneficiaries in Connecticut needing home health care who received adverse initial determinations on claims for coverage for their home health care, or notices of termination of services by the home health agency, and then had that action affirmed at the first two levels of administrative review, regardless of the merits of the claims.

2. The available information indicates that the combined denial rate for home health care coverage at these first two levels of review (*i.e.*, the affirmance rate of the adverse action) is about 98%. Put another way, the combined "success rate" for beneficiaries at these two levels is at or under 2%.

3. The denial rate has been rapidly increasing in recent years, coinciding with the implementation of a new administrative review process for Parts A and B of Medicare, which are commonly referred to collectively as "traditional Medicare."

4. Although the new review system was intended to provide a more efficient process for beneficiaries, the actual effect has been to discourage or preclude beneficiaries from obtaining an efficient and meaningful review of their claims by requiring them to take their claims to the third level of review, a hearing before an Administrative Law Judge (ALJ), if they want any realistic chance of coverage. Most beneficiaries do not have the time, resources, or advocacy support to take their claims to the ALJ level. As a practical matter, therefore, the second level of review, reconsideration, operates as the final decision of the Secretary and invariably is adverse.

5. Plaintiffs challenge this defective administrative review process as violations of the Medicare statute and the Due Process Clause of the Fifth Amendment. On behalf of themselves and the statewide class consisting of all other Medicare beneficiaries who are seeking home health care coverage and are harmed by this procedural irregularity that causes the institutional deprivation of a meaningful review process, plaintiffs seek declaratory, injunctive, and mandamus relief to correct the system of administrative review for the beneficiaries of traditional Medicare.

II. JURISDICTION AND VENUE

6. Jurisdiction is conferred on this Court by 42 U.S.C. § 405(g) as made applicable to and incorporated in the Medicare statute by 42 U.S.C. § 1395ff(b)(1)(A), and by 28 U.S.C. §§ 1331 and 1361. Plaintiffs seek a declaration of rights pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e) and 42 U.S.C. § 405(g).

III. PARTIES

7. Plaintiff CAROLYN HULL resides in Connecticut and was 78 and 79 years old

during the period at issue. At all relevant times she was a Medicare beneficiary.

8. Plaintiff PEGGY KNOX resides in Connecticut and was 63 years old during the period at issue. At all relevant times she was a Medicare beneficiary.

9. Plaintiff ROSANN STENGER resides in Connecticut and was 80 years old during the period at issue. At all relevant times she was a Medicare beneficiary.

10. Plaintiff ERMA THOMPSON resides in Connecticut and was 96 years old during the period at issue. At all relevant times she was a Medicare beneficiary.

11. Defendant KATHLEEN SEBELIUS is the Secretary of the Department of Health and Human Services (HHS) and is responsible for the overall operation of the Medicare program through the HHS division known as the Centers for Medicare & Medicaid Services (CMS). She is sued in her official capacity.

IV. CLASS ACTION ALLEGATIONS

12. Plaintiffs bring this action on behalf of themselves and all others similarly situated, pursuant to Rules 23(a) and (b)(2) of the Federal Rules of Civil Procedure. The class is defined as:

> All Medicare beneficiaries in Connecticut (1) who have received, are receiving, or will receive home health care services, (2) whose claims for coverage of those services under Medicare Part A or B (a) have been or will be denied at the initial determination stage, in whole or part, or who have received or will receive a notice of termination of coverage and (b) have been or will be denied, in whole or in part, at the two levels of review below the Administrative Law Judge level, and (3) for whom the initial determination or notice of termination of coverage was dated on or after January 1, 2012.

13. Joinder is impracticable due to the large number of class members and for other reasons, including, but not limited to, their geographic diversity, their ages and/or disabilities, and their relatively low incomes. Plaintiffs estimate the class to include at least hundreds of members.

14. There are questions of law and fact common to the class members. Common facts include that all class members have been denied an effective administrative review process for their Medicare claims because the defendant's review system almost always results in denial of appeals of adverse actions at the two lowest levels of review regardless of the merits of the beneficiaries' cases. The common questions of law include, *inter alia*, whether the Secretary's administrative review system violates the Medicare statute and/or the Due Process Clause.

15. The claims of the named plaintiffs are typical of those of the class members in that they have not been given efficient, effective, and meaningful administrative review as demonstrated by the overwhelming denial rate at the first two levels of review.

16. The named plaintiffs will fairly and adequately protect the interests of the class. They have no interests that are or may be potentially antagonistic to the interests of the class, and they seek the same resolution as the class members, a meaningful administrative review process that provides a realistic chance of success before the ALJ level. Moreover, the plaintiffs are represented by competent counsel from an established public interest law firm, the Center for Medicare Advocacy, Inc. The attorneys are experienced in federal litigation involving public benefit programs, especially Medicare, and they have represented classes in numerous other cases involving Medicare and other public benefit programs.

17. The defendant Secretary has acted or refused to act on grounds generally applicable to the class as a whole, thereby making appropriate final injunctive and declaratory

relief to the class as a whole, pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure.

V. STATUTORY AND REGULATORY FRAMEWORK

18. Medicare, which is codified as Title XVIII of the Social Security Act, is the federally funded and administered program of health insurance for those who are 65 and older, or are disabled. Under Part A of Medicare, for which eligibility is automatic for recipients of Social Security old age and disability benefits (Title II of the Social Security Act), beneficiaries are entitled to coverage for hospital care, skilled nursing facility care, home health care, and hospice services. Part B of Medicare establishes a voluntary program of supplemental medical insurance covering physician services, nurse practitioner services, home health care, physical, speech, and occupational therapy, diagnostic services, and durable medical equipment. Under Part C, beneficiaries may opt to enroll in a managed care plan in lieu of traditional Medicare. Part D provides for partial coverage of prescription drugs. This case concerns the administrative review process for traditional Medicare, Parts A and B.

19. The statutory authority for the system of administrative review of claims for Medicare coverage under Parts A and B of Medicare is set out in 42 U.S.C. § 1395ff.

20. Under the administrative review system that was previously in effect, Parts A and B had somewhat different processes, which were set out in 42 C.F.R. part 405, subparts G and H, respectively.

21. In that earlier system, for Part A after an adverse initial determination was issued by Medicare, the beneficiary could obtain a paper review from the contractor that had issued the initial determination. Further potential review consisted of the right to a de novo hearing before an ALJ and a paper review before the Medicare Appeals Council (MAC), if the amount in controversy requirement was satisfied. See 67 F.R. 69312, 69313 (Nov. 15, 2002); 70 F.R.

11420, 11421 (March 8, 2005); 74 F.R. 65296, 65297 (Dec. 9, 2009).

22. For Part B, after an adverse initial determination was issued, the beneficiary could obtain a paper review from the contractor that had issued the initial determination, and, if still dissatisfied and if the amount in controversy was met, the beneficiary could obtain an additional review in the form of a "carrier hearing" before a hearing officer. After that, the same review as in Part A was available, before an ALJ and the MAC, if the amount in controversy requirement was satisfied. See 67 F.R. at 69313; 70 F.R. at 11421-22; 74 F.R. at 65297.

23. In section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106-554, Congress amended 42 U.S.C. § 1395ff to create a unitary system of review applicable to both Parts A and B. See 67 F.R. at 69313-69314; 70 F.R. at 11422; 74 F.R. at 65297-98.

24. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, Congress made additional changes to the new review process for traditional Medicare, which had not yet been implemented. See 70 F.R. at 11422-11425; 74 F.R. at 65298. Among the most important of these was the transfer of the ALJ function from the Commissioner of the Social Security Administration to the Secretary. ALJs in the Office of Medicare Hearings and Appeals "are required to be organizationally and functionally independent from CMS and must report to and fall under the general supervision of the Secretary." 70 F.R. at 11422.

25. On March 8, 2005, the Secretary published an interim final rule to implement many of the changes created by BIPA and MMA, with an effective date of May 1, 2005. 70 F.R. 11420. Most of the new review system for Parts A and B, which was set out in 42 C.F.R. part 405, subpart I, was to be phased in between the effective date and January 1, 2006. *Id*. at 11425.

26. On December 9, 2009, the Secretary published the final rule, with an effective date of January 8, 2010. 74 F.R. 65296.

27. Claims processed prior to January 1, 2006 continued to be adjudicated pursuant to subparts G and H of 42 C.F.R. part 405. 70 F.R. at 11424. As of May 16, 2012, CMS determined that all such claims had been resolved and therefore declared subparts G and H obsolete and fully replaced by subpart I. 77 F.R. 29002, 29016-18 (May 16, 2012).

28. Under subpart I, all standard Part A and Part B claims proceed through the same process of administrative review. That review process includes a paper-review redetermination by the contractor that made the initial determination, followed by a paper-review reconsideration carried out by a separate entity that contracts with the Secretary (known as the Qualified Independent Contractor (QIC)), a hearing before an ALJ, and paper review by the Medicare Appeals Council. See 70 F.R. at 11447-11448. A chart summarizing the old and new systems appears at 67 F.R. at 69315 and 70 F.R. at 11426.

29. Under the new system, Part B's carrier fair hearing was replaced by reconsideration. Unlike the carrier fair hearings, reconsideration by a QIC does not provide for a hearing but is a purely paper review. 70 F.R. at 11448; 74 F.R. at 65310. The reconsideration stage for Part A claims represented an altogether new step for the Part A process. 67 F.R. at 69324.

30. At the redetermination and reconsideration stages, contractors and QICs are not limited to the original reasons for denying the claim but may raise and develop all issues that they believe are relevant to the claim. 70 F.R. at 11439-11440, 11448; 74 F.R. at 65311; see 42 C.F.R. §§ 405.948, .968(b)(5).

31. The general rule is that the contractor must issue a written notice of the redetermination within 60 calendar days of the date that the contractor receives a timely filed request for redetermination. 42 C.F.R. § 405.950(a).

32. The general rule is that the QIC must issue a written notice of the reconsideration within 60 calendar days of the date that the QIC receives a timely filed request for reconsideration. 42 C.F.R. § 405.970(a).

33. Under the prior system, the carriers and the carrier fair hearing officers were required to follow local coverage determinations, but the QICs under the present system are not so required. "QICs, like ALJs, would be bound only by law, regulations, CMS Rulings, and [national coverage determinations]." 67 F.R. at 69325. In the Secretary's view this is an important change because the past system was "marked by high reversal rates at the ALJ level" that often "stem[med] from the different criteria applied by Medicare contractors and ALJs in ruling on Medicare payment and coverage issues." *Id.*

34. The right to an ALJ hearing is contingent on the claim being taken through the initial determination, redetermination, and reconsideration stages. This means obtaining an initial determination and a redetermination, and almost always a reconsideration, with the one exception being that ALJ review is available in the absence of a reconsideration decision if the adjudication period for reconsideration has elapsed. 42 U.S.C. § 1395ff(a)(3)(B)(i), 1395ff(b)(1)(A), 1395ff(c)(3)(C)(ii), and 1395ff(d)(1); 42 C.F.R. §§ 405.940, .960, and .1000(a). In short, access to ALJ review is only available if both the redetermination and reconsideration stages have been completed.

35. Section 521 of BIPA also provides for an "expedited determination" and an "expedited reconsideration" when certain providers, including home health agencies, plan to

terminate services to the beneficiary. It is codified as 42 U.S.C. § 1395ff(b)(1)(F). The regulations implementing it, subpart J of 42 C.F.R. part 405, became effective July 1, 2005. 69 F.R. 69252 (Nov. 26, 2004).

36. Under the expedited process, a notice from the provider served at least two days prior to the planned termination of services gives the beneficiary the right to request review by an entity called the Quality Improvement Organization (QIO), which contracts with the Secretary to perform this task. 42 C.F.R. §§ 405.902 (definition of QIO), .1202.

37. The beneficiary may submit evidence to the QIO. Like a redetermination, the expedited determination is a paper review. The decision is supposed to be issued within 72 hours. 42 C.F.R. § 405.1202.

38. If dissatisfied with the QIO's expedited determination, the beneficiary may request an expedited reconsideration from the QIC, which is responsible for expedited reconsiderations as well as standard reconsiderations. 42 C.F.R. § 405.1204.

39. As at the expedited determination level, the beneficiary may submit evidence to the QIC. Like a reconsideration, the expedited reconsideration is a paper review. The decision is supposed to be issued within 72 hours. *Id.*

40. As in the standard review process, a beneficiary may obtain ALJ review only by first completing the expedited determination and reconsideration process (unless the QIC fails to issue a decision in 72 hours). 42 C.F.R. § 405.1204(c)(5).

41. There is no expedited ALJ review.

42. The Secretary believes that the changes effected by section 521 of BIPA were intended to "introduce[ ] greater efficiency and accuracy into the Medicare appeals system." 67 F.R. at 69316. The Secretary had discretion in designing the new reconsideration stage and

"attempted to use this discretion to design a process that will prove to be impartial, efficient, and accurate." *Id.* at 69324. Furthermore, the Secretary believed in 2005 that "these new procedures will lead, over time, to significant reductions in the need to pursue appeals at the later stages of the appeals system, such as ALJ hearings and MAC reviews." 70 F.R. at 11424.

43. Some individuals are enrolled in both Medicare and Medicaid and are commonly referred to as dual eligibles. Medicaid is a jointly funded and administered federal-state program, established by Title XIX of the Social Security Act. It pays for medical care for certain individuals who have low incomes and minimal assets. 42 U.S.C. §§ 1396-1396w-5.

44. For dual eligibles, Medicaid is intended to be the payer of last resort. 42 U.S.C. §1396a(a)(25). A Medicaid state agency that has paid for items or services furnished to dual eligibles may appeal for Medicare coverage of those items or services using the same administrative appeal system described above. A Medicaid state agency becomes a party to a Medicare appeal by filing a request at the redetermination level. 42 C.F.R. § 405.908. It participates as a statutory subrogee of the beneficiary. 42 U.S.C. § 1396k(a)(1); *e.g.*, Conn. Gen. St. § 17b-265.

45. Beneficiaries are parties to Medicare's initial determination and all levels of administrative review, except when they have assigned their appeal rights to a provider or supplier. 42 C.F.R. § 405.906(a), (b).

46. Medicaid state agencies are required to pursue recoupment of expenses paid on behalf of Medicaid beneficiaries from their estates in certain circumstances. 42 U.S.C. § 1396p(b); *e.g.*, Conn. Gen. St. § 17b-95.

47. Connecticut's Department of Social Services (DSS) is the agency in Connecticut that administers the Medicaid program.

VI. FACTUAL STATEMENT

A. Named plaintiffs' situations

Plaintiff Carolyn Hull

48. Carolyn Hull is a resident of Clinton, Connecticut and was 78 and 79 years old during the period at issue, March 4, 2012 through December 28, 2012. She is a beneficiary of both Medicare and Medicaid.

49. Ms. Hull lives alone in a trailer, where she is homebound. Ms. Hull suffers from severe orthopedic problems in her lower extremities. Her right hip is chronically dislocated as a result of a hip replacement that was not successful. During the period at issue she suffered from continuous pain due to severe degenerative joint disease and arthritis of the knee and hip. She was non-ambulatory, using a wheelchair to move about in her home and a walker to transfer between her wheelchair and her bed or a chair. She was limited in endurance and chronically incontinent. She left home only for medical care, which is not a disqualifying absence under the Medicare statute (42 U.S.C. § 1395f(a)), and when she did leave it took considerable and taxing effort due to her very limited mobility and poor endurance.

50. During the period at issue, Ms. Hull received intermittent skilled nursing services at her home from Middlesex Hospital Homecare, a Medicare-certified home health agency. Her physician ordered skilled nursing visits one to three times per week to observe and assess many aspects of her health, including checking cardiopulmonary status, observing for signs and symptoms of fluid retention, assessing and managing her pain, and evaluating, treating and managing her chronic wounds. The doctor also ordered home health aides to assist Ms. Hull with activities of daily living such as bathing, dressing, grooming, and toileting.

51. The visits from skilled nurses were particularly critical for Ms. Hull's wound

care. She had several stasis ulcers on her legs, which can result in serious infections of the skin (cellulitis) or bone (osteomyelitis). During their visits, the nurses measured Ms. Hull's wounds, noted color and any drainage, and checked for signs and symptoms of infection. The wounds were not stable; for example, in November-December 2012 multiple individual wounds connected to form one large wound measuring seven centimeters in length. Throughout the period the nurses cleansed the wounds and applied dressing and compression bandages, which required specialized knowledge, judgment, and skills.

52. The nurses also measured and assessed Ms. Hull's edema (swelling) in her legs to gauge the effectiveness of the wound treatment and the need for any adjustments. They auscultated her lung sounds. The nurses also taught Ms. Hull energy conservation and fall prevention techniques, pressure reduction techniques, and techniques to reduce the swelling in her legs. Ms. Hull's wound care protocols and oral medications were changed several times during the period at issue, and nurses evaluated the effectiveness of these changes.

53. A Medicare contractor determined that five claims of home health care, covering March 4, 2012 to December 28, 2012, were not covered by Medicare. The Connecticut Department of Social Services (DSS) appealed for Medicare coverage of these services, for which it had paid, as a subrogee of the rights of the beneficiary. DSS requested a redetermination of the initial determination, and subsequently, reconsideration.

54. The Medicare contractors that performed the redetermination and reconsideration had the medical records from the home health agency as evidence in the appeal. The records reflected the medical condition of Ms. Hull and the services she received, as described above.

55. Medicare's redetermination decision of July 9, 2013, denied coverage of the services in question, finding that she was not homebound because she "goes out to attend the

wound care clinic." The reconsideration decision of December 10, 2013 denied coverage because "[t]he documentation submitted for review did not support that the beneficiary was homebound. There was no evidence that the beneficiary's condition was such that there was a normal inability to leave the home and, consequently, leaving home would require a considerable and taxing effort. We have, therefore, determined that the home health services at issue were not reasonable and medically necessary. As a result, Medicare cannot cover the home health services at issue."

56. A request for an ALJ hearing on coverage of the services in question was submitted on January 17, 2014.

Plaintiff Peggy Knox

57. Peggy Knox is a resident of Torrington, Connecticut and was 63 years old during the period at issue, June 8, 2011 through February 2, 2012. She is a beneficiary of both Medicare and Medicaid.

58. Ms. Knox lives alone in an apartment, where she is homebound. Ms. Knox's primary diagnosis is venous insufficiency, meaning the veins in her legs are impaired in their ability to send blood back to the heart. This leads to lower extremity edema, intractable pain, and stasis ulcers or wounds on her lower extremities. Ms. Knox is also diagnosed with myalgia and myositis (muscle pain and swelling), gastroparesis (impairment of the stomach muscles), asthma, and diabetes.

59. During the period at issue, Ms. Knox had prescriptions for over twenty medications, as well as supplemental oxygen to be taken as needed for dyspnea (shortness of breath). She experienced dyspnea with minimal exertion, such as talking or any change of position, and therefore used the supplemental oxygen frequently, sometime continuously. Even

though she was prescribed and taking morphine, she consistently rated her pain at level 9 or 10 on the numerical pain scale, where "0" represents no pain and "10" represents the worst pain imaginable. She suffered from abdominal cramping and severe joint pain.

60. Ms. Knox spent most of her days in bed or a wheelchair. She was unable to stand for more than a few minutes and could take only a few steps, with supervision and assistance. She was required to keep her legs elevated as much as possible for her lower extremity edema. Absences from her home were infrequent and required considerable and taxing effort. During the period at issue, Ms. Knox was evaluated for a different wheelchair to increase elevation of her legs, with the goal of spending more time in the wheelchair and less time in bed.

61. Ms. Knox received intermittent skilled nursing services at her home from Visiting Nurses Services of Connecticut, a Medicare-certified home health agency. Her physician ordered skilled nursing visits once per week to observe and assess many aspects of her health, including her cardiovascular, gastrointestinal, and respiratory statuses, pain management, and evaluation of skin integrity. New wounds developed and worsened during the period. Nurses informed the doctor of new open areas, and the doctor instituted wound care orders and increased the frequency of skilled nursing visits. Ms. Knox's diabetic status made the healing process slower and increased her risk of wound infection and further ulceration.

62. The nurses carefully assessed Ms. Knox's lower extremity edema and wounds, noting their development and progression and keeping her doctor informed. During their visits, the nurses measured the wounds, noted color and drainage (which was significant), and checked for signs and symptoms of infection. The first set of wound care orders included application of antibiotic ointment, but when the wounds only grew worse the doctor changed the orders by discontinuing the ointment and ordering different forms of compression therapy to be used,

depending on what Ms. Knox could tolerate. The nurses provided instruction to Ms. Knox on wound care, particularly after the doctor's orders changed in August 2011. A particularly large wound developed that at one point extended almost completely around her lower leg. The knowledge, skills, and judgment of a nurse were required for this care.

63. The nurses also carefully evaluated Ms. Knox's respiratory function, sometimes detecting adventitious lung sounds, wheezing, and coughing. Ms. Knox experienced fevers and episodes of nausea and vomiting during the period, which the nurses also documented and assessed.

64. A Medicare contractor determined that four claims of home health care, covering June 8, 2011 to February 2, 2012, were not covered by Medicare. DSS appealed for Medicare coverage, requesting a redetermination of the initial determination, and subsequently, reconsideration.

65. The Medicare contractors that performed the redetermination and reconsideration had the medical records from the home health agency as evidence in the appeal. The records reflected the medical condition of Ms. Knox and the services she received, as described above.

66. Medicare's redetermination decision of August 7, 2012, denied coverage of the services in question, finding that Ms. Knox was not homebound. The reconsideration decision of May 15, 2013 found that she was homebound, but stated that Ms. Knox was receiving "chronic custodial care" and was "capable of self-managing her care needs." The contractor therefore found that the home health services she received were not reasonable and necessary and could not be covered by Medicare.

67. A request for an ALJ hearing on coverage of the services in question was submitted on July 2, 2013.

Plaintiff Rosann Stenger

68. Rosann Stenger is a resident of East Hartford, Connecticut, and was 80 years old during the period at issue, May 6, 2011 through March 4, 2012. She is a beneficiary of both Medicare and Medicaid.

69. Ms. Stenger has been disabled and essentially bedbound for over 30 years. Since suffering a stroke in the 1980s she has had left-side hemiparesis (weakness or inability to move).

70. During the period at issue Ms. Stenger required a Hoyer lift plus the assistance of two people to get out of bed. She generally spent about one hour per day sitting in her wheelchair and was otherwise in bed. She was unable to walk. She was normally unable to leave her home, and when she did it required considerable and taxing effort due to her extremely impaired mobility.

71. Ms. Stenger was dependent on a caregiver and home health aides for all self-care, including bathing, grooming, and toilet care. She was also diagnosed with diabetes, morbid obesity, edema, and, just prior to the period at issue, had been hospitalized for gastroenteritis. Her bladder and bowel incontinence and diabetic status greatly increased her risk of developing skin breakdown and bacterial and fungal infections.

72. Ms. Stenger received intermittent skilled nursing services as well as home health aide services at her home from Interim Healthcare, a Medicare-certified home health agency. Her physician ordered skilled nursing visits once per week to observe and assess many aspects of her health, including her cardiovascular, gastrointestinal, and endocrine status, as well as for assessing skin integrity and edema. The doctor also ordered home health aides to assist with her activities of daily living.

73. Ms. Stenger experienced gastrointestinal problems during the period at issue. She had recently been diagnosed with gastroenteritis and prescribed an antibiotic. In May 2011, the nurses noted that she was still experiencing vomiting and had an elevated temperature. A nurse alerted her doctor. In late May Ms. Stenger was still complaining of diarrhea and nausea. She went to the emergency room and was diagnosed with diarrhea. She was eventually referred to a gastroenterologist. The nurses continued to note diarrhea symptoms in June. Nausea, vomiting, and diarrhea can have a direct impact on diabetic control and therefore require immediate and close medical attention and management.

74. In July 2011 the nurses observed the development of respiratory issues that led to a hospitalization. Ms. Stenger was reporting dizziness along with her chronic diarrhea. On July 15 the nurse noted that she was struggling to breathe while talking. The nurse auscultated her lungs and measured the oxygen saturation of her blood, which was below normal. Two days later a nurse visited again because an aide had reported shortness of breath. The nurse observed and assessed Ms. Stenger's respiratory status. On July 19 a nurse contacted the doctor's office about the respiratory problems, and Ms. Stenger was sent to the emergency room. At the hospital Ms. Stenger was diagnosed with pleural effusion (a build-up of fluid between tissues lining the lungs and chest) and underwent thoracentesis, an invasive procedure to remove the fluid. When Ms. Stenger returned from the hospital the home health services resumed. She was started on supplemental oxygen at home, and skilled nursing services were needed to carefully observe and evaluate her respiratory function.

75. During the period, Ms. Stenger suddenly developed chronic edema and leg pain, raising concerns that she might have a blood clot. The nurses assessed her edema and pain, and, when her doctor grew concerned about a clot, provided instruction on signs and symptoms to

watch for, and when to seek medical help. Nurses called her doctor twice in January 2012 to report on the status of her leg.

76. The nurses also provided continuous assessment of Ms. Stenger's skin, which was at high risk for breakdown and infection. They noted issues such as a rash and skin tears. She developed wounds resulting from the use of a bedpan, and the nurses evaluated the wounds, provided instruction on wound care, and alerted Ms. Stenger's doctor when appropriate.

77. Ms. Stenger was evaluated by a physical therapist in January 2012 after complaining of left leg discomfort. The therapist devised an exercise plan to assist with the leg pain.

78. A Medicare contractor determined that five claims of home health care services Ms. Stenger received, from May 6, 2011 to March 4, 2012, were not covered by Medicare. DSS appealed for Medicare coverage, requesting a redetermination of the initial determination, and subsequently, reconsideration.

79. The Medicare contractors that performed the redetermination and reconsideration had the medical records from the home health agency as evidence in the appeal. The records reflected the medical condition of Ms. Stenger and the services she received, as described above.

80. Medicare's redetermination decision of January 16, 2013 denied coverage of the services in question, stating that Ms. Stenger was "chronic, stable, and…safe within her environment. Consequently, no skilled needs were identified." The reconsideration decision of October 18, 2013 found that Ms. Stenger was homebound but that she "was medically stable with no changes in clinical status, plan of care or medication regimen to support the medical necessity for skilled nursing visits." The contractor therefore found that the home health services she received were not reasonable and necessary and could not be covered by Medicare.

81. A request for an ALJ hearing on coverage of the services in question was submitted on December 6, 2013.

Plaintiff Erma Thompson

82. Erma Thompson is a resident of East Hartford, Connecticut and was 96 years old during the periods at issue, April 29, 2012 through August 21, 2012, and October 20, 2012 through December 18, 2012. She is a beneficiary of both Medicare and Medicaid.

83. Ms. Thompson lives on the first floor of a house with family members and is homebound. She has diabetes and associated neuropathy, hypertension, rheumatoid arthritis, and asthma. She is limited in endurance and ambulation and experiences dyspnea with minimal exertion. She is incontinent of bladder. During the period at issue she had a drug regimen of over 15 medications and used a walker to ambulate when she was able to walk. She also used a wheelchair.

84. Ms. Thompson received intermittent skilled nursing services at her home from Interim Healthcare, a Medicare-certified home health agency. Her physician ordered two skilled nursing visits per month to observe and assess her respiratory, endocrine, and genitourinary systems, as well as provide ongoing assessment of her risk for falls with safety instruction. Ms. Thompson also received home health aide services for assistance with activities of daily living such as bathing, grooming, and dressing.

85. At the beginning of the first period at issue a nurse saw the need for additional pain management for Ms. Thompson, and requested a pain assessment from her doctor, who prescribed Percocet. The nurse also noted congestion with expiratory wheezes, which developed into a upper respiratory infection. Ms. Thompson was prescribed an antibiotic (Augmentin), which in turn caused gastrointestinal distress with diarrhea. The nurse instructed Ms. Thompson

to halt the Augmentin until she heard from her doctor. Once the diarrhea resolved the nurse noted that Ms. Thompson was experiencing constipation. The nurse explained how the narcotic pain medication can cause constipation and provided instruction on relieving symptoms. During this time the nurses were also monitoring a left eye infection, which was eventually diagnosed as shingles and treated with medication.

86. In July 2012 the nurses documented and monitored pitting edema in Ms. Thompson's legs as well as an itching rash on her arms, legs, and back. The following month her health declined precipitously, which necessitated more frequent skilled nursing visits. Ms. Thompson's rash was worsening and she complained of feeling ill, weak, and unsteady. A nurse discovered that Ms. Thompson was making errors in her dosage of Lasix (a diuretic used to treat edema) and consulted with her doctor. Since the dosage error created a risk of dehydration, the nurse provided instruction to Ms. Thompson on increasing her fluids. Later, in August 2012 the nurses documented that Ms. Thompson was weak, shaking, and having difficulty walking. They also noted the development of a pressure wound, which was measured, documented, and treated.

87. During the second period at issue (October 20 – December 18, 2012), the nurses continued to carefully monitor Ms. Thompson for additional complications, which were highly likely given her very advanced age, overall condition, and recent adverse health events. The nurses noted that Ms. Thompson's legs were still edematous and "weeping" fluid. The chronic pressure wound was noted to be in a state where it would heal and then reopen. Nurses monitored and assessed these conditions and provided instruction on reducing symptoms.

88. A Medicare contractor determined that three claims for home health care, covering April 29 to August 21, 2012 and October 20 to December 18, 2012, were not covered by Medicare. DSS appealed for Medicare coverage, requesting a redetermination of the initial

determination.

89. The Medicare contractors that performed the redetermination and reconsideration had the medical records from the home health agency as evidence in the appeal. The records reflected the medical condition of Ms. Thompson and the services she received, as described above.

90. Medicare's redetermination decision of October 10, 2013, denied coverage of the services in question, finding that Ms. Thompson was "chronic and stable" and did not require skilled services. The reconsideration decision of May 22, 2014 similarly found that the services provided did not require the unique skills of a licensed nurse and therefore could not be covered by Medicare.

91. A request for an ALJ hearing on coverage of the services in question was submitted on May 29, 2014.

B. The increasing denial rate in redetermination and reconsideration decisions

92. In December 2012 the Acting Director of CMS' Medicare Enrollment and Appeals Group sent the information in this and the subsequent paragraph to plaintiffs' counsel via e-mail. In calendar year 2011, of home health redeterminations decided by the National Heritage Insurance Corporation, which is one of four contractors nationwide making initial determinations and redeterminations on home health claims and which, through October 18, 2013, was responsible for claims in Connecticut, 0.61% of those that were adjudicated resulted in reversal, *i.e.*, represented coverage for beneficiaries. That is a denial rate of 99.39%. For the first ten months of 2012, the "success rate" was 0.79%, which is a denial rate of 99.21%.

93. In calendar year 2011, the "success rate" at the reconsideration level for home health claims was 2.2%, a denial rate of 97.8%. For calendar year 2012, the "success rate" at the

reconsideration level for home health claims was 1.1%, a denial rate of 98.9%.

94. The Acting Director stated in her e-mail "that the reversal rates for these specific services are in-line with the appeals rate for [the Center for Medicare Advocacy's] appeals." That statement is correct, as the statistics compiled by plaintiffs' counsels' employer, the Center for Medicare Advocacy, Inc., demonstrate. In the 21 calendar years from 1993 through 2013, inclusive, its advocates handled home health care cases for which they received a total of 36,348 redetermination and reconsideration decisions. Excluding the 8-year period from 2002 through 2009 as unrepresentative because a demonstration project was in effect that drastically reduced the number of decisions (with a total of only 1,164 in that period and ten or fewer decisions in five of the eight years), the Center for Medicare Advocacy received 35,184 redetermination and reconsideration decisions, an average of 2,706 decisions per year.

95. Of these, 20,812 were resolved under the old administrative review system in the period from 1993 through 2001. Treating either a partial or fully favorable decision as a victory, the overall "success rate" in that period, was 23.36%, ranging from a high of 37.00% in 1993 to a low of 15.83% in 2000, and ending with 22.28% in 2001.

96. In the period after the conclusion of the demonstration project, from 2010 through 2013, when the new administrative review system was in effect, the number of decisions received was 14,372. The "success rates" for the four years were 4.34%, 0.61%, 2.87%, and 2.58%, respectively, an average of 2.41%. That average for the period when the new administrative review system has been in effect is just over one-tenth of the average for the first period.

97. The separate statistics on the two levels of review reveal the same low rates. Of the 10,421 redetermination decisions in the period from 2010 through 2013, there were only 219 partially or totally favorable decisions, an average "success rate" of 2.10%. Of the 3,951

reconsideration decisions in that period, there were only 130 partially or totally favorable decisions, an average "success rate" of 3.29%.

98. The Office of the Inspector General (OIG) of HHS reports that, from 2008 through 2012, as the number of all home health claim redeterminations dramatically increased nationwide, the percentage that were fully favorable to the appellants (the "success rate") dramatically declined, as follows:

2008: 13,385 redeterminations, 22% fully favorable, 76% unfavorable

2009: 17,116 redeterminations, 35% fully favorable, 61% unfavorable

2010: 46,037 redeterminations, 9% fully favorable, 89% unfavorable

2011: 58,713 redeterminations, 6% fully favorable, 94% unfavorable

2012: 112,844 redeterminations, 3% fully favorable, 95% unfavorable.

OIG (HHS), *The First Level of the Medicare Appeals Process, 2008-2012: Volume, Outcomes, and Timeliness*, OEI-01-12-00150 (Oct. 2013), at 26, Table A4.

99. At a meeting between plaintiffs' counsel and CMS employees on February 25, 2013 in Washington, D.C., the Acting Director of CMS' Medicare Enrollment and Appeals Group stated that the reversal rate at the ALJ level for all types of services in traditional Medicare was about 70%. According to the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS), in fiscal year 2010 62% of all ALJ decisions on home health and hospice together were fully favorable. OIG (HHS), *Improvements Are Needed at the Administrative Law Judge Level of Medicare Appeals*, OEI-02-10-00340 (Nov. 2012), at 10.

100. The increasing denial rate at the redetermination and reconsideration levels has a twofold impact. First, many beneficiaries, especially the overwhelming majority who are without advocates and who therefore lack knowledge of how the system works and how their chances of

success greatly improve at the ALJ level, cannot pursue their claims. They will thus lose coverage of necessary health services, which for many of them will result in a deprivation of health care. For most, the reconsideration level is their final decision, and they almost always lose.

101. On the other hand, some beneficiaries, especially those with advocates, do take their claims to the ALJ level. Because almost all claims are resolved unfavorably at the redetermination and reconsideration levels, the need to take more claims to the ALJ level dramatically increases the number of cases that ALJs must handle, contributing to a backlog that denies beneficiaries a speedy hearing and review. According to a Memorandum dated December 24, 2013 from the Chief Administrative Law Judge of the Office of Medicare Hearings and Appeals (OMHA), OMHA's workload grew by 184% from 2010 to 2013. The backlog of almost 357,000 claims, the Memorandum explained, led to the suspension of assignment of most new claims to ALJs, effective July 15, 2013. The Memorandum claims that the suspension does not apply to beneficiaries. Nevertheless, although ALJs are mandated to issue a decision (not merely hold a hearing) within 90 days of the filing of the hearing request, 42 U.S.C. § 1395ff(d)(1)(A); 42 C.F.R. § 405.1016(a), that timeline is virtually never met. Beneficiaries usually wait at least one and one-half to two years from the date a request for ALJ hearing is filed to receive a decision, and often much longer.

VII. INADEQUACY OF REMEDY AT LAW AND PROPRIETY OF ISSUANCE OF A WRIT OF MANDAMUS

102. Plaintiffs and the class are suffering and will continue to suffer irreparable injury by reason of defendant's actions complained of herein. Plaintiffs and the class are and will be deprived of their right to efficient and effective review of their claims for Medicare coverage, and the denial of that coverage will adversely affect their health.

103. Plaintiffs and the class have no adequate remedy at law. Only the declaratory, injunctive, and mandamus relief which this Court can provide will fully redress the wrongs done to them.

104. Plaintiffs and the class have a clear right to the relief sought. There is no other adequate remedy available to correct an otherwise unreviewable defect not related to a claim for benefits. The defendant has a plainly defined and nondiscretionary duty to provide the relief that plaintiffs and the class seek.

VIII. FIRST CAUSE OF ACTION: VIOLATION OF THE MEDICARE STATUTE AND REGULATIONS

105. By the imposition of policies and practices that deny appeals at the two lowest levels of review at a rate that virtually ensures that Medicare beneficiaries cannot obtain coverage of home health care services until the ALJ level, regardless of the merits of their claims, the Secretary has created a procedural irregularity that causes an unreasonable delay in the process and otherwise deprives beneficiaries of their right to timely and meaningful review guaranteed by the administrative review statute, 42 U.S.C. § 1395ff(a)-(c), and implementing regulations, 42 C.F.R. §§ 405.940-.978 and .1200-.1208.

IX. SECOND CAUSE OF ACTION:VIOLATION OF THE DUE PROCESS CLAUSE

106. By the imposition of policies and practices that deny appeals at the two lowest levels of review at a rate that virtually ensures that Medicare beneficiaries cannot obtain coverage of home health care services until the ALJ level, regardless of the merits of their claims, the Secretary has created a procedural irregularity that causes an unreasonable delay in the process and otherwise deprives beneficiaries of their right to timely and meaningful review guaranteed by the Due Process Clause of the Fifth Amendment.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully pray that this Court:

1. Assume jurisdiction over this action.

2. Certify at an appropriate time that this suit is properly maintainable as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure.

3. Declare that defendant's policy of ruling adversely to Medicare beneficiaries needing home health care at the two lowest levels of administrative review almost 100% of the time violates the Medicare statute and regulations and the Due Process Clause of the Fifth Amendment.

4. Grant and issue a permanent injunction, and/or an order of mandamus,

a. prohibiting defendant, her successors in office, her agents, employees, and all persons acting in concert with her, from continuing to implement and authorize a system of administrative review for plaintiffs and the class members that, because of a virtually automatic denial regardless of the merits at the two lowest levels of review, forces them either to abandon their claims or to proceed to the ALJ level to obtain a meaningful review;

b. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to revise any rules, provisions, guidelines, directives, or other written material under her control that is responsible for the procedural irregularity that results in a virtually automatic denial regardless of the merits at the two lowest levels of administrative review for plaintiffs and the class members;

c. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to direct contractors, QIOs, and QICs that render Medicare decisions at any level for plaintiffs and the class members (i) to correct any internal guidelines, directives, or other written material for employees that are involved in any aspect of decision-

making at the two lowest levels of administrative review for plaintiffs and the class members, and (ii) to educate those employees as to the correct approach to decision-making as required by the Medicare statute and regulations;

d. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to monitor contractors, QIOs, and QICs that render Medicare decisions for plaintiffs and class members regarding their progress in providing a meaningful and efficient review to plaintiffs and the class members at the two lowest levels of administrative review; and

e. ordering that, after the review process has been corrected, defendant, her successors in office, her agents, employees, and all persons acting in concert with her to re-review plaintiffs' and class members' claims for coverage at the lowest level of review, and, if denied in whole or part at that level, at the reconsideration level of review.

Plaintiffs pray in addition:

5. For costs of the suit herein.

6. For reasonable attorneys' fees.

7. For such other and further relief as the Court deems just and proper.

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Respectfully submitted,

/s/ Gill Deford
GILL DEFORD
Federal Bar No. ct19269
gdeford@medicareadvocacy.org
/s/ Judith A. Stein
JUDITH A. STEIN
Federal Bar No. ct08654
jstein@medicareadvocacy.org
/s/ Margaret M. Murphy
MARGARET M. MURPHY
Federal Bar No. ct05057
mmurphy@medicareadvocacy.org

/s/ Alice Bers
ALICE BERS
Federal Bar No. ct28749
abers@medicareadvocacy.org
Center for Medicare Advocacy, Inc.
P.O. Box 350
Willimantic, CT 06226
(860) 456-7790
Fax (860) 456-2614

Attorneys for Plaintiffs