UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

MARCELLA RYAN and JOHN HERBERT, on behalf of themselves and all others similarly situated, Plaintiffs, v. SYLVIA MATHEWS BURWELL, Secretary of Health and Human Services, Defendant.	CIVIL ACTION NO. 5:14-cv-269 COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF CLASS ACTION

PRELIMINARY STATEMENT

1. This case challenges the Secretary of Health and Human Services' failure to follow her own regulations and guidance governing appeals of Medicare coverage for home health services. Under Medicare policy, Medicare contractors and appellate reviewers are required to give great weight to a prior favorable final appellate decision finding him or her to be "confined to the home" (paraphrased as "homebound") when deciding whether or not a beneficiary is homebound in a subsequent appeal. Plaintiffs have received one or more favorable final appellate decisions finding that they are homebound, but have been subsequently denied Medicare coverage on the basis of their alleged non-homebound status without proper review of favorable final appellate decisions that found that Plaintiffs were homebound.

2. The Secretary routinely denies Medicare coverage for home health services on the basis that Plaintiffs were "not homebound," despite the fact that administrative law judges have issued favorable final decisions finding Plaintiffs homebound. These

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improper denials are the result of the Secretary's failure to apply the review criteria issued by the Centers for Medicare and Medicaid Services (CMS) concerning prior favorable final appellate decisions.

3. The Secretary acts, or refuses to act, first at the Redetermination level of review. At this level, the policy governing prior favorable decisions is binding on Medicare contractors, yet the contractors consistently refuse to follow it. Instead, contractors deny coverage for beneficiaries previously found homebound without considering prior favorable appellate decisions.

4. At the Reconsideration and Administrative Law Judge (ALJ) levels of review, Qualified Independent Contractors (QICs) and ALJs refuse to follow guidance instructing them to give great weight to prior ALJ decisions finding beneficiaries to be homebound. In so doing, they fail to remedy the error made at the redetermination level, all the while ignoring Medicare law, regulation, and guidance.

5. Accordingly, Plaintiffs, on behalf of themselves and the class, request declaratory, injunctive, and mandamus relief to compel the Secretary to follow her own policy and regulations, and to reopen and review the unfavorable decisions issued to class members after those members had already received a "favorable final appellate decision."

JURISDICTION & VENUE

6. Jurisdiction is conferred upon this Court by 42 U.S.C. § 405(g), which is incorporated by 42 U.S.C. § 1395ff(b)(1)(A). Jurisdiction is also conferred by 28 U.S.C. § 1331 and 28 U.S.C. § 1361.

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7. The amount in controversy in this matter exceeds the $1,430 threshold required for jurisdiction in this court. *See* 42 U.S.C. § 1395ff(b)(1)(E) and 78 F.R. 59702, 59703 (Sept. 27, 2013).

8. Venue is proper under 42 U.S.C. § 1395ff(b), 42 U.S.C. § 405(g), and 28 U.S.C. § 1391(e).

PARTIES

9. Plaintiff Marcella Ryan is a Medicare beneficiary and a resident of Chittenden County in the District of Vermont. Her Health Insurance Claim (HIC) number and date of birth have been submitted to the Court separately under seal.

10. John Herbert is a Medicare beneficiary and a resident of Rutland County in the District of Vermont. His Health Insurance Claim (HIC) number and date of birth have been submitted to the Court separately under seal.

11. Defendant Sylvia Mathews Burwell is the Secretary of Health and Human Services and as such is responsible for administration of the Medicare program through the Centers for Medicare and Medicaid Services (CMS). The Secretary of Health and Human Services is the proper defendant in this case and is sued in her official capacity. 42 C.F.R. § 405.1136(d).

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 beneficiaries of Medicare Parts A or B, in Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont (Medicare Administrative Contractor Jurisdiction K) who (a) have received Medicare coverage for home health nursing or therapy services

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on the basis of a "favorable final appellate decision" and (b) who have subsequently been denied, or will be denied, coverage for additional services on the basis of not being homebound, on or after January 1, 2010.

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.

14. There are questions of fact and law common to the class members. Common facts include, *inter alia*, that all class members have been found eligible for Medicare coverage of home health services, including that they are homebound, in a previous appeal (whereby each was found to be homebound in a "favorable final appellate decision"), have needed additional home health care, and were denied access to services or received a denial of coverage for provided home health services on the basis of not being homebound. The common questions of law include, *inter alia*, whether the Secretary violates Medicare regulations and guidance in refusing to follow the Prior Favorable Homebound Decision policy that requires Medicare reviewers to give great weight to a prior favorable final appellate decision finding him or her to be homebound.

15. The claims of the named Plaintiffs are typical of those of the class members in that they have been denied Medicare coverage, despite a prior favorable final appellate decision, because reviewers have issued decisions that demonstrate a failure to comply with the Prior Favorable Homebound Decision policy, including a failure to use the required review procedure set forth by the Secretary in the Medicare Program Integrity Manual.

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16. The named Plaintiffs will fairly and adequately protect the interests of the class. They have no interest that is or may be potentially antagonistic to the interests of the class

and seek the same relief as the class members, that is, proper review of subsequent claims for Medicare covered home health services after being granted home health coverage in a final fully favorable appellate decision. Moreover, Plaintiffs are represented by competent counsel from established public interest law firms, the Medicare Advocacy Project of Vermont Legal Aid, Inc., and the Center for Medicare Advocacy, Inc. The attorneys are experienced in federal litigation involving public benefit programs in general and Medicare in particular, have litigated other cases involving the Medicare homebound rule, and have represented classes in other cases involving Medicare and other public benefit programs.

17. The Secretary has acted or failed to act, and continues to act or fail to act, on grounds generally applicable to the class as a whole, thereby making appropriate final injunctive and declaratory relief with respect to the class as a whole, pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure.

LEGAL FRAMEWORK

18. Medicare is the federal program that provides health insurance to the aged and the disabled. It was established by Congress in 1965 as Title XVIII of the Social Security Act, codified at 42 U.S.C. § 1395 *et seq*. Part A of traditional Medicare covers institutional and community-based services including hospital, skilled nursing facility, home care, and hospice services. *Id.* at § 1395c *et seq.* Part B of traditional Medicare covers supplemental medical services such as home care, medical equipment, physician, therapy, and ambulance services. *Id.* at § 1395j *et seq.* Part C gives Medicare beneficiaries the option of receiving coverage for these same services under various alternative delivery systems, including managed care and private fee for service plans. *Id.*

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at § 1395w-21 *et seq.* Part D makes prescription drug coverage available to Medicare beneficiaries. *Id.* at § 1395w-101 *et seq.*

19. Medicare home health coverage is available under Parts A and B, and, by extension, under Part C through a Medicare private plan.

20. To be covered for home health services, a Medicare beneficiary must be confined to the home, under the care of a physician, and have a need for skilled nursing care (or for physical, speech, or occupational therapy) on an intermittent basis, which is provided by a participating agency based on a plan of care established and signed by the beneficiary's treating physician. 42 U.S.C. §1395f(a)(2)(C), 42 C.F.R. § 409.42.

21. When a Medicare beneficiary receives a denial of coverage, the beneficiary is then presumed to know that in "comparable situations thereafter [the beneficiary] shall, by reason of such notice . . . be deemed to have knowledge that payment cannot be made for such items or services or reasonably comparable items or services." 42 U.S.C. § 1395pp. Thus, a home health coverage denial binds a Medicare beneficiary to his or her detriment moving forward. *Anderson v. Sebelius,* 2010 WL 4273238, at *4 (D. Vt. 2010).

22. Under applicable Medicare law, an individual satisfies the confined to the home (or "homebound") requirement if she "has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered 'confined to his home', the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a

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considerable and taxing effort by the individual." 42 U.S.C. § 1395f. This standard allows absences from the home for medical treatment, as well as non-medical absences which are either short or infrequent. *Id.*

23. The Medicare Program Integrity Manual (the Program Integrity Manual or MPIM), CMS Pub. 100-08 Ch. 6 § 6.2.1 set out the claims processing policies for the Regional Home Health Intermediaries (RHHIs), who are charged with making the Medicare redetermination decision (the first level of Medicare appeals).

24. The Program Integrity Manual establishes a modified standard for determining homebound status when there is a "favorable final appellate decision" for previous home health claims. This guidance includes a specific requirement to "afford the favorable final appellate decision that a beneficiary is 'confined to home' great weight in evaluating whether the beneficiary is confined to the home when reviewing services rendered after the service date of the claim addressed in the favorable final appellate decision unless there has been a change in facts (such as medical improvement or an advance in medical technology) that has improved the beneficiary's ability to leave the home." Medicare Program Integrity Manual, CMS Pub. 100-08 Ch. 6 § 6.2.1.

25. The Program Integrity Manual instructs RHHIs that "[a]ll medical review that is done on claims for services performed after the service date of the claim that is addressed in the favorable final appellate decision should determine if (a) there has been a change in facts . . . that affects the beneficiary's ability to leave the home and (b) if the services provided meet all other criteria for home health care. If there have been no changes in facts that affect the beneficiary's ability to leave the home and if all other criteria for

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home health services are met, the claim would ordinarily be paid." Medicare Program Integrity Manual, CMS Pub. 100-08 Ch. 6 § 6.2.1.

26. The Program Integrity Manual further requires RHHIs to establish procedures to ensure that medical review of a beneficiary's claim, after the receipt by that beneficiary of a favorable final appellate decision related to 'confined to home,' is reviewed based on those criteria, and requires RHHIs to "maintain records containing information on the beneficiaries receiving favorable final appellate decisions related to 'confined to home.' These records should include at a minimum the beneficiary's name, HCIN [sic] number, service date of the claim that received the favorable final appellate decision and the date of this decision." Medicare Program Integrity Manual, CMS Pub. 100-08 Ch. 6 § 6.2.1.

27. In addition, the Program Integrity Manual requires that beneficiaries and affected home health agencies be notified "that the favorable final appellate decision related to 'confined to home' will be given 'great weight' in evaluating if the beneficiary is 'confined to home.' [Also, the contractor must] inform them of what steps should be taken if they believe a claim has been denied in error." Medicare Program Integrity Manual, CMS Pub. 100-08 Ch. 6 § 6.2.1.

28. After Redetermination, the next level of appeal in the Medicare appeals system is before a Qualified Independent Contractor, called QIC.

29. QICs are not bound by CMS program guidance, such as manual instructions, but should give "substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines . . . that the policy does not apply to the facts of the particular case." 42 C.F.R. § 405.968(b)(2). When a

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QIC declines to follow a Medicare policy, it must explain its reasons. *Id.* at § 405.968(b)(3).

30. After QIC, the next level of appeal is to an Administrative Law Judge (ALJ). After ALJ, the final level of appeal is to the Medicare Appeals Council.

31. ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as manual instructions, but should give "substantial deference to these policies if they are applicable to a particular case. If an ALJ . . . declines to follow a policy in a particular case, the ALJ . . . decision must explain the reason why the policy was not followed." 42 C.F.R. § 405.1062.

32. Since January 2003, the Medicare Appeals Council has posted significant decisions and actions to the web site of the Departmental Appeals Board, including *In re G.R.* (Oct. 15, 2007). In that case, the Medicare Appeals Council granted coverage to the beneficiary, finding that MPIM Ch. 6 § 6.2.1 merited substantial deference where an appellant beneficiary had a prior favorable ALJ decision. Applying the MPIM guidance, the Medicare Appeals Council found the beneficiary homebound. Usually, however, the guidance is not applied at any level of the Medicare appeals system, including at the Medicare Appeals Council.

33. The Secretary's failure to apply this policy at all levels of the Medicare appeals system is the subject of this complaint.

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ALLEGATIONS

A. Named Plaintiffs' Situations

Plaintiff Marcella Ryan

34. Plaintiff Ryan is wheelchair or bed bound as a result of her serious and life-long disabling conditions, including cerebral palsy and muscular dystrophy. She is legally blind. As of the filing of this complaint, she is 59 years old.

35. Medicare coverage for home health services is paid on an episodic basis, based on a 60 day certification period. For Ms. Ryan, this action includes the episodes from April 7, 2009 to March 24, 2010 and May 19 to July 18, 2010 (hereinafter the April 2009-July 2010 claims periods).

36. Her complex medical condition includes a principal diagnosis of pernicious anemia, and secondary diagnoses of muscular dystrophy, infantile cerebral palsy, esophageal reflux, myalgia and myositis (muscle pain and inflammation), and obstructive sleep apnea. Ms. Ryan was also diagnosed, during the April 2009-July 2010 claims periods, with gastroparesis, mitochondrial metabolic disease, and history of urinary tract infection.

37. Ms. Ryan has received home health care since at least 1998. While her claims are usually denied Medicare coverage initially and on redetermination, she has always ultimately prevailed on further appeal. As a result, she has seven favorable final appellate decisions for claims that predate the April 2009-July 2010 claims periods. Two of these prior favorable determinations are set out below.

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38. In the first, dated February 23, 2009, Administrative Law Judge Wanda Kamphius Zatopa issued a fully favorable decision for Ms. Ryan for the home health claims made for the period from February 9, 2006 through April 7, 2007.

39. In the second, dated June 11, 2011, Administrative Law Judge Christian J. Knapp issued a fully favorable decision for Ms. Ryan for the home health claims made in the period from February 8, 2008 through April 6, 2009 (immediately preceding the April 2009-July 2010 claims periods).

40. Ms. Ryan met the criteria for Medicare home health coverage during the April 2009-July 2010 claims periods. During those episodes Ms. Ryan (a) was confined to her home, (b) was under the care of a physician, (c) was in need of intermittent skilled nursing services, (d) received those services pursuant to valid Plans of Care established and signed by her treating physician, and (e) received those services from a participating Home Health Agency.

41. The treating physician certified Ms. Ryan was confined to her home and in need of skilled services on the plan of care for each episode during the April 2009-July 2010 claims periods.

42. Ms. Ryan was hospitalized seventeen (17) times during the April 2009-July 2010 claims periods.

43. Skilled nursing services were provided as ordered by the treating physician. This included intramuscular injection of B-12 to treat pernicious anemia, flushing and maintenance of a surgically implanted vascular catheter, observation and assessment of the condition of an unstable patient with chronic conditions, and overall management of her care plan.

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44. The substantial evidence in the record establishes that Ms. Ryan required skilled nursing as defined by applicable Medicare law and policy during the April 2009-July 2010 claims periods.

45. Ms. Ryan required an assistive device, a wheelchair, for mobility. Ms. Ryan had substantial functional limitations due to endurance, ambulation, and legal blindness. Ms. Ryan required assistance with all activities of daily living (ADLs), was unable to ambulate, and needed another person to transfer her from her hospital bed to her wheelchair.

46. Any effort by Ms. Ryan to increase her activity resulted in nausea and vomiting.

47. The substantial evidence in the record establishes that Ms. Ryan was homebound as defined by applicable Medicare law and policy during the April 2009-July 2010 claims periods.

48. Ms. Ryan's condition has not improved in any way affecting her ability to leave home since the time period for which ALJs Knapp and Zatopa held that she was confined to her home.

49. No technology has been developed that affects her ability to leave home since the time period for which ALJs Knapp and Zatopa held that she was confined to her home.

50. At the initial level of review, Medicare denied coverage for the home health services provided in each of the certification periods in the April 2009-July 2010 claims periods.

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51. Ms. Ryan made a timely request for redetermination of the Medicare home health coverage denial. The redetermination decision upheld the denial of coverage for her home health care.

52. The contractor that made the redetermination decision did not consider the prior favorable ALJ decisions that found Ms. Ryan to be "homebound" within the meaning of Medicare law and policy. The redetermination decision failed to address the prior favorable ALJ decisions, and it did not document any relevant change in Ms. Ryan's condition since the time periods covered by those decisions.

53. In reaching the redetermination decision, the Medicare contractor failed to comply with the procedure set out in the Program Integrity Manual and did not afford "great weight" to the prior favorable ALJ decisions.

54. The Qualified Independent Contractor (QIC) upheld the denial of coverage. The QIC did not consider the prior favorable ALJ decisions that found Ms. Ryan to be "homebound" within the meaning of Medicare law and policy. The QIC decision failed to address the prior favorable ALJ decisions and did not explain why it was not giving deference to the Secretary's guidance. It did not document any relevant change in her condition since the time periods covered by those decisions.

55. The QIC did not give substantial deference to the review procedure set out by Medicare concerning favorable final appellate decisions finding a beneficiary "confined to the home."

56. Ms. Ryan timely appealed the QIC denial to an Administrative Law Judge. The ALJ issued a decision denying Ms. Ryan's claims for each period during the April 2009-July 2010 claims periods.

57. The ALJ concluded that Ms. Ryan was not homebound, and that she was not entitled to Medicare coverage of the home health services. The ALJ did not give

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substantial deference to the procedure set out by Medicare concerning favorable final appellate decisions finding a beneficiary "confined to the home".

58. The ALJ mistakenly concluded that the Medicare Program Integrity Manual ch. 6 § 6.2.1 provided instructions to Medicare contractors and did not apply at the ALJ level.

59. The ALJ did find, based on the substantial evidence in the record that "the Beneficiary used a wheelchair, required assistance for transfers, and had a history of frequent admissions to the hospital for nausea with vomiting."

60. Ms. Ryan timely filed a request for review of the ALJ's decision by the Medicare Appeals Council on August 20, 2012. On October 23, 2014, she received an unfavorable decision, adopting the ALJ's decision.

61. Although the MAC has ruled in certain appeals, including *In re G.R.*, that MPIM ch. 6 § 6.2.1 should be applied at the ALJ and MAC levels when the beneficiary has a prior favorable final appellate decision, the Medicare Appeals Council did not apply the MPIM's policy in Ms. Ryan's appeal. It did not mention the MPIM or document any relevant change in condition since the time periods covered by Ms. Ryan's prior favorable final appellate decisions.

62. Ms. Ryan has exhausted all available administrative remedies for the denial of her claim for Medicare coverage of the home health care services that she received in the seven physician certification periods in the April 2009-July 2010 claims periods.

63. Subsequent to the episodes during the April 2009-July 2010 claims periods, Ms. Ryan has received additional initial denials of coverage for home health services for home health care received between July 18, 2010 and March 31, 2014. Ms. Ryan has successfully appealed one of these denials and received another "favorable final appellate

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decision." The other denials are pending appeal at various levels of the Medicare appeals system.

64. The Prior Favorable Homebound Decision policy has not been applied at any level of appeal in any of Ms. Ryan's appeals for coverage of her home health coverage for July 18, 2010 through March 31, 2014. None of the decisions that have been issued mention the MPIM, explain why the Secretary's instruction was not followed or given deference, or document any relevant change in condition since the time periods covered by Ms. Ryan's prior favorable final appellate decisions.

65. Ms. Ryan has an injury-in-fact because she has been denied Medicare coverage for the essential home health care for which she was entitled to receive coverage.

66. Ms. Ryan has a continuing need for home health care services.

67. Due to the Secretary's failure to enforce the Prior Favorable Homebound policy, Ms. Ryan will continue to receive improper denials of coverage for the reasonable and necessary home health care to which she is entitled.

68. Moreover, Ms. Ryan is injured because she is now on notice of Medicare's likely non-coverage, and faces potential financial liability for future uncovered home health claims.

Plaintiff John Herbert

69. Plaintiff John Herbert was injured in a skiing accident in 1992 and suffered an incomplete spinal cord injury which left him quadriplegic. He is wheelchair bound and substantially disabled. His diagnoses include peripheral vascular disease, stage II ulcer on the left heel, neurogenic bladder, neurogenic bowel, and quadriplegia. As of the date of filing this complaint, he is 52 years old.

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70. Mr. Herbert has received home health care since at least September 1, 1997. Between September 1, 1997 and February 14, 2009, Mr. Herbert has been repeatedly denied Medicare coverage for home health care upon initial review. He has successfully appealed all or part of each of those initial decisions. As a result, he has one partially favorable redetermination decision, one partially favorable final appellate decision, and five fully favorable final appellate decisions.

71. Most recently, on November 8, 2010, Administrative Law Judge Arthur A. Liberty issued a fully favorable decision for Mr. Herbert for the period from October 25, 2007 through February 14, 2009.

72. Mr. Herbert met the criteria for Medicare home health coverage during the three 60-day physician certification periods from August 10, 2010 through December 7, 2010 and April 7, 2011 to June 5, 2011 (hereinafter the August 2010-June 2011 claims periods). During these periods Mr. Herbert (a) was confined to his home, (b) was under the care of a physician, (c) was in need of intermittent skilled nursing services, (d) received those services pursuant to valid Plans of Care established and signed by his treating physician, and (e) received those services from a participating Home Health Agency.

73. The treating physician certified Mr. Herbert was confined to his home and in need of skilled care on the plans of care for the August 2010-June 2011 claims periods.

74. Skilled nursing services were provided as ordered by the treating physician. This included skilled foot care due to peripheral vascular disease. In addition, the physician ordered, and the skilled nurses performed, observation and assessment of gastrointestinal/genitourinary status, peripheral vascular disease status, cardiopulmonary

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status, skin integrity, medication effectiveness, and fall/safety risk. Also, patient education was ordered and performed related to disease process, PVD symptoms and side effects, and pressure ulcer interventions.

75. Mr. Herbert was hospitalized just before the start of the August 2010-June 2011 claims periods. His symptoms related to diagnoses of peripheral vascular disease, quadriplegia, and neurogenic bladder and bowel were assigned a symptom control rating of "4" which indicates symptoms poorly controlled, with history of hospitalizations.

76. The substantial evidence in the record establishes that Mr. Herbert required skilled nursing during the August 2010-June 2011 claims periods as defined by applicable Medicare law and policy.

77. Mr. Herbert required an assistive device, a wheelchair, for mobility. Mr. Herbert required daily assistance from home health aides with activities of daily living (ADLs), and was totally dependent for dressing and toileting. Mr. Herbert had substantial functional limitations due to paralysis, impaired endurance, impaired ambulation, and bowel and bladder incontinence.

78. Mr. Herbert was a significant fall risk because he needed a wheelchair, needed assistance with toileting, could not stand without assistance, and took medications that indicated a risk for falls.

79. The substantial evidence in the record established that Mr. Herbert was homebound during the August 2010-June 2011 claims periods as defined by applicable Medicare law and policy.

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80. Mr. Herbert's condition has not improved in any way affecting his ability to leave home since the time period for which ALJ Liberty held that he was confined to his home.

81. No technology has been developed that affects his ability to leave home since the time period for which ALJ Liberty held that he was confined to his home.

82. Despite meeting the coverage requirements for home health services, Medicare denied coverage for the home health services provided during the August 2010-June 2011 claims periods.

83. Mr. Herbert made a timely request for redetermination of his Medicare home health coverage denial. The redetermination contractor upheld the denial of coverage for his home health care. The contractor that made the redetermination decision did not consider the prior favorable ALJ decisions that found Mr. Herbert to be "homebound" within the meaning of Medicare law and policy. The redetermination decision failed to address the prior favorable ALJ decision, and did not document any relevant change in Mr. Herbert's condition since the time periods covered by those decisions.

84. In reaching the redetermination decision, the Medicare contractor failed to comply with the procedure set out in the Program Integrity Manual and did not afford "great weight" to the prior favorable ALJ decisions.

85. In response to Mr. Herbert's timely request for reconsideration, the QIC upheld the denial of coverage for the August 2010-June 2011 claims periods. The QIC did not consider the prior favorable ALJ decisions that found Mr. Herbert to be "homebound" within the meaning of Medicare law and policy. The QIC decision failed to address the prior favorable ALJ decisions and did not explain why it was not giving deference to the

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Secretary's guidance. It did not document any relevant change in Mr. Herbert's condition since the time periods covered by those decisions.

86. The QIC did not give substantial deference to the Prior Favorable Homebound Decision policy, including the review procedure set out by Medicare concerning favorable final appellate decisions finding a beneficiary "confined to the home."

87. Mr. Herbert timely requested an ALJ hearing for the August 2010-June 2011 claims periods. As part of the documentation submitted to the ALJ, Mr. Herbert submitted a copy of his prior favorable ALJ decision for consideration under the Prior Favorable Homebound Decision policy. In apparent disregard, the ALJ issued a decision denying Plaintiff Herbert's claims.

88. The ALJ did not give substantial deference to the review procedure set out by Medicare concerning favorable final appellate decisions finding a beneficiary "confined to the home." The ALJ decision failed to address the prior favorable ALJ decisions and did not explain why it was not giving deference to the Secretary's guidance. It did not document any relevant change in Mr. Herbert's condition since the time periods covered by those decisions.

89. Mr. Herbert filed a timely request for review of the ALJ's decision by the Medicare Appeals Council on October 27, 2014.

90. Mr. Herbert has an injury-in-fact because he has been denied Medicare coverage for essential home health care to which he was entitled to coverage.

91. Mr. Herbert has a continuing need for home health care services.

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92. Due to the Secretary's failure to enforce the Prior Favorable Homebound policy, Mr. Herbert may receive improper denials of coverage for the reasonable and necessary home health care to which he is entitled.

93. Moreover, Mr. Herbert is injured because he is now on notice of Medicare's likely non-coverage, and faces potential financial liability for future uncovered home health claims.

B. The Systemic Failure

94. The Medicare Program Integrity Manual represents the Secretary's binding instructions to its contractors. Thus, contractors have a nondiscretionary duty to follow the MPIM's instructions.

95. The Secretary has a nondiscretionary duty to ensure that her contractors are correctly applying her binding instructions.

96. Upon information and belief, Medicare contractors at all levels of appeal routinely ignore the Prior Favorable Homebound Decision policy and do not consider or review prior favorable final appellate decisions for beneficiaries who later seek additional coverage for subsequent home health care claims.

97. Upon information and belief, the Secretary does not ensure that her contractors correctly apply her binding instructions.

98. Although prior favorable appellate decisions should be considered and granted great weight as a matter of course, Plaintiffs' counsel has provided the redetermination contractor in other appeals with a copy of a prior favorable ALJ decision. Even when provided with a copy of the prior favorable appellate decision, the redetermination

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contractor does not appear to consider these decisions; it does not discuss the prior decisions' existence or its impact on the homebound determination in any cases.

99. On information and belief, the failure to apply the Prior Favorable Homebound policy results in Medicare beneficiaries receiving fewer, or losing altogether, reasonable and necessary home health services. Medicare beneficiaries who receive coverage denials based on not being homebound because the redetermination contractor does not follow the MPIM instructions, despite a prior favorable final appellate decision, are on notice of likely future Medicare non-coverage for subsequent claims.

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

100. 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 Medicare coverage of claims for home health care, or access to home health care, and the denial of that coverage will adversely affect their health.

101. Plaintiffs and the class have no adequate remedy at law. The Secretary systemically fails to enforce her own policy at the Redetermination level, and subsequent levels of appeal consistently disregard the Secretary's Prior Favorable Homebound Decision policy without explanation. Thus the established complex and time-consuming administrative appeals system offers beneficiaries no relief from the Secretary and her contractors' errors. Only the declaratory, injunctive, and mandamus relief which this Court can provide will fully redress the wrongs done to them.

102. 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

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claim for benefits. Defendant has a plainly defined nondiscretionary duty to provide the relief that Plaintiffs and the class seek.

FIRST CAUSE OF ACTION: VIOLATION OF MEDICARE STATUTE, REGULATION, AND MANUAL

103. The Secretary's denial of home health care coverage on the grounds that Plaintiffs are not homebound, without applying the Prior Favorable Homebound Decision policy and properly effectuating Medicare's procedure for processing claims involving a prior favorable final appellate decision that a beneficiary is confined to the home, violates Medicare regulations and guidance. The Secretary's actions deprive Plaintiffs and the class of their right to meaningful and timely review of their claims, as guaranteed by law. 42 U.S.C. §1395ff.

SECOND CAUSE OF ACTION: VIOLATION OF DUE PROCESS

104. The Secretary's policy and practice of depriving Medicare beneficiaries, including Plaintiffs and the class, Medicare home health coverage without proper review of a favorable final appellate decisions that the Plaintiffs were "confined to the home" as set forth by Medicare in policies and standards clearly laid out in regulation and manuals, violates the Due Process Clause of the Fifth Amendment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask this Court to:

1. Assume jurisdiction over this case.

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.

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3. Declare that the Defendant Secretary's policy of not following her own guidance in order to deny home health care coverage on the ground that the beneficiary is not homebound, without proper review of a favorable final appellate decision that the Plaintiffs were "confined to the home", violates the Medicare statute, Medicare regulations, the Medicare Benefit Policy Manual, the Medicare Program Integrity Manual, and the Due Process Clause of the Fifth Amendment.

4. Grant and issue a permanent injunction and a writ of mandamus

a. prohibiting the Defendant, her successors in office, her agents, contractors, employees, and all persons acting in concert with her from continuing to deny home health coverage to Plaintiffs and the class without following the Prior Favorable Homebound Decision policy, which instructs adjudicators to, first, give great weight to a prior favorable final appellate decision and, second, find the beneficiary homebound unless there has been a change in facts that affects the beneficiary's ability to leave home;

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 blanket failure of redetermination contractors to follow binding instructions, and reconsideration contractors and Administrative Law Judges' consistent failure to give deference to such instructions.

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

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members (i) to correct any internal guidelines, directives, or other written material for employees that are involved in any aspect of decision-making , and (ii) to educate those employees as to the correct approach to decision-making as required by the Medicare statute, regulations, and manuals;

d. ordering Defendant, her successors in office, her agents, employees, and all persons acting in concert with her to monitor contractors, QIOs, and QICs the render Medicare decisions for Plaintiffs and class members regarding their progress in establishing a system to know of and to apply the procedure established by Medicare for reviewing prior favorable final appellate decisions when considering subsequent home health claims;

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, re-review Plaintiffs' and class members' denied claims for coverage for home health care received after claims for which a favorable final appellate decision was issued.

5. Award the Plaintiff reasonable costs, attorney's fees, and expenses pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412.

6. Grant such other and further relief as the court deems just and proper.

Dated in Burlington, Vermont, this 19th day of December, 2014.

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