UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

RICHARD BAGNALL, MICHAEL SAVAGE, LEE BARROWS, GEORGE RENSHAW, SARAH MULCAHY, SHIRLEY BURTON, and DENISE RUGMAN, on behalf of themselves and all others similarly situated, Plaintiffs, vs. KATHLEEN SEBELIUS, Secretary of Health and Human Services, Defendant.	Civil Action No. COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF CLASS ACTION

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 who received inpatient hospital services, but were deprived of Medicare Part A coverage by being improperly classified as outpatients.

2. The Secretary has long had a policy under which Medicare beneficiaries in hospitals, instead of being formally admitted, are placed on what is commonly referred to as "observation status" (which the Secretary refers to as "observation services"). In some instances, beneficiaries who have been formally admitted have their status retroactively changed to observation.

3. Neither the term "observation status" nor any comparable term appears in either the Medicare statute or regulations.

4. Beneficiaries on observation status generally receive the same treatment as beneficiaries who have been formally admitted, but they are considered outpatients by the Secretary. Inpatient hospitalization is covered and billed under Medicare Part A, while outpatient services are covered and billed under Medicare Part B.

5. Under the Secretary's Medicare manual provisions, observation status is generally supposed to last no longer than 24 hours and occasionally up to 48 hours, but only "in rare and exceptional cases" may observation status last longer than 48 hours. Both the incidence of placing beneficiaries on observation status and the average time period in which beneficiaries are on observation status have been increasing dramatically in recent years.

6. The impact of using observation status is to deprive Medicare beneficiaries of the Medicare Part A coverage to which they are entitled. Several negative repercussions follow from this deprivation. First, the failure to formally admit may cause the beneficiary to absorb significant additional hospital costs that otherwise would have been paid for under Medicare Part A, including the unreimbursed cost of prescription drug medications and Part B cost sharing. Second, because Medicare coverage for post-hospitalization skilled nursing facility (SNF) care is conditioned on spending a minimum of three consecutive days *as an inpatient* in the hospital, many beneficiaries who in fact spend three or more consecutive days in a hospital do not qualify for Medicare coverage of their subsequent SNF care. This forces them either to forego the care altogether or to expend significant family resources on that care. For

those who are also eligible for Medicaid, their SNF stay will be paid for under that program, which is partly financed by the state.

7. Beneficiaries placed on observation status do not receive written notification of their status and have no appeal rights to challenge that status.

8. The use of observation status violates the Administrative Procedure Act, the Medicare statute, the Freedom of Information Act, and the Due Process Clause of the Fifth Amendment.

9. On behalf of themselves and the nationwide class of Medicare beneficiaries whom they represent and who are harmed by the use of observation status, the plaintiffs seek declaratory, injunctive, and mandamus relief to halt the use of observation status and to provide remedies to those already harmed by its application.

II. JURISDICTION AND VENUE

10. Jurisdiction is conferred on this court by 28 U.S.C. §§ 1331 and 1361 and by 42 U.S.C. § 405(g), as incorporated by 42 U.S.C. §§ 1395ff(b)(1)(A) and 1395w-22(g)(5). Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) and 42 U.S.C. § 405(g).

III. PARTIES

11. Plaintiff RICHARD BAGNALL resides in Connecticut and was 91 years old at the time of the events described. At all relevant times he was a Medicare beneficiary. Although he was hospitalized from July 9 to July 12, 2009, he was deemed to be on observation status for all the time that he was hospitalized and was never formally admitted.

12. Plaintiff MICHAEL SAVAGE, the son of Mildred Savage, is an executor

of her estate. Ms. Savage, who was 92 years old and a resident of Connecticut at the time of the events described, died on October 7, 2011. At all relevant times she was a Medicare beneficiary. Although she was hospitalized for all but one day from September 11 to September 19, 2010, for five of those days she was deemed to be on observation status.

13. Plaintiff LEE BARROWS, the widow of Lawrence Barrows, is the executrix of his estate. Mr. Barrows, who was 76 years old and a resident of Connecticut at the time of the events described, died on October 8, 2009. At all relevant times he was a Medicare beneficiary. Although he was hospitalized from July 3 to July 10, 2009 and although he was formally admitted before July 8, on July 8 his status was changed to observation status, retroactive to when he had been formally admitted.

14. Plaintiff GEORGE RENSHAW, the son of Charles Renshaw, is the executor of his estate. Mr. Renshaw, who was 89 years old and a resident of Connecticut at the time of the events described, died on November 11, 2010. At all relevant times he was a Medicare beneficiary. Although he was hospitalized from May 16 to May 20, 2010, he was deemed to be on observation status for all the time that he was hospitalized and was never formally admitted.

15. Plaintiff SARAH MULCAHY resides in Connecticut and was 96 years old at the time of the events described. At all relevant times she was a Medicare beneficiary. Although she was hospitalized from June 25 to June 29, 2010, she was deemed to be on observation status for all the time that she was hospitalized and was never formally admitted.

16. Plaintiff SHIRLEY BURTON, the sister of Nettie Jean Sapp, is the

executrix of her estate. Ms. Sapp, who was 77 years old and a resident of Texas at the time of the events described, died on April 16, 2011. At all relevant times she was a Medicare beneficiary. Although she was hospitalized from April 21 to April 26, 2010, she was deemed to be on observation status for all the time that she was hospitalized and was never formally admitted.

17. Plaintiff DENISE RUGMAN, the daughter of Florence Coffey, is the executrix of her estate. Ms. Coffey, who was 74 years old and a resident of Massachusetts at the time of the events described, died on September 13, 2010. At all relevant times she was a Medicare beneficiary. Although she was hospitalized from June 21 to June 24, 2010, she was deemed to be on observation status for all the time that she was hospitalized and was never formally admitted.

18. Defendant KATHLEEN SEBELIUS is the Secretary 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

19. 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 who, on or after January 1, 2009, have had or will have had any portion of a stay in a hospital treated as observation status and therefore not covered under Medicare Part A.

20. 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. On information and belief, plaintiffs estimate the class to include at least tens of thousands of members.

21. There are questions of fact and law common to the class members. Common facts include, *inter alia*, that all class members have been hospitalized and have had least part of their stay in the hospital designated as observation status rather than as formal admission. The common questions of law include, *inter alia*, whether the Secretary's policy of allowing hospitals to impose observation status on Medicare beneficiaries violates the Administrative Procedure Act, the Medicare statute, the Freedom of Information Act, and the Due Process Clause.

22. The claims of the named plaintiffs are typical of those of the class members in that they have been placed on observation status for at least part of their hospital stay and, as a consequence, have been deprived of Medicare Part A coverage for which they are eligible.

23. 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, elimination of the use of observation status. Moreover, plaintiffs are represented by competent counsel from two established public interest law firms, the Center for Medicare Advocacy, Inc. and the National Senior Citizens Law Center. The attorneys are experienced in federal litigation involving public benefit programs in general and Medicare in particular and have represented classes in numerous other cases involving Medicare and other public benefit programs.

24. The Secretary has acted and continues 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.

V. LEGAL FRAMEWORK

A. Overview of the Medicare program

25. 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 over or are disabled. Under Part A of Medicare, which is titled "Hospital Insurance Benefits for Aged and Disabled" and 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, which is titled "Supplementary Medical Insurance Benefits for Aged and Disabled," establishes a voluntary program of supplemental medical insurance providing coverage for physician services, nurse practitioner services, home health care, physical, speech and occupational therapy, diagnostic services, and durable medical equipment. Under Part C (the Medicare Advantage or MA program), beneficiaries may opt to enroll in a managed care plan in lieu of the traditional fee-for-service approach of "original Medicare," which is provided in Parts A and B. Part D provides for partial coverage of prescription drugs.

26. Under Medicare Part C, each plan must provide at least the actuarial equivalent of the value of coverage provided under Parts A and B. Each plan has different rules. The impact of placing a beneficiary on observation status differs

depending on which MA plan a beneficiary is enrolled in.

27. As a component of the hospitalization benefit under Part A, follow-up care in a SNF is part of the continuum of coverage for an acute event, is denoted "post-hospital extended care services," and is codified as a subsection of the hospitalization benefit. 42 U.S.C. §§ 1395d(a)(1) and (2)(A). The purpose of covering SNF care in this context is to extend the acute care provided in the hospital but in a less expensive setting.

28. A condition of this coverage is that the beneficiary must have been a hospital inpatient for at least three consecutive calendar days prior to her discharge from the hospital. 42 U.S.C. § 1395x(i). In calculating the number of days, the first calendar day in the hospital is counted, but not the day of discharge. 42 C.F.R. § 409.30(a).

29. As a general rule, Medicare beneficiaries receive written notification when adverse action involving coverage is to be taken. The notification advises them of their right to administrative review and the steps to take to effect that review.

30. Neither the Medicare statute, 42 U.S.C. § 1395 *et seq*., nor its implementing regulations, 42 C.F.R. Part 405 *et seq*., mentions or implements observation status or any comparable concept.

B. <u>The Administrative Review Process</u>

31. Under original Medicare (Parts A and B), a beneficiary against whom adverse action is planned regarding her coverage receives an "initial determination." This formal statement is provided as part of the Medicare Summary Notice (MSN), which is issued on a quarterly basis.

32. Under the standard review process, the beneficiary requests review of the MSN "initial determination" by filing a request for a redetermination. If the decision

remains adverse, the beneficiary may request reconsideration.

33. Under the expedited review process that is available for discharge from a SNF, home health care, or a hospice, the provider must generally give notice two days before the discharge or termination is to occur. The beneficiary has until noon of the next calendar day to request an expedited determination. If the provider's decision is upheld, the beneficiary has until noon of the next calendar day to seek reconsideration.

34. The remaining steps are the same for both standard and expedited review. These include a de novo review by an administrative law judge (ALJ) if the amount in controversy is at least $130 in 2011 and an on-the-record review of the ALJ's decision by the Medicare Appeals Council (MAC), with the same amount-in-controversy requirement. Review in federal district court is then available for cases in which the amount in controversy is at least $1,300 in 2011.

35. For claims under Part C, the path of review is similar: first, an initial determination, which is known as an "organization determination," and then an in-house reconsideration determination. When the reconsideration is adverse to the beneficiary, the case is automatically sent to an external review organization for further reconsideration.

36. If the decision remains adverse to the beneficiary, the remaining available steps are the same as for Parts A and B: ALJ, MAC, and federal district court.

C. Observation Status Defined and in Practice

37. The Medicare manuals claim that observation status is "a well-defined set

of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital." In practice, however, observation status is applied in an ad hoc fashion to Medicare beneficiaries who for all practical purposes are hospital inpatients.

38. In original Medicare, Medicare coverage for observation status is under Part B on the theory that the beneficiary is an outpatient. The beneficiary on observation status is considered an outpatient even though a patient on observation status is in a hospital bed and is frequently on a floor with other patients who have been formally admitted as inpatients.

39. Observation status is also applied to beneficiaries enrolled in a Part C MA plan. As in original Medicare, the beneficiary would be considered an outpatient. As in all MA plan contexts, the billing would be under Part C.

40. A patient is formally placed on observation status through the signature of her physician. The physicians, however, sign proposed orders provided by the hospitals, which follow commercially available screening tools, such as those from the McKesson Corporation (Interqual) and Milliman, to determine if an admission is appropriate. These are proprietary systems that are not publicly available. Medicare contractors use these criteria to evaluate hospital admissions. Hospitals also rely on them to reduce the likelihood that they will be sanctioned for an improper admission.

41. A patient who has been formally admitted may be reclassified, while still in the hospital, as an outpatient on observation status by the hospital's utilization review

committee (URC).

D. Absence of Procedural Rights in the Observation Status Context

42. Beneficiaries who are placed in observation status do not receive written notification of that status or of the significance of that status while they are in the hospital. Many, perhaps most, beneficiaries do not know that they have been classified as outpatients under Part B rather than inpatients under Part A until some time after they have left the hospital. Their first formal notification from Medicare occurs when they receive the MSN, which summarizes all of their Medicare activity for the most recent three-month period, including an indication that they were covered under Part B (if they were in original Medicare) while they were hospitalized. The MSN fails to give any indication that a beneficiary might want to appeal Part B coverage of their hospitalization on the ground that the coverage should have been under Part A.

43. Beneficiaries who are placed on observation status are not informed that they have any appeal rights to challenge that placement and to contend that they should be formally admitted and be covered under Part A.

44. Beneficiaries whose status as admitted inpatients is changed to observation status by the hospital's URC are supposed to receive written notification of that change in status. The notification does not inform them of any appeal rights to challenge that change and to contend that they should have remained as admitted inpatients and covered under Part A. On information and belief, in most instances beneficiaries in this situation do not in fact receive even the inadequate notification to which they are entitled under the Secretary's current policy.

E. Increasing Use of Observation Status

45. The Medicare manuals state that "[m]ost observation services do not exceed one day. Some patients, however, may require a second day of outpatient observation services. In only rare and exceptional cases do outpatient observations services span **more** than two calendar days." (Emphasis in original.) In noting the increasing number of observation status stays that exceed 48 hours, however, CMS observed almost four years ago that stays of over 48 hours "are not as rare and exceptional as we have stated they should be in the context of contemporary hospital outpatient clinical practice." 72 F.R. 66580, 66814 (Nov. 27, 2007).

46. If a beneficiary is admitted but that admission is later found to be improper, the hospital must refund the Part A payment to Medicare but cannot rebill under Part B. Consequently, hospitals have an incentive to place patients on observation status because that placement at least ensures that the hospital will receive some payment for the stay in the hospital. Hospitals have become particularly concerned about post-payment reviews because, in recent years, Recovery Audit Contractors have been carefully reviewing admissions, especially short-term admissions.

47. Furthermore, because the Affordable Care Act of 2010 penalizes hospitals for readmission of patients, hospitals now have an additional billing incentive to utilize observation status. By terming the original stay as on observation status, the hospital can avoid, if the patient must return to the hospital, a sanction for readmission, for the patient is not considered to have been an inpatient in the first stay. Conversely, if the patient was formally admitted on the original visit, on the return visit her placement on observation status will avoid the readmission sanction.

48. According to CMS, in 2006 about 17% of about 834,000 claims for

observation status were for periods lasting under 12 hours, about 43% were for periods of 13-24 hours, about 37% were for periods lasting 24 to 48 hours, and about 3% ("about 26,000 claims") lasted for periods of more than 48 hours. 72 F.R. 66580, 66813 (Nov. 27, 2007). Thus, according to CMS, in 2006 observation status lasting over one day represented about 40% of all claims. The Acting Administrator of CMS stated in a letter to the American Hospital Association on July 7, 2010 that, by 2008, the percentage of observation status claims for periods over 48 hours was "nearly 6 percent."

49. In a September 13, 2010 presentation, the Medicare Payment Advisory Commission (MedPAC), which advises Congress on Medicare matters, stated that, from 2006 to 2008, the number of observation status claims increased by 22.4%, the average period of observation status increased from 26 to 28 hours, and the claims for periods of 48 hours or longer increased by 70.3%, which accounted for 8% of all claims in 2006 and 12% of all claims in 2008.

50. Although discrepancies exist between the statistics from CMS and those from MedPAC, three facts are indisputable: (1) the number of claims for observation status is increasing; (2) the average period of time in observation status is increasing; and (3) the number of people in observation status for more than two days is increasing.

F. The Negative Financial Impact of Observation Status on Beneficiaries and States

51. Beneficiaries in original Medicare who are placed on observation status and therefore covered under Part B rather than being formally admitted and covered under Part A are responsible for the Part B co-payment, which is about 20% of the costs of the services.

52. If a beneficiary is formally admitted under original Medicare, all

medications received in the hospital are covered by the Part A payment to the hospital. By contrast, under observation status, beneficiaries have prescription medications only partially paid for under Part D. Since the hospital pharmacy is unlikely to be in the Part D plan's network, the beneficiary will be charged the out-of-network cost of the medications. In addition, any drugs administered by the hospital that are not on the Part D plan's formulary will not be covered at all.

53. Beneficiaries in original Medicare must spend a minimum of three days in the hospital as an inpatient in order to be covered for follow-up SNF care after the hospitalization. Consequently, since observation status is not considered inpatient, many beneficiaries who spend three or more days in a hospital are nonetheless not covered for subsequent SNF care because the days on observation status are not counted. Medicare beneficiaries, unless they have Medicaid coverage, must therefore choose between paying the exorbitant costs of SNF care or foregoing that care and possibly returning home with no follow-up care at all.

54. For Medicare beneficiaries also eligible for Medicaid, the Medicaid program will cover nursing facility care even if the care is not available under Medicare Part A. Such a beneficiary, however, may have cost sharing under Medicaid, depending on the beneficiary's income. Also, since Medicaid is partly financed by each state, placing beneficiaries on observation status rather than admitting them frequently shifts part of the cost of subsequent SNF care from the federal government to the states.

55. Beneficiaries enrolled in an MA plan (under Part C) may be affected by placement on observation status in none, some, or all of the ways that beneficiaries in original Medicare are affected, with the exact outcome determined by the terms of each

individual plan.

VI. FACTUAL STATEMENT

Plaintiff Richard Bagnall

56. During the period at issue, plaintiff Richard Bagnall, a retired physician, was 91 years old and a resident of Connecticut.

57. Dr. Bagnall had a history of inferior myocardial infarction, congestive heart failure, cerebrovascular accident, tremors, atrial fibrillation (abnormal heart rhythm), and chronic kidney disease. On July 9, 2009 he went to the emergency room of John Dempsey/University of Connecticut Health Center after three days of increasing lightheadedness and weakness. He was found to be in atrial fibrillation. He received an IV infusion, EKG and X-ray and was started on an atrial fibrillation monitor. On July 9 Dr. Bagnall signed a notice indicating he was a hospital inpatient and was later moved to a hospital floor. His fluid balance was strictly monitored. He was discharged on July 12, 2009, having been treated with IV fluids for dehydration, weakness, chronic kidney disease, atrial fibrillation, and hypertension.

58. Dr. Bagnall received a hospital level of care and should have been formally admitted. Nevertheless, he was on observation status for all of the three days in which he was in the hospital. He received a Medicare Summary Notice stating he was responsible for about $500 in Part B coinsurance payments for outpatient claims.

59. Because he was not formally admitted to the hospital and therefore did not satisfy the three-day rule, his subsequent care in a skilled nursing facility, from July 12 to July 27, 2009, was not covered by Medicare. The cost of that care, which he paid for out of pocket, was about $5,685.

60. Dr. Bagnall's timely request for review of the determination that his hospital stay was for observation status and therefore covered under Part B rather than Part A was denied at the redetermination and reconsideration levels. The decision was appealed to an administrative law judge (ALJ). On July 5, 2011, an ALJ hearing was held. A decision has not been issued.

Plaintiff Michael Savage

61. During the period at issue, Mildred Savage was 92 years old and a resident of Connecticut. She died on October 7, 2011 and is represented in this action by Michael Savage, her son and an executor of her estate.

62. After a fall caused hip pain, Ms. Savage was hospitalized at William W. Backus Hospital from September 11, 2010 to September 16, 2010. She was sent to a skilled nursing facility on September 16 but had to return to the hospital on September 17, where she stayed until September 19, 2010. Ms. Savage had a history of peripheral arterial disease, atrial fibrillation, hypertension, and deep vein thrombosis. At the hospital she received a chest and hip x-rays, CT scans of the head, pelvis, and lower extremities, lab work, and injections of anticoagulant medication. Her diagnoses at discharge were severe left hip pain, hypertension, atrial fibrillation, diabetes, mild dementia, and hypothyroidism.

63. At all times Ms. Savage received a hospital level of care and should have been formally admitted, but she was only formally admitted on her return to the hospital, for two days, September 17 through September 19, 2010. For her original stay in the hospital of five days, she was on observation status for the entire period. She received a Medicare Summary Notice stating she was responsible for about $400 in Part B

coinsurance payments for outpatient claims.

64. Because she was not formally admitted to the hospital until her return stay and therefore did not satisfy the three-day rule, her subsequent care in a skilled nursing facility, from September 20, 2010 to November 5, 2010, was not covered by Medicare. The cost of that care, which she paid for out of pocket, was $17,388.

65. Ms. Savage timely requested review of the determination that her hospital stay from September 11-16, 2009 was for observation status. On July 29, 2011 a redetermination decision denied her appeal for coverage as an inpatient, but only addressed dates of service September 11–13, 2009. Ms. Savage subsequently learned that the hospital is now barred for billing for September 14-15, 2009 because of a Medicare rule prohibiting billing for hospital care received just before a readmission. This leaves Ms. Savage, who was physically in the hospital for five consecutive days receiving a hospital level of care, without a qualifying three-day stay, not only because her status was originally misclassified, but also because the hospital is not allowed to bill Medicare at all for two of the days she was there. A request for reconsideration was filed on October 5, 2011.

Plaintiff Lee Barrows

66. During the period at issue, Lawrence Barrows was 76 years old and a resident of Connecticut. Mr. Barrows died on October 8, 2009 and is represented in this action by Lee Barrows, his widow and executrix of his estate.

67. Mr. Barrows had spinocerebellar ataxia type 8 (a disease of the nervous system) and walked with a walker. Two weeks before going to the hospital, Mr. Barrows became less steady on his feet and was falling with increasing frequency. As a

consequence of these episodes, he was hospitalized at John Dempsey/ University of Connecticut Health Center from July 3 to July 10, 2009. In the emergency room Mr. Barrows received a head CT scan, chest X-ray, and was tested for a urinary tract infection. The neurology department was consulted, his medications were adjusted, and a neurologist completed an admission assessment to have Mr. Barrows admitted to the hospital. Because of concern that Mr. Barrows was suffering from cervical myelopathy (a spinal disorder), he received an MRI of the cervical, thoracic, and lumbar spine. Mr. Barrows continued to have a very unsteady gait and an episode of confusion. His heart rate began to vary and he was noted to have significantly elevated blood pressure over the next several days, with several adjustments in medication and administration of IV medication.

68. At some unknown point between July 3 and July 8, 2009, Mr. Barrows was formally admitted to the hospital, but at some point on July 8 his status was changed from inpatient to observation. A notice was not issued.

69. Mr. Barrows received a hospital level of care and should have been formally admitted. Nevertheless, he was on observation status for all of the seven days in which he was in the hospital. He received a Medicare Summary Notice stating he was responsible for about $400 in Part B coinsurance payments for outpatient claims.

70. Because he was not formally admitted to the hospital and therefore did not satisfy the three-day rule, his subsequent care in a skilled nursing facility, from July 10 to July 28, 2009, was not covered by Medicare. The cost of that care, for which his family has been billed, is about $30,400. His widow and executrix, Lee Barrows, negotiated a lower bill and has been paying it off in installments.

71. The timely request for review of the determinations that his hospital stay was for observation status and therefore covered under Part B rather than Part A, and that his skilled nursing facility stay was not covered, was denied at the redetermination and reconsideration levels. On April 21, 2011, the ALJ affirmed the denials of Part A coverage for hospitalization and for his skilled nursing facility stay. On May 5, 2011, his estate appealed the ALJ decision to the Medicare Appeals Council. A decision is pending.

Plaintiff George Renshaw

72. During the period at issue, Charles Renshaw was 89 years old and a resident of Connecticut. Mr. Renshaw died on November 11, 2010 and is represented in this action by George Renshaw, his son and executor of his estate.

73. Charles Renshaw had a history of rectal tumor, a bowel resection and ileostomy that had been reversed, hip replacement, and depression. On or about May 16, 2010, Mr. Renshaw became ill and fell while in his home. As a consequence of this fall, Mr. Renshaw was transferred by ambulance to Backus Hospital. He was hospitalized from May 16, 2010 until May 20, 2010.

74. While in the hospital, Mr. Renshaw had an EKG, a CT scan and received consultations with nutrition and physical therapy. He was discharged with a diagnosis of "fall/diarrhea."

75. Mr. Renshaw received a hospital level of care and should have been formally admitted. Nevertheless, he was on observation status for all of the four days in which he was in the hospital.

76. Because he was not formally admitted to the hospital and therefore did not

satisfy the three-day rule, his subsequent care in a skilled nursing facility, from May 20, 2010 until June 3, 2010, was not covered by Medicare. The cost of that care, which his family paid for out of pocket, was about $4,725.

77. On June 14, 2011, Mr. Renshaw's estate requested reconsideration of the determinations that his hospital stay was for observation status and therefore covered under Part B rather than Part A, and that his skilled nursing facility stay was not covered. The reconsideration was denied on August 12, 2011 and a request for an ALJ hearing was filed on October 5, 2011.

Plaintiff Sarah Mulcahy

78. During the period at issue, Sarah Mulcahy was 96 years old and a resident of Connecticut.

79. Ms. Mulcahy had a history of breast cancer, hypertension, and macular degeneration and she had suffered a stroke in October 2009. After a fall she had such severe pain that she could not walk and experienced urinary incontinence and nausea. As a consequence, she went to the emergency room and was hospitalized at Manchester Memorial Hospital from June 25 to June 29, 2010. She received IV medications for nausea and vomiting. The doctor also ordered incentive spirometry (a device to assist lung functioning) to prevent respiratory infection and venodynes (compression cuffs) to prevent deep vein thrombosis. She had chest and rib X-rays and a CT scan of the head. Ms. Mulcahy was noted to have increasing blood pressure and her medication regimen was adjusted. She was also diagnosed with a urinary tract infection.

80. Ms. Mulcahy received a hospital level of care and should have been formally admitted. Nevertheless, she was on observation status for all of the four days in

which she was in the hospital. She received a Medicare Summary Notice stating she was responsible for about $335 in Part B coinsurance payments for outpatient claims.

81. Because she was not formally admitted to the hospital and therefore did not satisfy the three-day rule, her subsequent care in a skilled nursing facility, from June 29 to October 7, 2010, was not covered by Medicare. The cost of that care, which she paid for out of pocket, was about $30,000.

82. On August 5, 2011, Ms. Mulcahy timely requested review of the determination classifying her hospital stay as observation status. The ALJ hearing was held on October 25, 2011.

Plaintiff Shirley Burton

83. During the period at issue, Nettie Jean Sapp was 77 years old and a resident of Texas. Ms. Sapp died on April 16, 2011 and is represented in this action by Shirley Burton, her sister and executrix of her estate.

84. Ms. Sapp had a history of breast cancer, Parkinson's disease, and rheumatoid arthritis. Prior to the hospitalization in question she had experienced profound weight loss, weakness, episodes of memory loss and several falls.

85. After suffering another fall in her home, Ms. Sapp was hospitalized at Scott and White Hospital from April 21 through April 26, 2010. At the hospital she received a CT scan of the head, X-ray of the lumbar spine, an EKG, a bilateral carotid ultrasound, and an MRI of the brain. A urinary tract infection was also noted and she was treated with IV and then oral antibiotics. She had consultations with physical and occupational therapy. She was diagnosed with syncope and discharged to a skilled nursing facility.

86. Ms. Sapp received a hospital level of care and should have been formally admitted. Nevertheless, she was on observation status for all of the five days she was in the hospital. She received multiple Medicare Summary Notices listing Part B outpatient claims for the services she received in the hospital, including one listing about $575 in coinsurance payments for which she was responsible.

87. Because she was not formally admitted to the hospital and therefore did not satisfy the three-day rule, her subsequent care in a skilled nursing facility, from April 26, 2010 through June 24, 2010, was not covered by Medicare. Ms. Sapp's family paid about $9,200 out of pocket to the skilled nursing facility. She subsequently moved to an assisted living facility because she could not afford the cost of the nursing facility. She died in the assisted living facility.

88. Ms. Sapp's sister, Shirley Burton, has attempted to appeal the observation status classification. She appealed a June 18, 2010 Medicare Summary Notice, explaining in writing that she was disputing the listed hospital and nursing facility charges because of the observation status issue. She received a letter from the Medicare appeals contractor dated August 11, 2010 which stated that they had no record of a five-day stay in the hospital. After receiving a call from a Medicare representative on September 17, 2010 providing instructions on how to appeal, Ms. Burton mailed a written appeal to Medicare again on September 17, 2010. She received a letter from Medicare dated October 5, 2010 stating that they were unable to locate the claim in their system. She also appealed an October 14, 2010 Medicare Summary Notice. She has no record of a response. She wrote to Medicare again on January 20, 2011 and July 11, 2011, attaching copies of earlier appeals, but has no record of a response. Most recently she

appealed a September 17, 2011 Medicare Summary Notice listing more claims for services received in the hospital. Ms. Burton also attempted to resolve her sister's observation status issue by writing to the hospital, to her sister's Congressman, to CMS Administrator Donald Berwick, to HHS Secretary Kathleen Sebelius, and to the Associate Regional Administrator for Region VI of CMS. She also filed a complaint with the Texas Department of Health Services.

Plaintiff Denise Rugman

89. During the period at issue Florence Coffey was 74 years old and a resident of Massachusetts. Ms. Coffey died on September 13, 2010 and is represented in this action by Denise Rugman, her daughter and executrix of her estate.

90. Ms. Coffey had metastatic breast cancer as well as muscular dystrophy which caused her to walk with a cane. She was suffering from generalized weakness and dizziness which had caused her to fall two or three times in the month before she went into the hospital.

91. On June 21, 2010 Ms. Coffey suffered another fall at home and went to the emergency room at South Shore Hospital. She was moved to a hospital room later that day and stayed through June 24, 2010. She received IV fluids, a head CT scan, a shoulder X-ray, brain MRI, consultation with physical therapy, and a hematology/oncology consult.

92. Ms. Coffey received a hospital level of care and should have been formally admitted. Nevertheless, she was on observation status for the three days she was in the hospital. She received a Medicare Summary Notice stating she was responsible for about $560 in Part B coinsurance payments for outpatient claims.

93. Because she was not formally admitted to the hospital and therefore did not satisfy the three-day rule, her subsequent care in a skilled nursing facility, from June 24 to September 13, 2010, was not covered by Medicare. Her family paid close to $30,000 for that care.

94. Ms. Coffey's family was first told of her observation status when she arrived at the skilled nursing facility to which she had been discharged. On June 25, 2010, the family called South Shore Hospital about the classification but was told there was no appeal process. Nonetheless, on June 27, 2010, Ms. Coffey and her son wrote to South Shore Hospital requesting that her status be changed to inpatient. The nursing facility then advised her family to appeal the Notice of Exclusion of Medicare Benefits, which had been issued by the facility, to the Medicare appeals contractor for the area. The family submitted their first appeal to Medicare on or about July 1, 2010. In September Ms. Coffey's family received a call from Medicare saying there was nothing to appeal because the nursing facility had not billed Medicare. The facility then submitted claims to Medicare and when they were denied, the family again appealed on December 4, 2010, and then again on April 19, 2011, sending documentation of the appointment of Denise Rugman as the legal representative of Ms. Coffey's estate, as Medicare had requested. Ms. Rugman then received a response from CMS's Beneficiary Services dated June 8, 2011. The letter inexplicably referred to a stay at "Tucson Medical Center" and stated, *inter alia*, "There is no limit on the amount of time a patient may be an outpatient in a hospital getting observation care." The letter stated that because a physician did not order the hospital to admit Ms. Coffey, her stay could not be classified as inpatient. The letter made no mention of appeal rights.

95. Ms. Rugman resubmitted an appeal of the classification to the Medicare contractor on July 27, 2011 and wrote to the hospital to dispute the classification again on August 10, 2011. She received another denial from Medicare dated September 13, 2011. The letter stated "The appeal process is for denied claims. The hospital claim from South Shore Hospital was paid. If a claim had been paid for services that were never received, you would appeal that payment. You state the stay should have been an inpatient three day stay and not observation status. Medicare processed the claim according to how it was submitted by the provider." The letter went on to advise Ms. Rugman to appeal the denied nursing facility claims rather than the hospital claims, despite the fact that Ms. Rugman had clearly explained in her appeal letter that the family started the whole process by trying to appeal the non-coverage of the nursing facility stay. In response to the September 13 denial Ms. Rugman submitted another appeal to Medicare on October 27, 2011.

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

96. Plaintiffs suffer irreparable injury by reason of defendants' actions complained of herein. The plaintiffs are deprived of Part A coverage to which they are entitled, which in turn forces them to bear the financial responsibility for hospitalization and prescription drugs that are covered under Part A. They are denied the right to coverage of their SNF care and may be forced to pay the cost of that care or be unable to obtain that care at all. They do not receive notification of their status, nor do they have any right to appeal that status, thus depriving them of administrative review of their placement in observation status.

97. Plaintiffs have no adequate remedy at law. Only the declaratory,

injunctive, and mandamus relief that this Court can provide will fully redress the wrongs done to plaintiffs.

98. Plaintiffs 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 seek.

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

99. By allowing observation status, a billing mechanism, to deprive intended beneficiaries of Part A coverage, defendant violates the Medicare statute and the purpose of Medicare Part A, which is to provide coverage for hospitalization and for follow-up SNF care after hospitalization for an acute event, as established in 42 U.S.C. § 1395d(a).

IX. SECOND CAUSE OF ACTION: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

100. The Administrative Procedure Act prohibits rulemaking without first publishing the rule in proposed form and allowing members of the public an opportunity to comment on the proposed rule. 5 U.S.C. § 553. As a rule applied to Medicare beneficiaries that limits or prevents coverage to which they are otherwise entitled, defendant's policy of allowing hospitals to place beneficiaries on observation status violates the notice-and-comment requirements of the Administrative Procedure Act, which renders the rule void and of no force and effect.

X. THIRD CAUSE OF ACTION: VIOLATION OF THE PROCEDURAL REQUIREMENTS OF THE MEDICARE STATUTE

101. The Medicare statute prohibits the promulgation of a rule that "establishes or changes a substantive legal standard governing the scope of benefits, the payment for

services, or the eligibility of individuals … to … receive services or benefits under this subchapter … unless it is promulgated by the Secretary" through notice-and-comment rulemaking. 42 U.S.C. § 1395hh(a)(2). As a rule applied to Medicare beneficiaries that limits or prevents coverage to which they are otherwise entitled, defendant's policy of allowing hospitals to place beneficiaries on observation status violates the notice-and-comment requirements of the Medicare statute, which renders the rule void and of no force and effect.

XI. FOURTH CAUSE OF ACTION: VIOLATION OF THE FREEDOM OF INFORMATION ACT

102. The Freedom of Information Act requires publication in the Federal Register "of substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency." 5 U.S.C. § 552(a)(1)(D). Observation status meets this criterion, but it has not been published in the Federal Register. Accordingly, it cannot be applied, and the rule is void and of no force and effect.

XII. FIFTH CAUSE OF ACTION: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

103. Defendant's policy of allowing hospitals to limit or prevent Medicare coverage to which beneficiaries are otherwise entitled, by allowing beneficiaries to be deemed on observation status, violates the Administrative Procedure Act's prohibition against agency action that is arbitrary, capricious, or an abuse of discretion, 5 U.S.C. § 706(2)(A).

XIII. SIXTH CAUSE OF ACTION: VIOLATION OF RIGHT TO NOTIFICATION GUARANTEED BY THE MEDICARE STATUTE AND THE DUE PROCESS CLAUSE

104. Defendant's failure to provide written notification to Medicare beneficiaries, or to require that they receive written notification, of their placement on observation status, of the consequences of that placement for their Medicare coverage, and of their right to challenge that placement violates the Medicare statute, 42 U.S.C. §§ 1395ff and 1395w-22(g), and the Due Process Clause of the Fifth Amendment.

XIV. SEVENTH CAUSE OF ACTION: VIOLATION OF THE RIGHT TO ADMINISTRATIVE REVIEW GUARANTEED BY THE MEDICARE STATUTE AND THE DUE PROCESS CLAUSE

105. Defendant's policy of not providing Medicare beneficiaries with the right to administrative review, including expedited review, of their placement on observation status violates the Medicare statute, 42 U.S.C. §§ 1395ff and 1395w-22(g), and the Due Process Clause of the Fifth Amendment.

XV. EIGHTH CAUSE OF ACTION: VIOLATION OF THE MEDICARE STATUTE

106. Defendant's policy of allowing hospitals to place Medicare beneficiaries on observation status based on criteria that are not publicly known interferes with the practice of medicine in violation of the Medicare statute, 42 U.S.C. § 1395.

XVI. NINTH CAUSE OF ACTION: VIOLATION OF THE MEDICARE STATUTE

107. Defendant's policy of allowing hospitals, through their utilization review committees, to reverse the decision of a beneficiary's physician to formally admit the beneficiary as an inpatient, and to retroactively place that beneficiary on observation status, interferes with the practice of medicine in violation of the Medicare statute, 42 U.S.C. § 1395.

XVII. 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 implementation and use of observation status for Medicare beneficiaries violates the Medicare statute, the Administrative Procedure Act, the Freedom of Information Act, and the Due Process Clause of the Fifth Amendment.

4. Grant 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 allowing Medicare beneficiaries to be placed on observation status and thus to deprive them of Medicare Part A coverage to which they are entitled;

b. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to provide written notification, or to ensure that written notification is provided, to any Medicare beneficiary who is placed on observation status of the nature of the action, of the consequences for Medicare coverage, and of the right to administrative and judicial review of that action;

c. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to establish a procedure for administrative review of a decision to place a Medicare beneficiary on observation status, including the right to expedited review;

d. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to review all coverage decisions for

the named plaintiffs and class members involving Part B coverage for beneficiaries on observation status, to determine whether observation status required each beneficiary to spend more money than would have been required had she been formally admitted as an inpatient and covered under Part A, and to refund the difference to the beneficiary; and

e. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to review all coverage decisions for the named plaintiffs and class members of post-hospitalization SNF care, to determine whether placement on observation status precluded them from obtaining Part A coverage of SNF care to which they would have otherwise been entitled, and to reimburse them for any amounts that they paid for post-hospitalization care.

Plaintiffs pray in addition:

5. For costs of the suit herein.

6. For reasonable attorneys' fees and expenses pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412.

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

DATED: November 3, 2011

Respectfully submitted,

/s/ Gill Deford

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