UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

LEE BARROWS, MICHAEL SAVAGE, ANNE PELOW, GEORGE RENSHAW, SARAH MULCAHY, SHIRLEY BURTON, and DENISE RUGMAN, on behalf of themselves and all others similarly situated,

Plaintiffs,

LOUIS DZIADZIA, BERNICE MORSE, LORETTA JACKSON, MARTHA LEYANNA, IRMA BECKER, and CHARLES HOLT, on behalf of themselves and all others similarly situated,

Intervenor-Plaintiffs,

DOROTHY GOODMAN, on behalf of herself and all others similarly situated,

Applicant Intervenor-Plaintiff,

v.

SYLVIA MATHEWS BURWELL, Secretary of Health and Human Services,

Defendant.

Civil Action No. 3:11-cv-1703-MPS

COMPLAINT IN INTERVENTION

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 original seven plaintiffs filed

this proposed class action lawsuit on November 3, 2011 under the name *Bagnall et al. v. Sebelius*. Seven intervenor-plaintiffs filed a Complaint in Intervention on April 9, 2012. While the case was on appeal, one intervenor-plaintiff died without a substitution of party, leaving thirteen plaintiffs currently in the case.

2. The applicant intervenor-plaintiff, Dorothy Goodman, is a Medicare beneficiary who was placed on observation status while hospitalized, thereby depriving her of Medicare coverage of her post-hospital nursing facility care. She did not receive notice or an opportunity to appeal her classification as observation status.

3. 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.

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

5. Beneficiaries on observation status 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.

6. 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.

7. Several negative repercussions follow from the observation status classification. 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 forgo 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 states.

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

9. The lack of notice and appeal rights for Medicare beneficiaries placed on observation status violates the Due Process Clause of the Fifth Amendment.

10. On behalf of herself and the nationwide class of Medicare beneficiaries whom she represents and who are harmed by the lack of notice and appeal rights for observation status, the intervenor-plaintiff seeks declaratory, injunctive, and mandamus relief to establish notice and appeal rights for beneficiaries placed on observation status and to provide remedies to those already harmed by the lack of notice and appeal rights.

II. JURISDICTION AND VENUE

11. 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

12. Intervenor-plaintiff DOROTHY GOODMAN resides in Idaho and was 91 years old at the time of the events described. At all relevant times she was a Medicare beneficiary. She was deemed to be on observation status when she was hospitalized from January 31, 2014 to February 3, 2014.

13. Defendant SYLVIA MATHEWS BURWELL 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

14. Intervenor-plaintiff brings this action on behalf of herself 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.

15. 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, intervenor-plaintiff estimates the class to include at least tens of thousands of members.

16. 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 failing to provide or require hospitals to provide notice to beneficiaries of being placed on observation status, and failing to provide appeal rights to beneficiaries to challenge their classification as observation status, violates the Due Process Clause.

17. The claims of the named intervenor-plaintiff are typical of those of the class members in that she has been placed on observation status for at least part of her hospital stay and was not provided with notice and an opportunity to challenge her classification.

18. The named intervenor-plaintiff will fairly and adequately protect the interests of the class. She has no interest that is or may be potentially antagonistic to the interests of the class and seeks the same relief as the class members, that is, notice and appeal rights for beneficiaries placed on observation status. Moreover, intervenor-plaintiff is represented by competent counsel from two established public interest law firms, the Center for Medicare Advocacy, Inc. and Justice in Aging (formerly 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.

19. 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

20. 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.

21. 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.

22. 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.

23. 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).

24. 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.

25. 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>

26. 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.

27. 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.

28. 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.

29. 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 $150 in 2015 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 $1,460 in 2015.

30. 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.

31. 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**

32. 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."

33. 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.

34. 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.

35. 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.

36. 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).

37. Since the original case was filed, CMS has modified its policies on hospital admissions. In August 2013, the agency issued the 2014 Inpatient Prospective Payment System Final Rule, CMS-1599-F, which became effective on October 1, 2013. 78 F.R. 50496 (Aug. 19, 2013). The final rule, *inter alia*, created a new standard, known as the "two-midnight rule," to establish the medical necessity (and thus coverage) of Part A inpatient hospital admissions.

38. Under this rule, when a patient enters a hospital and the physician expects to keep the patient in the hospital for a period of time that does not cross two midnights, "the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used a bed." 42 C.F.R. § 412.3(d)(1). Conversely, "[s]urgical procedures, diagnostic tests, and other treatment are generally appropriate for inpatient admission and inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights." *Id*. The agency specifies that "the expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event," and those factors must be documented in the medical record. *Id*.

39. The two-midnight rule pertains only to CMS's view of the propriety of inpatient admissions. It does not change the requirement that beneficiaries must have been hospitalized as an inpatient for at least three consecutive days, not including the day of discharge, to be eligible for coverage of their post-hospital SNF care.

40. CMS has explained that when deciding whether a beneficiary will meet the two-midnight "benchmark," a physician may consider total time spent receiving services in the hospital, including time spent in observation status and the emergency room. However, the inpatient admission for the beneficiary does not begin until formal admission through a doctor's inpatient order occurs. For the beneficiary, inpatient status is only prospective, starting from the time of the formal admission order.

41. CMS specified in the final rule that use of an intensive care unit (ICU), by itself, does not justify inpatient admission. There must be an expectation of a two-midnight stay.

42. CMS also explained that in selecting hospital admission claims for medical review or audit, its contractors will presume that claims showing two or more midnights *after* formal inpatient admission begins are appropriate for inpatient admission. It will not focus on those claims for audits. Its contractors will still review shorter inpatient stays.

43. After much protest from hospitals, CMS and then Congress delayed the start of post-payment reviews by Medicare's Recovery Audit Contractors (RACs) of hospital admissions under the two-midnight rule through March 31, 2015. In anticipation of further Congressional action, CMS announced on April 1, 2015 that it would delay post-payment reviews again through April 30, 2015. However, the rule has already been in effect through the agency's "probe and educate" program, under which Medicare Administrative Contractors conduct pre-payment medical reviews of a sample of each hospital's Medicare Part A inpatient claims. If a hospital is found to be out of compliance with the two-midnight rule during the probe and educate period, educational

outreach and additional reviews will occur.

44. On information and belief, many hospitals are now using both the two-midnight rule and commercial screening tools to determine beneficiaries' classification.

45. On information and belief, the two-midnight rule has caused hospitals to admit fewer patients as inpatients and place more on observation status.

D. Absence of Procedural Rights in the Observation Status Context

46. 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.

47. 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.

48. 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.

49. Beneficiaries with legal counsel or advice have sometimes managed to submit appeals of their hospital classification and deprivation of post-hospital care into Medicare's standard (non-expedited) administrative appeal system. They often receive correspondence from various levels of administrative adjudicators stating that they cannot appeal the issue, or they simply hit dead-ends.

50. Recently, beneficiaries with legal assistance who have reached the Medicare Appeals Council, the highest level of administrative review, have received decisions stating that under policies announced first in CMS Ruling 1455-R, 78 F.R. 16632 (Mar. 18, 2013), and then in the 2014 Inpatient Prospective Payment System Final Rule, beneficiaries cannot appeal the classification of their hospital stay. The CMS policies relied on by the Appeals Council to state that administrative adjudicators cannot alter the classification of a hospitalization at the request of a *beneficiary*, actually address limits on *hospitals'* appeals for payment under Medicare Part B when a claim is denied under Part A.

E. <u>Increasing Use of Observation Status</u>

51. 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 over seven 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).

52. When the case was filed, if a beneficiary was admitted but that admission was later found to be improper, the hospital was required to refund the Part A payment to Medicare but could not rebill under Part B. Consequently, hospitals had an incentive to place patients on observation status because that placement at least ensured 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.

53. Since the case was filed, CMS has modified its policies regarding rebilling under Part B when a hospital claim is denied under Part A. With CMS Ruling 1455-R and then the 2014 Inpatient Prospective Payment System Final Rule, CMS has allowed hospitals to rebill to Part B certain claims that have been denied under Part A. However CMS imposes several conditions to this rebilling that strictly limit hospitals' ability to make use of it. Most importantly, there is a one-year time limit from the date of service for hospitals to rebill a claim, despite the fact that most RAC Part A denials are issued more than one year after the date of service of the claim – often several years later.

54. 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.

55. 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."

56. 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.

57. A 2012 study by researchers at Brown University found that the ratio of observation stays to inpatient admissions increased 34%, from an average of 86.9 observation stay events per 1,000 inpatient admissions per month in 2007 to 116.6 in 2009. The study also identified 814,692 hospital observation stays involving 742,888 unique fee-for-service beneficiaries in 2007, compared with 1,019,881 observation stays for 918,180 beneficiaries in 2009—increases of 25% and 24%, respectively.

58. Although some discrepancies exist among the various sets of statistics, 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

59. 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.

60. 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.

61. 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 forgoing that care and possibly returning home with

no follow-up care at all.

62. 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.

63. 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

Intervenor-Plaintiff Dorothy Goodman

64. During the period at issue, Dorothy Goodman was 91 years old and a resident of Idaho. Her underlying medical condition included severe aortic stenosis (narrowing of the heart's aortic valve), mild congestive heart failure, hypothyroidism, memory loss, and a history of deep vein thrombosis (DVT). She was on anticoagulation medication (Coumadin), putting her at risk for dangerous bleeding.

65. From January 31, 2014 to February 3, 2014, Mrs. Goodman was hospitalized at Clearwater Valley Hospital. The morning of January 31 she had slipped out of her wheelchair at her assisted living facility, hit her head, and was unable to stand up because of pain. She reported her pain level to ambulance personnel as "10" on the pain scale of 0 to 10. Mrs. Goodman was transported to the emergency room and was

diagnosed with bilateral pubic rami (pelvic) fractures. Her hemoglobin and hematocrit (red blood cell) levels were found to be low, which could indicate long-term or short-term blood loss.

66. She was admitted as an inpatient to the hospital by the emergency room doctor who had examined her. The doctor's dictated record of January 31, 2014 states "The patient will be admitted. She will need long-term care and physical therapy, and we will need to follow her hematocrit. I believe this patient does qualify for an inpatient stay. She will be here clearly at least 2 or 3 days as she is slowly mobilized."

67. The doctor also signed an "Admission Order & Certification" on January 31, on which he checked a box marked "Admit to Inpatient," and also checked a box marked "I certify that services for an estimated two midnights[] or longer are medically necessary for this patient in accordance with applicable regulations" (footnote omitted).

68. On January 31, 2014, Mrs. Goodman also received and signed a notice titled "An Important Message from Medicare About Your Rights," explaining her rights "as a hospital inpatient."

69. Also on January 31, a fax was sent from Clearwater Valley Hospital to Executive Health Resources (EHR) for "Admission Review" for Mrs. Goodman. According to its website, EHR is "the leading provider of medical necessity compliance solutions to more than 2,400 hospitals and health systems across the country." Its website states that "EHR's Real-time Medicare & Medicaid Medical Necessity Certification and Clinical Compliance Management solution is delivered through expertly trained Physician Advisors. EHR Physician Advisor teams, trained in Medicare and Medicaid rules and regulations pertaining to observation and inpatient status, provide the

required secondary, concurrent physician review of Medicare/Medicaid observation status cases and inpatient admissions that do not meet case management's medical necessity screening criteria."

70. A client testimonial on the EHR website states in part, "EHR has been our most important defense against the RACs."

71. On January 31, 2014, a "Physician Advisor" employed by EHR, who had never seen or examined Mrs. Goodman, issued an "EHR Medical Necessity Recommendation." The Physician Advisor wrote a summary of Mrs. Goodman's medical condition and concluded that "[o]bservation services are appropriate."

72. Also on January 31, a nurse employed by EHR, who had never seen or examined Mrs. Goodman, performed an "InterQual® Review Summary" of Mrs. Goodman's inpatient admission. InterQual is one of the commercial screening guides referred to in paragraph 35, *supra*. The report concluded, "CRITERIA NOT MET." It listed her expected length of stay as "<2MN," which on information and belief means less than two midnights. Under "Reasons" it stated "Criteria issue – No criteria to cover indication/level/diagnosis/procedure." It also listed what appear to be various medical criteria with check marks next to them, for example, "Fracture of femur, hip, or pelvis and not a surgical candidate," and "DVT prophylaxis or patient ambulatory."

73. During her hospitalization, Mrs. Goodman was still in severe pain and resistant to moving at all. Because she was allergic to a number of pain medications, options for treating her uncontrolled pain were limited. An "Inpatient Progress Note" dated February 1, 2014 dictated by Dr. Kimberly Campbell, who treated Mrs. Goodman in the hospital, notes that she said it was "very, very painful for her to get up and walk."

The farthest she could walk with services from physical therapy was five feet, and the therapist noted to the doctor that she was concerned for Mrs. Goodman's safety due to impaired decision-making. Dr. Campbell noted that "she will need to be here several days working on physical therapy, mobility, and pain control."

74. During the hospitalization Mrs. Goodman's hemoglobin and hematocrit levels were also carefully monitored. Dr. Campbell also ordered daily blood clotting tests (INRs), and Mrs. Goodman was monitored for bleeding, a risk of her anticoagulation medication and recent fall.

75. On February 1, a second nurse employed by EHR, who had never seen or examined Mrs. Goodman, performed an "InterQual® Review Summary" of Mrs. Goodman's status. The report concluded, "CRITERIA NOT MET," apparently for classification as observation status.

76. On February 2, 2014 an "Inpatient Progress Note," dictated by Dr. Campbell, stated that Mrs. Goodman was only not in pain "when she is not moving, but this is obviously not good for her." She was resisting taking pain medication. Dr. Campbell encouraged her to move and not to remain lying down or immobile for long periods of time, which can increase the risk for pneumonia. Dr. Campbell also changed the prescription for Mrs. Goodman's oral pain medication (tramadol) from "as needed" to scheduled every six hours, which appeared to help her sit up for longer periods of time.

77. Also on February 2, the hospital changed Mrs. Goodman's status from inpatient to observation. The medical record states, "Change status to observation, VORB [verbal order read back] Dr. Campbell/K. Phelps RN," indicating that a nurse received and documented the order from Dr. Campbell. The verbal order was

authenticated by signature on February 19, 2014. The change in status was in response to EHR's recommendation of January 31.

78. Mrs. Goodman was not notified of her switch from inpatient to observation status while she was in the hospital.

79. Later on February 2, a second Physician Advisor employed by EHR who had never seen or examined Mrs. Goodman, issued an "EHR Medical Necessity Recommendation." This Physician Advisor wrote that Mrs. Goodman "was not having much pain when she didn't move and was taking pain medications only very rarely, and no longer required IV pain medications….Services in a non-acute setting are appropriate on 02/02/2014 for this 91 year-old woman as she is hemodynamically stable, requires no IV pain medication, and her anticoagulation is therapeutic. The plan of care includes tramadol 50 mg every 4 hours as needed, physical therapy, and anticoagulation management."

80. This second Physician Advisor missed several important facts, including that Mrs. Goodman's remaining free from pain when she did not move was, in fact, a problem; that she was actually resisting taking pain medication, that she had never been given IV pain medications, and that her treating doctor had increased her dosage of tramadol from "as needed" to scheduled. He concluded that "this patient is not appropriate for inpatient or observation services," recommending that she be treated in a "non-acute setting," in other words, not in a hospital.

81. Later on February 2, a third nurse employed by EHR, who had never seen or examined Mrs. Goodman, performed an "InterQual® Review Summary" of Mrs. Goodman's status. The report concluded, "CRITERIA NOT MET," apparently for

inpatient admission, although at this point Mrs. Goodman had been switched by the hospital to observation status.

82. Mrs. Goodman received skilled physical therapy services at the hospital, but her pain remained severe. On the discharge summary, Dr. Campbell wrote that Mrs. Goodman was able to do "very limited motion" with physical therapy "and was felt not to be safe to go back to [her assisted living facility] secondary to her pain and her high needs." She was transferred on February 3, 2014 to a skilled nursing facility (SNF) for rehabilitation, including physical and occupational therapy, to prepare her to return to her assisted living facility.

83. Later on February 3, a third Physician Advisor employed by EHR who had never seen or examined Mrs. Goodman, issued an "EHR Post Discharge Medical Necessity Recommendation," which stated that "neither inpatient admission nor observation services can be supported." This Physician Advisor again reviewed Mrs. Goodman's medical condition and hospitalization, noting that she had been admitted as an inpatient. The Physician Advisor wrote that "[t]he patient was mobilized with Physical Therapy and pain was managed with minimal analgesic use." She noted the discharge to a skilled nursing facility. The report concluded, "The recommendation for this patient is Outpatient. Although documentation in the medical record supports a clinical recommendation for inpatient or observation services, all regulatory requirements have not been met for this patient." The report does not specify which "regulatory requirements" were not met.

84. Because Mrs. Goodman was categorized by the hospital as an inpatient for two days, and as an outpatient for one day, she did not have a three-day inpatient hospital

stay that would have made her eligible for Medicare coverage of her post-hospital SNF care. She was thus responsible for the cost of that care, for which she paid approximately $20,000.

85. Mrs. Goodman's son, Gary Goodman, to whom she has granted power of attorney, assisted Mrs. Goodman with paperwork and other matters when she was admitted to the SNF. On the second day of his mother's admission to the facility, Mr. Goodman was told that Medicare would not cover her stay because she had been placed on observation status at the hospital. Mr. Goodman called the hospital to ask them to review and change his mother's classification. The hospital told him that they generally cannot change a patient's status once she is discharged.

86. After conducting on-line research about how to address an observation status classification, Mr. Goodman requested that the SNF submit a "demand bill" to Medicare for his mother's services in early February 2014, so that she could receive a Medicare Summary Notice with a denial of services that could be appealed. The facility was apparently confused about how to submit such a bill, and did not successfully act on his request until May 2014, at which point he received a written "Advance Beneficiary Notice of Noncoverage" from the facility dated May 5, 2014, stating that Medicare would not cover Ms. Goodman's care because she "[d]id not receive 3 night qualifying stay."

87. In March 2014 Mr. Goodman obtained a letter from his mother's primary care physician, Dr. Phillip Peterson, which stated that although he was "not the person primarily responsible for that hospital stay and did not sign orders during her hospital stay….[i]t is my opinion that this 92-year-old woman with fall and pelvic fracture was appropriate for inpatient admission. That opinion is my personal observation."

88. Soon after his call to the hospital, Mr. Goodman drove 80 miles to his mother's Congressman's office to request assistance. The office of Representative Raul Labrador referred the matter to Qualis, which was the Medicare QIO (a contractor handling both expedited appeals and quality-of-care complaints) for Mrs. Goodman's region.

89. Five months later, on July 22, 2014, Qualis issued a letter in response to Mr. Goodman's inquiry. Qualis treated Mr. Goodman's objection to his mother's hospital status as a quality-of-care complaint. A QIO's response to a quality-of-care complaint is not reviewable by Medicare's administrative appeal system.

90. The Qualis letter noted the "somewhat confusing" medical record "given the varying opinions among the providers of care and that of the three physician advisors who were asked to render medical necessity determinations." The letter went on to state: "Based on the peer review performed by Qualis Health, we agree that your mother ultimately did not qualify for inpatient status based on not meeting the required criteria. Medicare follows medical necessity guidelines for a patient's severity of illness and intensity of service that dictate which patient stays should be classified as inpatient admissions as opposed to outpatient admissions. Doctors and hospitals have to follow these guidelines and show medical necessity in order for Medicare to pay for services….[Y]our mother did not meet the Medicare criteria for inpatient status."

91. The Qualis letter found that the hospital had not appropriately informed Mrs. Goodman of her change in status, which was a "quality issue." It stated that it would request that the hospital participate in a quality improvement initiative to address the issue of delayed notification.

92. The letter stated that Qualis had "no authority" to address the impact of the hospital classification on Mrs. Goodman's financial liability, and recommended that Mr. Goodman call 1-800-Medicare to request contact information for Medicare's fiscal intermediary.

93. Mr. Goodman also continued to correspond with the hospital about what had happened to his mother. A letter dated November 24, 2014 from the hospital's chief administrative officer attempted to explain the confusion about Mrs. Goodman's status, but made no offer to alter or change it. It stated: "As you know your mother was admitted as an inpatient on 1/31/14. Our utilization review process (EHR) suggests she did not meet inpatient criteria and should be placed on observation status. Our physician did not change the order at that time and your mother remained an inpatient. The next day we submitted it for review to EHR again. Because she was still in inpatient status they stated that could [sic] not recommend either inpatient or observation, even though documentation in the medical record supports a clinical recommendation, since they had not seen a new order for observation status. It was at that point we changed your mother's status to observation. We gave her the required notification paperwork making her aware of the change at that time. The regulatory requirement EHR refers to is the observation order that had not been placed at the time of Dr. Moldovanyi's [the third EHR Physician Advisor's] review."

94. Mr. Goodman also consulted with Idaho's Senior Health Insurance Program (a federally-funded insurance counseling service for Medicare beneficiaries, available in every state), CMS's Regional Office in Seattle, and Idaho's state insurance

agency. None was able to provide him with a clear method of addressing or challenging his mother's hospital classification.

95. After many months of research and inquiries, Mr. Goodman eventually submitted appeals to Medicare on behalf of his mother using the "Medicare Redetermination Request Form." A September 2014 letter from CMS's Regional Office in Seattle to Congressman Labrador suggested that Mr. Goodman use those forms. He submitted appeals about his mother's hospitalization and denial of coverage for SNF care around September 2014.

96. Mr. Goodman received a redetermination decision for the SNF appeal dated October 16, 2014. The decision stated that Medicare cannot cover the nursing facility services at issue because Mrs. Goodman lacked a qualifying inpatient hospital admission. The decision also notes that "the inpatient hospital did not notify beneficiary timely of the change in the patient's status from inpatient to outpatient. Please note that this determination would not affect the qualifying criteria for SNF benefits."

97. Mr. Goodman received a redetermination decision for the hospital appeal dated October 24, 2014. The Medicare appeals contractor apparently thought the appeal had to do with a coinsurance payment. It stated that "the amount in question is for coinsurance. This is your share of the cost for these services. Since this amount is your share, no further payment can be made. Please refer to the Medicare and You Handbook for further details on amounts you may owe."

98. Mr. Goodman timely appealed the redetermination of his mother's SNF claim to the reconsideration level, where it is pending.

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

99. Intervenor-plaintiff suffers irreparable injury by reason of defendants' actions complained of herein. The intervenor has been deprived of an opportunity to challenge her classification as observation status while hospitalized, and thus forced to pay for her post-hospital SNF care. She did not receive adequate and timely notification of her status, nor does she have right to challenge that status, thus depriving her of administrative review of her placement in observation status.

100. Intervenor-plaintiff has no adequate remedy at law. Only the declaratory, injunctive, and mandamus relief that this Court can provide will fully redress the wrongs done to intervenor.

101. Intervenor-plaintiff has 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 intervenors seek.

VIII. FIRST CAUSE OF ACTION: VIOLATION OF RIGHT TO NOTIFICATION GUARANTEED BY THE DUE PROCESS CLAUSE

102. 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 Due Process Clause of the Fifth Amendment.

IX. SECOND CAUSE OF ACTION: VIOLATION OF THE RIGHT TO ADMINISTRATIVE REVIEW GUARANTEED BY THE DUE PROCESS CLAUSE

103. 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 Due Process Clause of the Fifth Amendment.

X. PRAYER FOR RELIEF

Wherefore, Intervenor-Plaintiff respectfully prays 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 failure to provide beneficiaries with notice and an opportunity to challenge their placement on observation status, including on an expedited basis, violates the Due Process Clause of the Fifth Amendment.

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

a. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to provide adequate written notification, or to ensure that adequate 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;

b. 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;

c. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to provide an opportunity for the named plaintiffs and class members to challenge their classification as observation status, and, if it is found that inpatient admission was appropriate, adjust the Medicare coverage of each beneficiary's hospitalization and post-hospital SNF care accordingly.

Intervenor-plaintiff prays 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: May 11, 2015

Respectfully submitted,

/s/ Gill Deford

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CERTIFICATE OF SERVICE

I hereby certify that on May 11, 2015, a copy of the foregoing Complaint in Intervention was filed electronically and served by mail on anyone unable to accept the electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail as indicated on the Notice of Electronic Filing. Parties may access this filing through the Court's CM/ECF System.

/s/ Gill Deford
Gill Deford
Center for Medicare Advocacy, Inc.