UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASANTE ROUGE VALLEY MEDICAL CENTER ASANTE THREE RIVERS MEDICAL CENTER, ASANTE ASHLAND COMMUNITY HOSPITAL, LONGMONT UNITED HOSPITAL, DENVER HEALTH, INDIAN RIVER MEMORIAL HOSPITAL, HAMILTON MEDICAL CENTER, THOREK MEMORIAL HOSPITAL D/B/A BLESSING HOSPITAL, DAUTERIVE HOSPITAL, THIBODAUX REGIONAL MEDICAL CENTER, ABBEVILLE GENERAL HOSPITAL, IBERIA MEDICAL CENTER, LAKE CHARLES MEMORIAL HOSPITAL, WINN PARISH MEDICAL CENTER, AVOYELLES HOSPITAL, OAKDALE COMMUNITY HOSPITAL, HEART HOSPITAL OF LAFAYETTE, LAKELAND HOSPITAL MEDICAL CENTER-SAINT JOSEPH, OAKLAWN HOSPITAL, PEMISCOT MEMORIAL HEALTH CENTER, THE NEBRASKA MEDICAL CENTER,	)	Case No. 16-0032

SALEM HOSPITAL,

UNITED REGIONAL HEALTH CARE D/B/A UNITED REGIONAL ELEVENTH STREET CAMPUS,

CHEYENNE REGIONAL MEDICAL CENTER

AVERA SACRED HEART HOSPITAL,

AVERA QUEEN OF PEACE HOSPITAL,

AVERA ST LUKE'S HOSPITAL,

AVERA ST. MARY'S HOSPITAL,

AVERA MCKENNAN HOSPITAL,

AVERA HEART HOSPITAL OF SOUTH DAKOTA,

JOHN C. LINCOLN HOSPITAL – NORTH MOUNTAIN D/B/A HONORHEALTH JOHN C. LINCOLN MEDICAL CENTER,

JOHN C. LINCOLN HOSPITAL-DEER VALLEY D/B/A HONORHEALTH DEER VALLEY MEDICAL CENTER,

SARITORI MEMORIAL HOSPITAL,

COVENANT MEDICAL CENTER,

ST. FRANCIS HOSPITAL,

WHEATON FRANCISCAN HEALTH CARE ALL SAINTS,

WHEATON FRANCISCAN INC.,

WHEATON HEALTHCARE FRANKLIN,

MIDWEST ORTHOPEDIC SPECIALTY HOSPITAL,

SCOTTSDALE HEALTHCARE OSBORNE MEDICAL CENTER,

SCOTTSDALE HEALTHCARE SHEA MEDICAL CENTER,

SCOTTSDALE HEALTHCARE THOMPSON PEAK MEDICAL CENTER D/B/A HONORHEALTH SCOTTSDALE THOMPSON PEAK MEDICAL CENTER,

FORSYTH MEDICAL CENTER D/B/A NOVANT HEALTH FORSYTH MEDICAL CENTER,

ROWAN MEDICAL CENTER D/B/A NOVANT HEALTH ROWAN MEDICAL CENTER,

FRANKLIN MEDICAL CENTER D/B/A NOVANT HEALTH FRANKLIN MEDICAL CENTER

PRESBYTERIAN MEDICAL CENTER D/B/A NOVANT HEALTH PRESBYTERIAN MEDICAL CENTER,

THOMASVILLE MEDICAL CENTER D/B/A NOVANT HEALTH THOMASVILLE MEDICAL CENTER,

MEDICAL PARK HOSPITAL,

CHARLOTTE ORTHOPEDIC HOSPITAL D/B/A NOVANT HEALTH CHARLOTTE ORTHOPAEDIC HOSPITAL,

BRUNSWICK MEDICAL CENTER,

MATTHEWS MEDICAL CENTER D/B/A NOVANT HEALTH MATTHEWS MEDICAL CENTER,

HUNTERSVILLE MEDICAL CENTER D/B/A NOVANT HEALTH HUNTERSVILLE MEDICAL CENTER,

GAFFNEY MEDICAL CENTER D/B/A MARY BLACK HEALTH SYSTEM – GAFFNEY,

LAWRENCE AND MEMORIAL HOSPITAL, and

THE WESTERLY HOSPITAL,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

COMPLAINT FOR JUDICIAL REVIEW OF FINAL ADVERSE AGENCY DECISIONS ON MEDICARE REIMBURSEMENT

Plaintiffs Asante Rouge Valley Medical Center, Asante Three Rivers Medical Center, Asante Ashland Community Hospital, Longmont United Hospital, Denver Health, Indian River Memorial Hospital, Hamilton Medical Center, Thorek Memorial Hospital d/b/a Blessing Hospital, Dauterive Hospital, Thibodaux Regional Medical Center, Abbeville General Hospital, Iberia Medical Center, Lake Charles Memorial Hospital, Winn Parish Medical Center, Avoyelles Hospital, Oakdale Community Hospital, Heart Hospital of Lafayette, Lakeland Hospital Medical Center-Saint Joseph, Oaklawn Hospital, Pemiscot Memorial Health Center, The Nebraska Medical Center, Salem Hospital, United Regional Health Care d/b/a United Regional Eleventh Street Campus, Cheyenne Regional Medical Center, Avera Sacred Heart Hospital, Avera Queen of Peace Hospital, Avera St Luke's Hospital, Avera St. Mary's Hospital, Avera McKennan Hospital, Avera Heart Hospital of South Dakota, John C. Lincoln Hospital – North Mountain d/b/a HonorHealth John C. Lincoln Medical Center, John C. Lincoln Hospital-Deer Valley d/b/a

HonorHealth Deer Valley Medical Center, Saritori Memorial Hospital, Covenant Medical Center, St. Francis Hospital, Wheaton Franciscan Health Care All Saints, Wheaton Franciscan Inc., Wheaton Healthcare Franklin, Midwest Orthopedic Specialty Hospital, Scottsdale Healthcare Osborne Medical Center, Scottsdale Healthcare Shea Medical Center, Scottsdale Healthcare Thompson Peak Medical Center d/b/a HonorHealth Scottsdale Thompson Peak Medical Center, Forsyth Medical Center d/b/a Novant Health Forsyth Medical Center, Rowan Medical Center d/b/a Novant Health Rowan Medical Center, Franklin Medical Center d/b/a Novant Health Franklin Medical Center, Presbyterian Medical Center d/b/a Novant Health Presbyterian Medical Center, Thomasville Medical Center d/b/a Novant Health Thomasville Medical Center, Medical Park Hospital, Charlotte Orthopedic Hospital d/b/a Novant Health Charlotte Orthopaedic Hospital, Brunswick Medical Center, Matthews Medical Center d/b/a Novant Health Matthews Medical Center, Huntersville Medical Center d/b/a Novant Health Huntersville Medical Center, Gaffney Medical Center d/b/a Mary Black Health System – Gaffney, Lawrence and Memorial Hospital, and The Westerly Hospital (collectively, the "Hospitals") by and through their undersigned attorney, bring this action against defendant Sylvia Mathews Burwell in her official capacity as Secretary of Health and Human Services (the "Defendant"), and state as follows:

JURISDICTION AND VENUE

1. This is a civil action arising under Title XVIII of the Social Security Act, as amended (42 U.S.C. §§ 1395 *et seq*.) (hereinafter referred to as the "Medicare Act" or the "Act"), to obtain judicial review of a final adverse agency decision of the Secretary of the United States Department of Health and Human Services.

2. This Court has jurisdiction under 42 U.S.C. § 1395oo(f).

3. Venue lies in this judicial district under 42 U.S.C. § 1395oo(f) and 28 U.S.C. § 1391.

PARTIES

1. Plaintiff Asante Rouge Valley Medical Center (Medicare provider number 38-0018) is located in Medford, OR and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

2. Plaintiff Asante Three Rivers Medical Center (Medicare provider number 38-0002) is located in Grants Pass, OR and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

3. Plaintiff Asante Ashland Community Hospital (Medicare provider number 38-0005) is located in Ashland, OR and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

4. Plaintiff Longmont United Hospital (Medicare provider number 06-0003) is located in Longmont, CO and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

5. Plaintiff Denver Health (Medicare provider number 06-0011) is located in Denver, CO and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

6. Plaintiff Indian River Memorial Hospital (Medicare provider number 10-0105) is located in Vero Beach, FL and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

7. Plaintiff Hamilton Medical Center (Medicare provider number 11-0001) is located in Dalton, GA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

8. Plaintiff Thorek Memorial Hospital d/b/a Blessing Hospital (Medicare provider number 14-0015) is located in Quincy, IL and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

9. Plaintiff Dauterive Hospital (Medicare provider number 19-0003) is located in New Iberia, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

10. Plaintiff Thibodaux Regional Medical Center (Medicare provider number 19-0004) is located in Thibodaux, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

11. Plaintiff Abbeville General Hospital (Medicare provider number 19-0034) is located in Abbeville, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

12. Plaintiff Iberia Medical Center (Medicare provider number 19-0054) is located in Iberia, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

13. Plaintiff Lake Charles Memorial Hospital (Medicare provider number 19-0060) is located in Lake Charles, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

14. Plaintiff Winn Parish Medical Center (Medicare provider number 19-0090) is located in Winnfield, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

15. Plaintiff Avoyelles Hospital (Medicare provider number 19-0099) is located in Marksville, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

16. Plaintiff Oakdale Community Hospital (Medicare provider number 19-0106) is located in Oakdale, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

17. Plaintiff Heart Hospital of Lafayette (Medicare provider number 19-0263) is located in Lafayette, LA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

18. Plaintiff Lakeland Hospital Medical Center-Saint Joseph (Medicare provider number 23-0021) is located in Saint Joseph, MI and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

19. Plaintiff Oaklawn Hospital (Medicare provider number 23-0217) is located in Marshall, MI and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

20. Plaintiff Pemiscot Memorial Health Center (Medicare provider number 26-0070) is located in Hayti, MO and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

21. Plaintiff The Nebraska Medical Center (Medicare provider number 28-0013) is located in Omaha, NE and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

22. Plaintiff Salem Hospital (Medicare provider number 38-0051) is located in Salem, OR and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

23. Plaintiff United Regional Health Care d/b/a United Regional Eleventh Street Campus (Medicare provider number 45-0010) is located in Witchita Falls, TX and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

24. Plaintiff Cheyenne Regional Medical Center (Medicare provider number 53-0014) is located in Cheyenne, WY and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

25. Plaintiff Avera Sacred Heart Hospital (Medicare provider number 43-0012) is located in Yankton, SD and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

26. Plaintiff Avera Queen of Peace Hospital (Medicare provider number 43-0013) is located in Mitchell, SD and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

27. Plaintiff Avera St Luke's Hospital (Medicare provider number 43-0014) is located in Aberdeen, SD and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

28. Plaintiff Avera St. Mary's Hospital (Medicare provider number 43-0015) is located in Pierre, SD and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

29. Plaintiff Avera McKennan Hospital (Medicare provider number 43-0016) is located in Sioux Falls, SD and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

30. Plaintiff Avera Heart Hospital of South Dakota (Medicare provider number 43-0095) is located in Sioux Falls, SD and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

31. Plaintiff John C. Lincoln Hospital – North Mountain d/b/a HonorHealth John C. Lincoln Medical Center (Medicare provider number 03-0014) is located in Phoenix, AZ and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

32. Plaintiff John C. Lincoln Hospital-Deer Valley d/b/a HonorHealth Deer Valley Medical Center (Medicare provider number 03-0092) is located in Phoenix, AZ and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

33. Plaintiff Saritori Memorial Hospital (Medicare provider number 16-0040) is located in Cedar Falls, IA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

34. Plaintiff Covenant Medical Center (Medicare provider number 16-0067) is located in Waterloo, IA and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

35. Plaintiff St. Francis Hospital (Medicare provider number 52-0078) is located in Milwaukee, WI and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

36. Plaintiff Wheaton Franciscan Health Care All Saints (Medicare provider number 52-0096) is located in Racine, WI and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

37. Plaintiff Wheaton Franciscan Inc. (Medicare provider number 52-0136) is located in Milwaukee, WI and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

38. Plaintiff Wheaton Healthcare Franklin (Medicare provider number 52-0204) is located in Franklin, WI and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

39. Plaintiff Midwest Orthopedic Specialty Hospital (Medicare provider number 52-0205) is located in Franklin, WI and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

40. Plaintiff Scottsdale Healthcare Osborne Medical Center (Medicare provider number 03-0038) is located in Scottsdale, AZ and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

41. Plaintiff Scottsdale Healthcare Shea Medical Center (Medicare provider number 03-0087) is located in Scottsdale, AZ and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

42. Plaintiff Scottsdale Healthcare Thompson Peak d/b/a HonorHealth Scottsdale Thompson Peak Medical Center (Medicare provider number 03-0123) is located in Phoenix, AZ

and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

43. Plaintiff Forsyth Medical Center d/b/a Novant Health Forsyth Medical Center (Medicare provider number 34-0014) is located in Louisburg, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

44. Plaintiff Rowan Medical Center d/b/a Novant Health Rowan Medical Center (Medicare provider number 34-0015) is located in Salisbury, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

45. Plaintiff Franklin Medical Center d/b/a Novant Health Franklin Medical Center (Medicare provider number 34-0036) is located in Louisburg, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

46. Plaintiff Presbyterian Medical Center d/b/a Novant Health Presbyterian Medical Center (Medicare provider number 34-0053) is located in Charlotte, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

47. Plaintiff Thomasville Medical Center d/b/a Novant Health Thomasville Medical Center (Medicare provider number 34-0085) is located in Thomasville, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

48. Plaintiff Medical Park Hospital (Medicare provider number 34-0148) is located in Winston-Salem, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

49. Plaintiff Charlotte Orthopedic Hospital d/b/a Novant Health Charlotte Orthopaedic Hospital (Medicare provider number 34-0153) is located in Charlotte, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

50. Plaintiff Brunswick Medical Center (Medicare provider number 34-0158) is located in Bolivia, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

51. Plaintiff Matthews Medical Center d/b/a Novant Health Matthews Medical Center (Medicare provider number 34-0171) is located in Matthews, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

52. Plaintiff Huntersville Medical Center d/b/a Novant Health Huntersville Medical Center (Medicare provider number 34-0183) is located in Huntersville, NC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

53. Plaintiff Gaffney Medical Center d/b/a Mary Black Health System – Gaffney (Medicare provider number 42-0043) is located in Gaffney, SC and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

54. Plaintiff Lawrence and Memorial Hospital (Medicare provider number 07-0007) is located in New London, CT and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

55. Plaintiff The Westerly Hospital (Medicare provider number 41-0013) is located in Westerly, RI and furnishes inpatient and outpatient hospital services to, *inter alia*, patients entitled to benefits under the Medicare program.

56. The plaintiff Hospitals were at all relevant times general acute care hospitals that participated in the Medicare and Medicaid programs.

57. Defendant Sylvia Mathews Burwell is the Secretary of Health and Human Services ("HHS"), the federal department that contains the Centers for Medicare & Medicaid Services ("CMS"). CMS is the agency within HHS that is responsible for the administration of the Medicare program.

MEDICARE PAYMENT UNDER THE INPATIENT PROSPECTIVE PAYMENT SYSTEM ("IPPS")

58. The Medicare Program establishes a system of health insurance for the aged, disabled, and individuals afflicted with end-stage renal disease. Pursuant to 42 U.S.C. § 1395cc, the Hospitals entered into written agreements with CMS to provide hospital services to eligible individuals.

59. Short term acute care hospitals, such as the plaintiff Hospitals, are paid under the inpatient prospective payment system ("IPPS"), as provided for in 42 U.S.C. § 1395ww(d).

60. Calculating prospective-payment rates begins with determining the "standardized amount," which roughly reflects the average cost incurred by hospitals nationwide for each

patient they treat and then discharge. *See* 42 U.S.C. § 1395ww(d)(2)(A)-(B); 49 *Fed. Reg*. 234, 251 (1984).

61. The standardized amount is then adjusted for each hospital to account for variances in wage-related costs nationwide and to account for different patient diagnoses:

a. To account for differences in wage-related costs, CMS divides the standardized amount into two parts (i) the standardized amount attributable to wage-related costs, and (ii) the standardized amount not attributable to wage-related costs. CMS then multiplies the standardized amount attributable to wage-related costs by a "wage index," which reflects the relationship between the local average of hospital wages and the national average of hospital wages. *See* 42 U.S.C. § 1395ww(d)(2)(H), (d)(3)(E). To arrive at the adjusted amount that takes into account wage variance considerations, CMS then adds (i) [the standardized amount multiplied by the percentage of the standardized amount not attributable to wage-related costs] to (ii) [the standardized amount multiplied by the percentage of the standardized amount attributable to wage-related costs multiplied by the wage index]. Therefore, the amount a hospital is paid is affected by how much the average of hospital wages locally is greater or less than the national average.

b. To account for hospitals that treat more costly or less costly patient diagnoses, CMS then multiplies the adjusted amount calculated above by a "DRG weight." Medicare patients are classified into different groups based on their diagnoses. Each of these "diagnosis-related groups" (DRGs) is assigned a particular "weight" representing the relationship between the cost of treating patients within that group and the average cost of treating all Medicare patients. *See* 42 U.S.C. § 1395ww(d)(4). Therefore, CMS pays hospitals different amounts based on the hospital's treatment of patients that are more or less costly to treat.

62. Short-term acute care hospitals such as the plaintiff Hospitals are paid for inpatient care rendered to Medicare recipients based on the prospectively determined per case DRG rates as described above.

63. CMS does not calculate the standardized amount from scratch each year. Instead, following Congress's directive, it calculated the standardized amount for a base year and has since carried that figure forward, updating it annually for inflation. *See* 42 U.S.C. § 1395ww(b)(3)(B)(i), (d)(2), (d)(3)(A)(iv)(II); 42 C.F.R. § 412.64(c)–(d). Unlike the standardized amount, however, the wage indexes are calculated by CMS anew each year instead of being carried forward from one year to the next.

64. Payment to providers of services is commonly carried out by Medicare fiscal intermediaries which act as agents of CMS pursuant to contracts with it. An intermediary is assigned to each hospital that participates in Medicare. Fiscal intermediaries make periodic interim payments to providers that are subject to subsequent adjustments for overpayments or underpayments. 42 U.S.C. § 1395h.

65. At the close of its fiscal year ("FY"), a hospital must submit a cost report showing both the cost incurred by it during the fiscal year and the appropriate portion of those costs to be allocated to Medicare. 42 C.F.R. §§ 413.24, 413.50. The hospital's intermediary is then required to analyze and audit the cost report and issue a Notice of Program Reimbursement ("NPR"), which informs the hospital of the final determination of its Medicare reimbursement for the cost reporting period in compliance with law.

THE MEDICARE PROVIDER REIMBURSEMENT APPEALS PROCESS

66. Section 1878(a) of the Social Security Act, 42 U.S.C. 1395oo(a), provides that, under certain circumstances, a provider of services may obtain a hearing before the Provider

Reimbursement Review Board (PRRB) if it has timely filed a cost report and received a final determination from its fiscal intermediary or the Secretary with which it is dissatisfied or the amount in controversy is $10,000 or more, and the provider files a request for a hearing within 180 days after notice of such determination was received.

67. The statute provides that a provider has the right to judicial review of any final decision of the PRRB, or of any reversal, affirmance, or modification by the Secretary (whose decisionmaking authority has been delegated to the CMS Administrator), by a civil action commenced within 60 days of the date on which notice of any final decision by the PRRB or of any reversal, affirmance, or modification by the Secretary is received. 42 U.S.C. 1395oo(f). *See also* 42 C.F.R. §§ 405.1801, 405.1877. The statute also provides, however, that a provider has the right to obtain judicial review of any action of the fiscal intermediary that involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. *Id.* *See also* 42 C.F.R. §405.1842. The right to obtain judicial review through this latter route is known as the right to expedited judicial review ("EJR").

PROCEEDINGS BELOW

68. On August 19, 2013 the Secretary published the Fiscal Year (FY) 2014 IPPS final rule (hereinafter "Final Rule") in the Federal Register. 78 *Fed. Reg*. 50496. In the Final Rule, CMS decreed that operating and capital IPPS payment rates for FY 2014 – 2018 are decreased by 0.2 percent, or $220 million in the aggregate for each year. *Id.* at 50508, 50746-47. In the Final Rule, CMS instituted what is colloquially known as the "2 Midnights" policy with respect to determinations of whether a hospital encounter is appropriately inpatient or outpatient. CMS

claims that the policy will result in increased inpatient stays (as opposed to outpatient treatments), which supposedly will increase Medicare expenditures under Part A for inpatient admissions by $220 million (net of savings for the alleged decrease in outpatient treatments) each year from FY 2014 – 2018. Because of this purported increase in the number of stays, the Final Rule reduces the reimbursement rates for inpatient admissions. Specifically, in the Final Rule, CMS asserts its claimed authority in sections 1886(d)(5)(I) and (g) of the Act (42 U.S.C. §1395ww(d)(5)(I) and (g)) to take back the supposed $220 million increase in Part A payments.

69. Within 180 days of the date of the Final Rule, the Hospitals timely filed an appeal with the PRRB. The Hospitals also requested that the PRRB grant EJR. In their appeal, the Hospitals challenged the legal sufficiency of the $220 million decrease in reimbursement, asserting that the action taken in the Final Rule is procedurally and substantively invalid.

70. In a decision dated November 5, 2015 and received by the Hospitals on November 9, 2015, the PRRB assumed jurisdiction of the appeal and granted EJR, holding that it was without authority to rule on the legal sufficiency of the Final Rule. A true and accurate copy of the PRRB's decision is attached as **Exhibit A** to this Complaint.

71. This Complaint is filed within 60 days of receipt of the PRRB's decision granting EJR.

THE 2 MIDNIGHTS POLICY

72. The Final rule purports to adopt a time-based benchmark, "2 Midnights" as to when an inpatient stay is appropriate, and states that previous guidance has also used such an approach (although framed in terms of 24 hours and not 2 midnights). CMS's decision to institute a 0.2 percent decrease in each IPPS hospital's payments is based on CMS's assumption that inpatient stays will increase as a result of the 2 Midnights Policy, which is in turn based on

an assumption as to how hospitals and CMS's contractors will react to the 2 Midnights policy; however, the policy, as set forth in the preamble and the text of the Final Rule, is confusing, ambiguous and internally inconsistent.

73. Although the Final Rule purports to adopt a time-based approach as to when an inpatient stay is appropriate, the Rule is confusing, ambiguous and internally inconsistent in this regard. First, it is far from clear whether the Rule actually adopts a time-based approach. In declaring that it is adopting a time-based approach for determining when a hospital encounter is appropriately inpatient, CMS states that, "we do not refer to 'level of care' in guidance regarding hospital inpatient admission decisions." 78 *Fed. Reg.* at 50945, 50948. The Final Rule also states that "We do not believe beneficiaries treated in an intensive care unit should be an exception to [the requirement that the physician have a reasonable expectation that the beneficiary will spend at least 2 midnights in the hospital], as our 2-midnight benchmark policy is not contingent on the level of care required or the placement of the beneficiary within the hospital." *Id*. at 50946 Elsewhere, however, the Final Rule states that the decision whether to admit a patient involves the "complex medical judgment" of the ordering physician. 78 *Fed. Reg.* at 50945, 50948, and that "we will presume that generally services spanning less than 2 midnights should have been provided on an outpatient basis, *unless there is clear physician documentation in the medical record supporting the physician's order and expectation that the beneficiary required an inpatient level of care*." *Id*. at 50977 (emphasis added). Moreover, CMS's current manual instructions provide that the decision to admit a patient involves a "complex medical judgment" that includes, among other things, consideration of "the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting." Section 10 of Chapter 1,

Medicare Benefit Policy Manual, CMS Pub. 100-02. Further, whereas CMS noted that a commenter stated that a time-based policy contradicts instructions in the Program Integrity Manual pertaining to the use of screening tools as part of the review of inpatient hospital claims, it did not respond to this comment other than to say that Medicare review contractors must abide by CMS payment policies, 78 *Fed. Reg.* at 50948, and CMS's Program Integrity Manual provides that admissions are appropriate where the beneficiary "receives services of such intensity that they can be furnished safely and effectively only on an inpatient basis," and that "[t]he reviewer shall consider, in his/her review of the medical record, any pre-existing medical problems or extenuating circumstances that make admission of the beneficiary medically necessary." Section 6.5.2 of Chapter 2, Program Integrity Manual, CMS Pub. 100-08. Other commenters suggested that evidence based guidelines offered through the Agency for Healthcare Research and Quality (AHRQ), various medical societies and commercial hospital screening guidelines could be helpful in formulating criteria to determine whether an inpatient stay is appropriate, and some commenters suggested that such sources could be used to *deem* admissions appropriate. CMS responded that the ordering physician and Medicare review contractors are permitted to take into account evidence-based guidelines and commercial utilization tools that may aid in making a determination of whether an admission was appropriate. However, commercial utilization tools such as those developed by InterQual and Milliman and others focus on intensity of service and severity of illness, rather than a time-based approach.

74. Thus, the Final Rule's statements on a time-based approach are internally inconsistent and some statements are inconsistent with the existing Manual instructions. The following issues are left open: (a) whether or how the ordering physician's perceived level of

care for a beneficiary, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting factor into the determination of whether admission was appropriate; (b) whether or how the concept of a time-based benchmark for determining the appropriateness of an inpatient admission is consistent with the policy statements in the Medicare Benefit Policy Manual as well as the review requirements of the Program Integrity Manual; (c) the weight to be given to evidence-based guidelines, including whether an admission will be deemed to be appropriate if certain guidelines are followed.

75. Because of the ambiguity of whether and to what extent the Final Rule adopts a time-based approach to the exclusion of an approach that considers the intensity of the services needed for purposes of determining whether an admission is appropriate, it cannot be predicted with any degree of certainty or reliability to what extent hospitals will consider the intensity level of services when deciding to admit or not to admit patients or the extent to which Medicare contractors will take into account the intensity level of services when determining whether to admit or deny stays .

76. Second, the Final Rule is confusing, ambiguous and internally inconsistent as to the extent a one-day stay (a stay in which the patient was not expected to, and does not, cross 2 midnights) can be appropriately inpatient.

77. As added by the Final Rule, 42 C.F.R. §412.3(e)(1) states that when a patient enters a hospital for a surgical procedure that is not included on the "inpatient only list" and the ordering physician expects to keep the patient for a period that does not cross 2 midnights, the services furnished are "generally inappropriate" for inpatient admission. The language "generally inappropriate" is the mirror image of the "generally appropriate" language elsewhere

in the same paragraph that pertains to stays that do cross 2 midnights. Thus, the language "generally inappropriate" could be read as establishing no more than a presumption that one-day stays are not appropriately inpatient, because, after all, according to CMS, the "generally appropriate" language is intended to create a presumption for stays that cross 2 midnights. However, paragraph (e)(2) of section 412.3 then states that "[i]f an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis." This language can be read to mean that, in all cases (except for ones in which a patient is to receive a procedure on the inpatient-only list) the ordering physician must have an expectation that the beneficiary will cross 2 midnights in the hospital. The preamble of the text is similarly susceptible to two interpretations. For example, the preamble of the Final Rule states that "[t]he 2-midnight benchmark, rather, provides that hospital stays expected to last less than 2 midnights are generally inappropriate for inpatient hospital admission and Part A payment absent rare and unusual circumstance to be further detailed in sub-regulatory instruction. 78 *Fed. Reg*. at 50946 (emphasis added). On the one hand, this language can be read to say that one-day stays are only presumed to be inappropriate, but on the other hand, this language may also suggest that, unless and until CMS specifies circumstances in which one-day stays will be considered appropriate all one-day stays not involving procedures on the inpatient-only list will be denied Part A payment. Other language in the preamble suggests this latter interpretation. For example, the preamble to the Final Rule states that "[f]or those hospital stays in which the physician cannot reliably predict the beneficiary to require a hospital stay greater than 2 midnights, the physician should continue to treat the beneficiary as an outpatient and then admit as an inpatient if and when additional information suggests a longer stay or the passing of

the second midnight is anticipated." 78 *Fed. Reg.* at 50945. Also, the Final Rule reminds hospitals that hospitals should have documentation of the physician's expectation that the beneficiary is expected to cross two midnights, without acknowledging that the physician may have expected the beneficiary to be in the hospital for less than two midnights. See, e.g., *id.* at 50946 ("we acknowledge that an [against medical advice] departure is usually an unexpected event and that an inpatient admission could still be appropriate provided that the medical record demonstrates a reasonable expectation of a 2-midnight stay when the admission order is written"); *id.* at 50949 ("Medicare review contractors will (a) evaluate the physician order for inpatient admission to the hospital, along with the other required elements of the physician certification, [and] (b) the medical documentation supporting the expectation that care would span at least 2 midnights . . . .").

78. The Final Rule notes that the Medicare Benefit Policy Manual (section 10 of Chapter 1) allows Part A payment for one-day stays, and states that the 2-midnight policy is simply another way to measure the 24 hours needed to show that the admission was presumptively appropriate. CMS states that:

> Our previous guidance also provided for a 24-hour benchmark, instructing physicians that, in general, beneficiaries who need to stay at the hospital less than 24 hours should be treated as outpatients, while those requiring care greater than 24 hours may usually be treated as inpatients. Our proposed 2-midnight benchmark, which we now finalize, simply modifies our previous guidance to specify that the relevant 24 hours are those encompassed by 2 midnights. While the complex medical decision is based upon an assessment of the need for continuing treatment at the hospital, the 2-midnight benchmark clarifies when beneficiaries determined to need such continuing treatment are generally appropriate for inpatient admission or outpatient care in the hospital.

78 *Fed. Reg*. at 50945. Although the Final Rule states that the 2-midnight benchmark is simply another way of measuring 24 hours ("the relevant 24 hours are those encompassed by 2

midnights"), a stay that crosses 2 midnights (and only 2 midnights) will encompass more than 24 hours and as much as 47+ hours. Thus, to the extent that stays that are expected to last 24 hours but not expected to cross 2 midnights do not qualify for Part A payment, the Final Rule represents an unexplained departure from the current Manual instructions, and the language quoted above is inaccurate. One cannot tell whether the Final Rule creates only a presumption that one-day inpatient stays are not appropriate, or whether the Final Rule means that one-day stays that do not involve procedures on the inpatient-only list will be automatically denied Part A payment, or whether the Final Rule does not intend a change in policy from the Manual instructions because it (incorrectly) equates a stay that crosses 2 midnights with a one-day stay.

79. On January 14, 2014, during a MLN Connects National Provider Call, CMS addressed the issue of whether one-day stays can receive payment under Part A. A representative of CMS stated:

> And I do just want to point out what the difference is between what we consider to be exceptions from the previous topic, which were the unforeseen circumstances. With the unforeseen circumstances, there is an expectation that the patient will require a 2-midnight stay when the inpatient order is written. With these exceptions, we are saying that an inpatient hospital admission will be appropriate even if the physician does not have an expectation that the patient may require a 2-midnight stay. So this patient could stay for either no midnights or 1 midnight, and it would still be an appropriate inpatient admission. So this includes medically necessary procedures on the inpatient-only list, and also other circumstances that will be approved by CMS and outlined in sub-regulatory guidance. You may have heard of this referred previously as one of our rare and unusual circumstances. As of today's date, we have identified one such circumstance, which is the New Onset Mechanical Ventilation. As a note, this exception does not apply to anticipated intubations that are related to minor surgical procedures or other treatments. So we are currently in – in talks with the public and also through the reviews about other exceptions that may be appropriate for an inpatient admission for these short inpatient stays, and we are inviting feedback from the public in our IPPS Admissions mailbox.

CMS did not indicate during this National Provider Call whether the *only* one-day stays (i.e., stays not lasting more than 24 hours and which were not expected by the ordering physician to last more than 24 hours) are ones in which the patient received a procedure on the "inpatient-only list" or other circumstances approved by CMS and outlined in sub-regulatory guidance.

80. The Final Rule may be intended to deny Part A payment for one-day stays (or at least create a presumption that one-day stays are not appropriate), and that even if such is not the intent of the Final Rule, the Medicare review contractors may read the Final Rule as meaning that they should deny every one-day stay that did not involve procedures on the "inpatient only" list.

81. The Final Rule creates ambiguity concerning the following issues: (a) whether one-day stays that do not involve procedures on the "inpatient-only" list can qualify for Part A payment; (b) if the answer to (a) is yes, what is the basis for the Final Rule's statement that stays that last at least 24 hours but do not cross 2 midnights are "generally inappropriate," and whether or how that position squares with the Manual provision that states that physicians should use a 24-hour benchmark; (c) if the answer to (a) is yes, but that CMS will "specify . . . potential exceptions" (in addition to those contained in the "inpatient only list") and that only one-day stays that meet such exceptions can qualify for Part A payment, whether and how that position squares with the position in the Manual that a physician should use his or her complex medical judgment, which position is adopted in the Final Rule; (d) if the answer to (a) is no, whether and how that answer squares with the stated position in the Final Rule that it is simply redefining the 24-hour period without changing the policy in the Manual; and (e) whether the distinction between a one-day stay and a stay that crosses 2 midnights is only one of audit guidelines, meaning that Medicare review contractors will be instructed that they can look behind a one-day

stay to determine if the ordering physician reasonably determined that the beneficiary expected to need hospital care for at least 24 hours but will be instructed not to audit admissions for appropriateness if the beneficiary crossed 2 midnights (in the absence of evidence that the hospital may have prolonged the stay).

82. Because of the ambiguity of whether and to what extent one-day stays that do not involve procedures on the "inpatient only" list or do not involve "rare and unusual circumstances" specified by CMS are considered appropriately inpatient under the Final Rule, it cannot be predicted to what extent hospitals will bill for such one-day stays or the extent to which Medicare contractors will allow such one-day stays.

83. Third, the Final Rule is confusing, ambiguous and internally inconsistent as to the nature of and effect of the "presumption" regarding hospital stays that cross 2 midnights. The preamble of the Final Rule states that Medicare contractors "would also adopt a presumption that a medically necessary stay surpassing 2 midnights after being admitted as an inpatient was appropriately provided as an inpatient service." However, the Final Rule is unclear as to what the nature of the presumption is, whether the presumption is rebuttable (and if so, by what standard of proof), or whether there is even a presumption in the first place. At various places language in the Final Rule supports a reading that (a) there is a presumption that an admission was appropriate where the medical record demonstrates that the ordering physician had a reasonable expectation that the patient would cross 2 midnights in the hospital; or (b) there is a presumption that that an admission was appropriate where the medical record demonstrates that the ordering physician had a reasonable expectation that the patient would cross 2 midnights in the hospital *and* the beneficiary in fact spends 2 midnights in the hospital; or (c) there is no presumption but rather an audit guideline that provides that Medicare contractors will not review

whether an admission was appropriate if the beneficiary spends at least 2 midnights in the hospital (absent gaming by the hospital and assuming that the services were reasonable and necessary).

84. As added by the Final Rule the text of 42 C.F.R. §412.3 may support choice (a) in the paragraph 41 above, as it says "Surgical 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." There is no requirement in the regulations text that, in order to be afforded the presumption of an appropriate admission, the beneficiary did in fact have a stay of at least 2 midnights. The preamble in places contains very similar language to that of § 412.3. *See 78 Fed. Reg*. at 50949. *See also 78 Fed. Reg*. at 50950 ("In other words, if it was reasonable for the physician to expect the beneficiary to require a stay lasting 2 midnights, and that expectation is documented in the medical record, inpatient admission is generally appropriate, and payment may be made under Medicare Part A").

85. However, in many places, the preamble indicates that choice (b) in paragraph 41 above is correct. Immediately following preamble language that is similar to that in the text of § 412.3, the preamble states:

> We proposed, and are now finalizing, two distinct, though related, medical review policies, a 2-midnight presumption and a 2-midnight benchmark. Under the 2-midnight presumption, inpatient hospital claims *with lengths of stay greater than 2 midnights* after the formal admission following the order will be presumed generally appropriate for Part A payment and will not be the focus of medical review efforts absent evidence of systematic gaming, abuse or delays in the provision of care in an attempt to qualify for the 2-midnight presumption . . . .

78 *Fed. Reg*. at 50949 (emphasis added). *See also 78 Fed. Reg*. at 50950 ("If the physician admits the beneficiary as an inpatient but the beneficiary is in the hospital for less than 2

midnights after the order is written, CMS and its medical review contractors will not presume that the inpatient hospital status was reasonable and necessary for payment purposes, but may instead evaluate the claim pursuant to the 2-midnight benchmark"); *id*. ("Claims in which a medically necessary inpatient stay spans at least 2 midnights after the beneficiary is formally admitted as an inpatient will be presumed appropriate for inpatient admission and inpatient hospital payment and will generally not be subject to medical review of the inpatient admission"); *id*. at 50952 ("We also are clarifying in this final rule how we will instruct contractors to review inpatient stays spanning less than 2 midnights after admission. Such claims would not be subject to the presumption that services were appropriately provided during an inpatient stay rather than an outpatient stay because the total inpatient time did not exceed 2 midnights"); *id*. at 50977 ("Under our final policy, Medicare's external review contractors will presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than one Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services. Similarly, we will presume that generally services spanning less than 2 midnights should have been provided on an outpatient basis, unless there is clear physician documentation in the medical record supporting the physician's order and expectation that the beneficiary required an inpatient level of care").

86. However, it is not clear that 42 C.F.R. §412.3 establishes any presumption as the word "presumption" appears only in the preamble to the Final Rule and not in the regulation's text (only the words "generally appropriate" and "generally inappropriate" appear in the regulations text). Because the Final Rule requires that the physician have a reasonable expectation that the beneficiary would cross two midnights, which can be determined only through an examination of the medical record, and, conversely, because the question of whether

the beneficiary spent at least 2 midnights in the hospital can be determined simply by the number of the utilization days appearing on the MedPAR file, the question is raised as to whether the Final Rule sets forth any presumption of correctness (or error) of the physician's order for admission, but instead simply creates an audit guideline by which review contractors will not review the issue of whether an inpatient stay was appropriate (as opposed to whether the underlying services were reasonable and necessary) if the beneficiary crossed 2 midnights in the hospital.

87. Hospitals are confused about what the requirements of the 2 Midnights policy are. For example, in a joint letter to CMS dated November 8, 2013, the American Hospital Association and the American Medical Association stated: "The fundamentally flawed, overly-complicated two-midnight policy does not provide the clarity needed for consistent decision-making by either providers or reviewers. . . . [M]any questions about the two-midnight policy remain unanswered. The October 1, 2013 implementation date has now passed, yet the agency has issued only minimal guidance – most of which lacks clarity and only raises new questions for both hospitals and physicians. To date, only minimal guidance and instructions have been issued, despite the agency's statements that such additional guidance would be forthcoming. We cannot support implementation of the two-midnight policy under these circumstances and without clear, detailed, and precisely written guidance for hospitals, physicians, and Medicare review contractors."

CMS'S PREDICTION THAT INPATIENT STAYS AND PART A EXPENDITURES WILL INCREASE

88. The FY 2014 IPPS proposed rule (the "Proposed Rule") did not contain sufficient information concerning CMS's rationale as to the predicted increase in inpatient stays to afford

hospitals or other interested parties a meaningful opportunity to comment. The Proposed Rule states that:

> Our actuaries have estimated that our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 ‘‘midnights’’) in the hospital receiving medically necessary services, as discussed in section V.N.3. of the preamble of this proposed rule, would increase IPPS expenditures by approximately $220 million. These additional expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some encounters of less than 2 midnights moving from the IPPS to the OPPS. Specifically, our actuaries examined FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters and estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters. These estimated shifts of 400,000 encounters from outpatient to inpatient and 360,000 encounters from inpatient to outpatient represent a significant portion of the approximately 11 million encounters paid under the IPPS. The net shift of 40,000 encounters represents an increase of approximately 1.2 percent in the number of shorter stay hospital inpatient encounters paid under the IPPS. Since shorter stay hospital inpatient encounters currently represent approximately 17 percent of the IPPS expenditures, our actuaries estimated that 17 percent of IPPS expenditures would increase by 1.2 percent under our proposed policy. These additional expenditures are partially offset by reduced expenditures from the shift of shorter stay hospital inpatient encounters to hospital outpatient encounters. Our actuaries estimated that on average the per encounter payments for these hospital outpatient encounters would be approximately 30 percent of the per encounter payments for the hospital inpatient encounters.

78 *Fed. Reg*. at 27649-50.

89. Although CMS stated that it examined FY 2009 through FY 2011 Medicare claims data for “extended” hospital outpatient encounters and “shorter stay” hospital inpatient encounters, the Proposed Rule did not identify how many claims were examined by its actuaries

or explain what it meant by "extended" hospital outpatient encounters or "shorter stay" hospital inpatient encounters.

90. The Proposed Rule indicates that CMS's actuaries estimated that approximately 400,000 encounters will shift from outpatient to inpatient and approximately 360,000 encounters will shift from inpatient to outpatient, causing a net gain of 40,000 inpatient stays—but critically, the Proposed Rule does not indicate what the actuaries understood about the 2 Midnights policy. To the contrary, the Proposed Rule indicates that inaccurate and incomplete information may have been given to the actuaries concerning the policy. The Proposed Rule states that "[o]ur actuaries have estimated that *our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day* (defined by encounters crossing 2 'midnights') in the hospital receiving medically necessary services . . . would increase IPPS expenditures by approximately $220 million." 78 *Fed. Reg.* at 27649 (emphasis added). Thus, the Proposed Rule indicates that CMS's actuaries may have been acting under the assumption that any stay that crossed 2 midnights would be billed under Part A and paid by the Medicare contractor. In fact, the proposed policy: (1) did not, strictly speaking, propose any presumption, conclusive or otherwise; (2) did not propose that stays that cross 2 midnights necessarily are payable under Part A irrespective of whether the admitting physician or practitioner had a reasonable belief that the beneficiary needed hospital care for a period that would span 2 midnights; (3) did not propose that stays that cross 2 midnights necessarily are payable under Part A irrespective of whether the medical record documents that the admitting physician or practitioner had a reasonable belief that the beneficiary needed hospital care for a period that would span 2 midnights; and (4) did not propose that a hospital's billing records would go

unaudited irrespective of the hospital's past billing history for short stays. Moreover, the Proposed Rule does not indicate what, if anything, the CMS actuaries understood as whether or to what extent one-day stays could be billed properly under Part A. Nor does the Proposed Rule indicate what assumptions, if any, the CMS actuaries made with respect to hospitals' billing behavior (e.g., whether they will bill Part B in close cases), or contractors' behaviors with respect to the denials of claims, or the rate or appeals of denied claims or the success rate of appealed denials.

91. The Final Rule repeats the above-quoted language from the Proposed Rule and does not offer any different or additional rationale for CMS's prediction that approximately 400,000 encounters will shift from outpatient to inpatient and approximately 360,000 encounters will shift from inpatient to outpatient, causing a net gain of 40,000 inpatient stays, with a resulting increase (before the clawback) of $220 million expenditures under Part A. 78 *Fed. Reg*. at 50952-53. In making its prediction, CMS assumed that any claims for which the time in the hospital spanned 2 or more midnights would be billed and paid as inpatient claims under the 2 Midnights policy and that any claims for which the time in the hospital did not span at least 2 midnights in the hospital would be billed and paid outpatient claims. CMS makes no attempt to justify these assumptions, and they cannot be justified due to the ambiguity, confusion and internal inconsistency of the 2 Midnights policy.

92. Although CMS assumes that hospitals will always bill stays lasting at least 2 midnights as inpatient claims, the Final Rule directs hospitals *not* to bill stays that ended up lasting 2 or more midnights if the ordering physician did not have a reasonable expectation that the stay would last at least 2 midnights. 78 *Fed. Reg*. at 50945-46.

93. In addition, the Final Rule requires that the decision to admit be documented. It can be presumed that hospitals will bill in accordance with the requirements of the Final Rule (at least insofar as they understand them), particularly given the potential liability under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and therefore will not bill for stays in which the ordering physician did not document his or her reasonable expectation that the patient would require a stay lasting at least 2 midnights or did not have such a reasonable expectation in the first place.

94. In addition to potential liability under the False Claims Act or the Civil Monetary Penalty Statute, 42 U.S.C. § 1320a-7a, or other statutes, hospitals are disincentivized from billing under Part A for stays lasting 2 midnights or more where the hospital is uncertain whether the stay is payable under Part A, due to the Part B Inpatient Billing policy set forth in the Final Rule. Under the Part B Inpatient Billing policy, a claim that is denied as inpatient can be rebilled under Part B only within 12 months of the date of service (see 78 *Fed. Reg*. at 59035, 50965) and it is exceedingly rare for the Recovery Auditors ("RACs") or other contractors to reopen determinations on claims for hospital services within 12 months of the date of service; therefore, if such reopening occurs after 12 months after the date of service, it follows that the claim cannot be rebilled under Part B. Accordingly, in some indeterminate number of close cases involving stays that crossed 2 midnights, hospitals will bill Part B at the outset rather than risk billing under Part A and having the claim denied on reopening and be foreclosed from rebilling under Part B.

95. It does not appear that, in making its prediction that the 2 Midnights policy would result in an additional 400,000 inpatient stays each year, CMS took into account the fact that hospitals will not bill for stays lasting 2 midnights or more where the attending physician did not

have the reasonable expectation that the beneficiary would cross 2 midnights in the hospital, but in fact the beneficiary did cross 2 midnights without ever being admitted by the physician,

96. It does not appear that, in making its prediction that the 2 Midnights policy would result in an additional 400,000 inpatient stays each year, CMS took into account the fact that hospitals will not bill for stays lasting 2 midnights or more where the hospital believes that the admitting physician did not document the medical record with his or her reasonable belief that the stay was expected to last at least 2 midnights (or believes that the contractor will deny the claim on the basis that the record is not sufficiently documented).

97. Although CMS assumes that stays lasting at least 2 midnights will always be paid by its contractors, the Final Rule does not require the contractors to pay all stays that last at least 2 midnights, nor does it prevent the contractors from reviewing stays that last at least 2 midnights.

98. It does not appear that, in making its prediction that the 2 Midnights policy would result in an additional 400,000 inpatient stays each year, CMS took into account the fact that contractors will deny, correctly or incorrectly, some indeterminate amount of stays lasting 2 midnights or more, and that some indeterminate amount of these denials will not be appealed or will not be overturned on appeal.

99. Although CMS assumes that claims for encounters that last less than 2 midnights will always be billed as outpatient and paid as outpatient, neither assumption is warranted. The Final Rule is unclear as to the extent to which one-day stays are not billable as inpatient stays. Therefore, for this reason or due to other reasons some indeterminate number of one-day stays will be billed as inpatient and initially paid as inpatient, but later denied upon post-payment review by the RACs or other contractors. Almost none of these denied claims will be paid as

outpatient. That is because the Final Rule provides that a claim that is denied as inpatient can be rebilled under Part B only within 12 months of the date of service (*see* 78 *Fed. Reg*. at 59035, 50965) and it is exceedingly rare for the RACs or other contractors to reopen determinations on claims for hospital services within 12 months of the date of service, and if such reopening occurs after 12 months after the date of service, it follows that the claim cannot be rebilled under Part B. Because such claims cannot be rebilled under Part B, the supposed $220 million in additional Part A payment to hospitals is offset by this loss in Part B payment.

100. In finalizing its prediction of the number of encounters that would shift from inpatient to outpatient, CMS examined inpatient claims containing a surgical MS–DRG only. Claims that contained medical MS–DRGs were excluded. 78 *Fed. Reg*. at 50953. The Final Rule provided no explanation as to why claims containing medical MS-DRGs were excluded. The predicted number of number of encounters that would shift from inpatient to outpatient, 360,000, is artificially low because claims containing medical MS-DRGs were excluded.

101. The Secretary did not reveal that surgical MS-DRGs only were included in her prediction while medical MS-DRGs were excluded prior to the close of the notice and comment period. The Secretary's failure to disclose these critical assumptions relied upon by the HHS actuaries deprived Hospitals and other members of the public of a meaningful opportunity to comment on the proposed 0.2 percent reduction. The undisclosed information was central to the analysis that led to the Secretary's conclusion that 40,000 discharges would shift to inpatient status in 2014 and, without that information, commenters had no basis to understand or to critique the Secretary's conclusion.

102. CMS's Medicare Provider Analysis and Review (MedPAR) claims data shows that there were more than 1.5 million one-day inpatient stays in 2011. *See*

http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2012.html. The number of one-day stays in 2011 does not support the Final Rule's assumption that only 360,000 one-day inpatient stays would shift to outpatient encounters and be billed under the Outpatient Prospective Payment System.

THE *SHANDS* CONSOLIDATED CASES

103. In a group of cases consolidated as *Shands Jacksonville Medical Center v. Burwell*, Consolidated Civil Case No. 1:14-cv-263-RDM (D.D.C.), hundreds of hospital plaintiffs challenged the same rate reduction at issue in this case.

104. On October 6, 2015, the *Shands* court remanded the case to the Secretary for further proceedings. *Shands* ECF No. 50.

105. The *Shands* court found "the Secretary did not provide sufficient notice of the actuarial assumptions and methodology she employed," "disclosure of that information was essential to communicate the basis for the proposed adjustments and to permit meaningful public comment," and that "this error was not harmless." *Shands* ECF No. 50 at 33.

106. The Secretary published a notice in the Federal Register by December 1, 2015, inviting interested parties to submit comments by February 2, 2016. Medicare Program; Inpatient Prospective Payment Systems; 0.2 Percent Reduction; Notice with Comment Period, 80 Fed. Reg. 75,107 (Dec. 1, 2015).

COUNT I

PROCEDURALLY INVALID RULEMAKING

107. The Hospitals hereby incorporate by reference paragraphs 1 – 106.

108. The Proposed Rule did not provide an adequate explanation of the basis for CMS's estimate that the proposed 2 Midnights policy would result in an additional 400,000

inpatient admissions each year. The Proposed Rule did not provide adequate information as to what assumptions the CMS actuaries made with respect to the proposed policy, hospitals' billing behavior, and contractors' behavior in allowing or denying claims, or an adequate explanation of the claims data relied upon CMS's actuaries. Most notably, the Proposed Rule did not provide information as to the actuaries' exclusion of medical MS-DRGs from their prediction. For these reasons, interested parties were not given a meaningful opportunity to comment on the proposal to reduce operating and capital IPPS payments by 0.2 percent.

109. The Proposed Rule did not provide an adequate explanation of its basis for its conclusion that the proposed 2 Midnights policy would result in only 360,000 inpatient encounters shifting to outpatient encounters each year, or an adequate explanation of the data relied upon CMS's actuaries, so as to give interested parties a meaningful opportunity to comment on the proposal to reduce operating and capital IPPS payments by 0.2 percent.

110. The Final Rule is not a logical outgrowth of the Proposed Rule because the Proposed Rule did not propose to exclude medical MS-DRGs from the estimates of how many hospital encounters would move from inpatient to outpatient.

111. The Secretary's actions were in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, and were "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

COUNT II

ARBITRARY AND CAPRICIOUS RULEMAKING

112. The Hospitals hereby incorporate by reference paragraphs 1 – 111.

113. The Final Rule is arbitrary and capricious because its assumptions, that approximately 400,000 encounters will shift from outpatient to inpatient and approximately

360,000 encounters will shift from inpatient to outpatient, causing a net gain of 40,000 inpatient stays, are mere speculations based on CMS's faulty assumptions concerning how hospitals and Medicare contractors will react to the 2 Midnights policy, which is confusing, ambiguous, and internally inconsistent.

114. The Final Rule is arbitrary and capricious because CMS assumed that all beneficiary encounters spanning 2 midnights will be billed as inpatient, without taking into account that hospitals are prohibited from billing as inpatient those encounters that spanned two midnights but for which the medical record does not contain sufficient documentation that the admitting physician or practitioner had a reasonable belief that the beneficiary would need to receive hospital care for a period spanning at least 2 midnights. CMS made no adjustment for those stays spanning more than 2 midnights for which hospitals will not bill as inpatient because (1) they believe the medical record does not support that the admitting physician or practitioner had a reasonable belief that the beneficiary would need to receive hospital care for a period spanning at least 2 midnights, or (2) because they are uncertain as to whether the medical record contains such support and consequently will bill the encounter as outpatient because they realize that if they bill the encounter as inpatient and the claim is reopened and denied, they will be unable to rebill under Part B.

115. The Final Rule is arbitrary and capricious because the provision imposing a 0.2 percent payment reduction is contrary to CMS's own data, e.g., data that shows that the number of encounters CMS predicted as moving from inpatient to outpatient (360,000) is grossly understated. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action must be set aside "if the agency has . . . offered an explanation for its

decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

116. The Final Rule is arbitrary and capricious because CMS failed to include hospital encounters involving medical MS-DRGs in making its prediction as to how many encounters would move from inpatient to outpatient, notwithstanding that CMS proposed and adopted that the 2-Midnights policy to apply to inpatient stays resulting from admissions after surgery (surgical DRGs) as well as admissions made for medical purposes (medical DRGs). *See* 78 *Fed. Reg*. at 27648; 78 *Fed. Reg*. at 50944.

117. The Final Rule is arbitrary and capricious because it makes no provision for adjusting or reversing payments cut if the speculative assumption that there will be a net increase of 40,000 inpatient stays proves to be overstated.

118. The Final Rule is arbitrary and capricious because it takes into account only CMS's conclusion that the 2 Midnights policy will result in increased Medicare Part A payments to hospitals of $220 million per year, but does not take into account that the closely-related Inpatient Part B billing policy reduces Medicare payments by almost a billion dollars a year.

119. Under the APA, 5 U.S.C. § 706(2)(A), this Court is required to hold unlawful and set aside final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

COUNT III

RULEMAKING NOT IN ACCORDANCE WITH LAW

120. The Hospitals hereby incorporate paragraphs 1 – 119.

121. The 0.2 percent cut in hospital reimbursement is invalid because it exceeds CMS's statutory authority. The statutory authority relied upon by CMS in the Final Rule, i.e.,

sections 1886(d)(5)(I)(1) and 1886(g) of the Act (42 U.S.C. §§1395ww(d)(5)(I)(i), 1395ww(g)), as delegated by the Secretary to CMS, does not permit CMS to make across-the-board decreases in the base amount of operating and/or capital inpatient prospective payments due to hospitals.

122. Sections 1886(d)(5)(I)(i) (42 U.S.C. §§1395ww(d)(5)(I)(i)) permits CMS to make payment adjustments only to specific hospitals or specific types of hospitals rather than payment adjustments to all hospitals.

123. Section 1886(g) of the Act (42 U.S.C. §1395ww(g)) permits CMS to except certain hospitals from the capital inpatient prospective payment system and does not permit CMS to adjust the capital payments for all hospitals.

124. The Final Rule's provision imposing an across-the-board payment reduction is inconsistent with Congress's reserved power to set the annual update to the base payments under the IPPS and is in conflict with the statutorily prescribed market basket update "for all hospitals in all areas," as set forth in section 1886(b)(3)(B) of the Act (42 U.S.C. §1395ww(b)(3)(B)).

125. The Final Rule's provision imposing an across-the-board payment reduction is inconsistent with the statutory mandate in section 1886(d) of the Act (42 U.S.C. §1395ww(d)) to make a DRG-based payment to each hospital for each of the hospital's discharges because under the Final Rule hospitals are paid nothing for their share of the 40,000 net increase in inpatient admissions that CMS predicts will occur as a result of the 2 Midnights policy.

126. Under the APA, 5 U.S.C. § 706(2)(A), this Court is required to hold unlawful and set aside final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

RELIEF REQUESTED

For the reasons stated above, the Hospitals request that the Court enter an Order:

a. Declaring invalid, setting aside, and vacating the Final Rule's 0.2 percent payment decrease to the operating and capital IPPS payment rates, and requiring the Secretary to recalculate the appropriate increase in the standardized amount and the capital standard federal payment rates for FY 2014 in order to offset the aggregate decrease in IPPS payments resulting from adoption of the two-midnight rule and pay the Hospitals the additional sums due them as a result of such recalculation;

b. Awarding the Hospitals interest calculated in accordance with 42 U.S.C. § 1395oo(f)(2);

c. Awarding the costs of suit incurred by the Hospitals; and

d. Providing such other relief as the Court deems proper.

Date: January 8, 2016

Respectfully submitted,

/s/ Lori A. Rubin

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Health Forsyth Medical Center, Rowan Medical Center d/b/a Novant Health Rowan Medical Center, Franklin Medical Center /b/a Novant Health Franklin Medical Center, Presbyterian Medical Center d/b/a Novant Health Presbyterian Medical Center, Thomasville Medical Center d/b/a Novant Health Thomasville Medical Center, Medical Park Hospital, Charlotte Orthopedic Hospital d/b/a Novant Health Charlotte Orthopaedic Hospital, Brunswick Medical Center, Matthews Medical Center d/b/a Novant Health Matthews Medical Center, Huntersville Medical Center d/b/a Novant Health Huntersville Medical Center, Gaffney Medical Center d/b/a Mary Black Health System – Gaffney, Lawrence and Memorial Hospital, and The Westerly Hospital