

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

 THE AMERICAN HOSPITAL ASSOCIATION,)
 325 Seventh Street, NW, Suite 700)
 Washington, DC 20004;)
)
 MISSOURI BAPTIST SULLIVAN HOSPITAL,)
 751 Sappington Bridge Road)
 Sullivan, MO 63080;)
)
 MUNSON MEDICAL CENTER,)
 1105 6th Street)
 Traverse City, MI 49684;)
)
 LANCASTER GENERAL HOSPITAL,)
 555 North Duke Street)
 Lancaster, PA 17602; and)
)
 TRINITY HEALTH CORPORATION,)
 20555 Victor Parkway)
 Livonia, MI 48152,)
)
 Plaintiffs,)
)
 v.)
)
 KATHLEEN SEBELIUS, in her official capacity)
 as Secretary of Health and Human Services,)
 200 Independence Avenue, SW)
 Washington, DC 20204,)
)
 Defendant.)

Case No. 1:12-cv-1770

COMPLAINT

Plaintiffs the American Hospital Association, Missouri Baptist Sullivan Hospital, Munson Medical Center, Lancaster General Hospital, and Trinity Health Corporation (“Plaintiffs”) bring this action to end an unlawful government practice: The Medicare program has been refusing to pay hospitals for hundreds of millions of dollars’ worth of care provided to patients, even though all agree that the care provided was reasonable and medically necessary as

the Medicare Act requires. The government's refusal to pay for this care is harming hospitals and patients. More pertinent here, it violates the Medicare Act and is otherwise unlawful.

Plaintiffs seek a declaration to that effect as well as monetary and other relief.

INTRODUCTION

1. When a patient comes to a hospital for treatment, the attending physician must decide whether the patient should be admitted to the hospital. If the patient is admitted, he or she is treated on an "inpatient" basis; if not, he or she is treated on an "outpatient" basis. There are differences between the two, but in some cases the same services can be provided in both settings. For example, a young, healthy patient may be a good candidate to have surgery in an outpatient setting, while an older patient who has a higher risk of complications should have the same surgery on an inpatient basis.

2. Traditionally, the decision to admit a patient for inpatient treatment has been committed to the expert judgment of the attending physician. But in recent years, the Secretary of Health and Human Services (HHS) acting through the Centers for Medicare & Medicaid Services (CMS) has employed private third parties—known as Recovery Audit Contractors, or RACs—to engage in wide-ranging review of physicians' decisions to admit patients. These contractors are paid based on the amount of Medicare reimbursement they can "claw back" from hospitals. And though they operate with nothing but a cold paper record, they now regularly overrule physicians' expert medical judgments long after the fact, determining that particular Medicare patients—patients whom they have never even seen—should not have been admitted to the hospital to receive inpatient care. CMS then takes back all the payments it made to the hospital for the patients' care and gives the RAC a percentage of those funds.

3. For example, a hospital will care for a Medicare patient on an inpatient basis and submit a bill for reimbursement under Medicare Part A, which covers inpatient hospital care. CMS will pay the hospital. But months or, typically, years later, a RAC will overrule the physician's decision to admit the patient on the ground that, in the RAC's opinion, the patient could have been treated in the outpatient setting, and will demand that the hospital give back the entire Part A payment amount.

4. The RACs' decisions often are overturned on appeal. But even where they are not, payment to hospitals for the services they provided should be made under Medicare Part B, which covers hospital outpatient services. After all, federal law requires Medicare to reimburse hospitals for reasonable and medically necessary services provided to patients, and no one in these cases questions that the care hospitals gave their patients was reasonable and medically necessary; the RACs that demanded the payments back disagreed only with the *setting* in which the care was provided. At bottom, if payment cannot be made for medically necessary hospital care under Part A, it must be made under Part B.

5. But CMS has categorically refused to provide that Part B reimbursement. Specifically, CMS has adopted a policy (the "Payment Denial Policy") that prohibits Part B reimbursement for most items and services that were billed under Part A when, in the RAC's judgment, the patient *should* have been treated on an outpatient basis. Under the policy, CMS in that circumstance will pay hospitals only for a few ancillary items like splints and casts—items that typically amount to a small percentage of the total cost of care.

6. In short, CMS simply refuses to pay hospitals for services *that it acknowledges are covered under Medicare Part B and that it acknowledges were reasonable and medically necessary in the particular case*. That policy has resulted in hospitals losing hundreds of

millions of dollars for necessary care—surgeries, drugs, observation care, and on and on—that the hospitals provided to Medicare beneficiaries months or years earlier.

7. Prolonged uncertainty about whether Medicare will ultimately pay for the services previously provided wreaks havoc on hospital financial planning, including the ability to assess capital and staffing needs. Both the uncertainty and the actual loss of Medicare funds ultimately may adversely affect patient care.

8. CMS has made no effort to articulate a statutory justification—or any justification—for this policy. Nor could it. Put simply, when a hospital furnishes reasonable and medically necessary items and services, if payment cannot be made under Part A, it must be made under Part B.

9. In this Complaint, Plaintiffs ask the Court to set aside CMS's Payment Denial Policy on the grounds that it is contrary to federal law, arbitrary and capricious, and invalid for failure to undergo notice and comment. Plaintiffs also seek an order that CMS must repay hospitals for the reasonable and medically necessary services they provide to patients. No matter whether it was provided in the inpatient or outpatient setting, Medicare must pay hospitals for such medically necessary care.

PARTIES

10. Plaintiff the American Hospital Association (AHA) is a national organization that represents and serves nearly 5,000 hospitals, health care systems, and networks, plus 42,000 individual members. Its principal place of business is at 325 Seventh Street, NW, Washington, DC 20004.

11. Plaintiff Missouri Baptist Sullivan Hospital (Missouri Baptist) is a not-for-profit hospital providing primary community hospital services to three counties southwest of St. Louis,

Missouri. CMS has designated Missouri Baptist as a “critical access” hospital, *i.e.*, a small hospital that provides crucial services to a typically rural community. It is one of 13 hospitals in the BJC HealthCare network, which covers the spectrum of hospitals in terms of size and specialty. BJC HealthCare includes small rural hospitals, suburban community hospitals, and an academic children’s hospital and tertiary care academic hospital, both affiliated with Washington University School of Medicine. Together, BJC HealthCare’s hospitals have 3,445 beds and employ nearly 30,000 people in the greater St. Louis, southern Illinois, and mid-Missouri regions.

12. Plaintiff Munson Medical Center (Munson) is a not-for-profit, 391-bed hospital in Traverse City, Michigan. Munson opened its doors in 1915, making it northern Michigan’s first general hospital. It is the largest hospital in the Munson Healthcare System, which employs more than 6,500 people and offers a continuum of health care services in 24 counties across northern Michigan.

13. Plaintiff Lancaster General Hospital (Lancaster General) is a 631-bed, community-based, not-for-profit hospital in Lancaster, Pennsylvania that employs 7,500 people. Founded in 1893, Lancaster General is the keystone of an integrated health care delivery system in the Lancaster area that includes a freestanding Women & Babies Hospital, multiple outpatient centers, and 40 other health care-related organizations, such as the Visiting Nurse Association.

14. Plaintiff Trinity Health Corporation (Trinity Health) is one of the largest Catholic health care systems in the United States, owning 35 hospitals and managing 12 more. Those hospitals stretch across the country from Maryland to California and employ more than 56,000 full-time equivalent employees.

15. Defendant Kathleen Sebelius is the Secretary of Health and Human Services. In that capacity, she is responsible for the conduct and policies of HHS, including the conduct and policies of CMS. Secretary Sebelius is sued in her official capacity only.

JURISDICTION AND VENUE

16. This action arises under the Medicare Act, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*; and the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.*

17. This Court has jurisdiction over this action pursuant to 42 U.S.C. § 1395ff(b)(1)(a), which provides for “judicial review of the Secretary’s final decision after [a] hearing as is provided in section 405(g) of this title.” Section 405(g) in turn provides that “[a]ny individual, after any final decision of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the [Secretary] may allow.” 42 U.S.C. § 405(g).

18. Jurisdiction also exists under the APA, 5 U.S.C. § 706(2), which authorizes a court to “set aside agency action, findings, and conclusions of law found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” or “without observance of procedure required by law”; and § 704, which provides a right to judicial review of all “final agency action for which there is no other adequate remedy in a court.”

19. This Court also has jurisdiction under 28 U.S.C. § 1361, which grants district courts “original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff[s].”

20. This Court may issue a declaratory judgment pursuant to 28 U.S.C. §§ 2201–2202.

21. Venue lies in this judicial district pursuant to 42 U.S.C. § 405(g).

STATUTORY AND REGULATORY BACKGROUND

A. Medicare Act

22. Title XVIII of the Social Security Act establishes a program of health insurance for the aged and disabled, commonly known as Medicare. 42 U.S.C. §§ 1395 *et seq.* The Plaintiff hospitals qualify as providers of hospital services under Title XVIII, commonly known as the Medicare Act.

23. The Medicare program is divided into four parts, A through D. Parts A and B are the only parts relevant to this proceeding. Part A, the hospital insurance program, provides for reimbursement of inpatient hospital services. 42 U.S.C. §§ 1395c–1395i-5. Part B, the supplemental medical insurance program, pays for various “medical and other health services” not covered by Part A, including physician services and hospital outpatient services. 42 U.S.C. § 1395k(a); *id.* §§ 1395j–1395w-4j. Thus, for an individual who receives a particular treatment on an outpatient basis, payment to the hospital may be made under Part B, while for an individual whose risk factors support providing the same treatment on an inpatient basis, payment to the hospital may be made under Part A.

24. To be covered by Medicare Part A or Part B, medical services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” *Id.* § 1395y(a).

25. Under 42 U.S.C. § 1395hh(a)(1), the Secretary is required to “prescribe such regulations as may be necessary to carry out the administration” of the Medicare program. That statute provides:

No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title

shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1). [*Id.* § 1395hh(a)(2)].

26. The Secretary has implemented the Medicare program through guidance published in various manuals, such as the Medicare Benefits Policy Manual. These manual provisions are not promulgated in accordance with the notice and comment provisions of the APA, and therefore are not binding rules.

B. The RAC Program and CMS's Payment Denial Policy

27. Traditionally, a hospital's decision to admit a patient as an inpatient has been committed to the expert judgment of a physician, with oversight from the hospital and input from the patient. As CMS recognizes, the decision to admit a patient is a complex medical judgment that involves the consideration of many factors.

28. Nonetheless, in order to receive Medicare Part A reimbursement, a hospital must establish that admitting the patient for inpatient treatment was medically necessary. 42 U.S.C. § 1395y(a).

29. Physicians' decisions to admit patients began coming under more regular scrutiny with the birth of the RAC program. In 2003, Congress enacted section 306 of the Medicare Modernization Act of 2003 — the "RAC Demonstration Project" — and tasked the Secretary with implementing it. *See* Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256-57. Acting through CMS, the Secretary began the RAC Demonstration Project in 2005.

30. RACs are private entities that contract with the federal government to audit payments made to providers and suppliers by the Medicare program.

31. RACs typically conduct their audits by reviewing records and opining on the propriety of treatment decisions. RACs receive payment for their auditing services on a

contingent basis; the more money they recover from “improper payments” to providers, the more RACs stand to benefit financially.

32. During the three-year RAC Demonstration Project, the RACs claimed to have identified more than \$1.03 billion in “improper” payments. Ninety-six percent of those were overpayments. CMS, *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration 2* (June 2008) (“*Project Evaluation*”).

33. The demonstration proved highly cost-effective from CMS’s point of view. CMS reported that factoring in underpayments, operating costs, and so forth, the Demonstration Project returned \$693.6 million to the Medicare coffers.

34. Congress made the program permanent in 2006. *See* Pub. L. No. 109-432, 120 Stat. 292 (2006), codified at 42 U.S.C. § 1395ddd.

35. The RAC Program has been a continued financial “success” for CMS and the RACs: RACs collected \$1.86 billion in overpayments from October 2009 through March 2012. Over that same time period, RACs identified only \$245.2 million in underpayments. CMS, *Medicare Fee-for-Service Recovery Audit Program, May 2012*, 1 (“*May 2012 Report*”).

36. Because RACs are paid on a contingent basis, they established their claim-review strategies to focus on high-dollar improper payments. *Project Evaluation* 18. One such high-dollar item is inpatient hospital care, which, depending on the care provided, can cost tens of thousands of dollars per patient.

37. During the RAC Demonstration Project, 41 percent of the purported “errors” the RACs found involved situations where medical services supposedly were provided in the wrong setting. *Id.* at 14–15. That often meant that—according to the RACs—hospitals could have provided services on an outpatient basis rather than on an inpatient basis.

38. The RACs have continued to focus on this same type of claim in the permanent RAC program, putting an extraordinary burden on hospitals. In the first quarter of 2012, the most frequently cited “error” that led RACs throughout the country to demand repayment was the provision of service on an inpatient basis when, according to the RACs, only outpatient treatment was necessary. *May 2012 Report* 1.

39. The RACs are quite frequently wrong in their assertions about what a physician, confronted with a patient in need of medical treatment, should have done months or years earlier. Indeed, hospitals report that when they pursue appeals through the administrative appeals process—an expensive and burdensome exercise—they are successful in overturning RAC denials *75 percent* of the time.

40. Despite this alarming error rate, when a RAC determines that a provider was paid for inpatient hospital services but that the patient in question should have been treated as an outpatient, CMS takes back the entire Part A payment.

41. Moreover, CMS takes the position that once an inpatient claim that was paid under Medicare Part A is later—usually years later—denied, the hospital cannot receive Medicare Part B payment except for a few ancillary services.

42. As a result, when a RAC concludes that a hospital should have provided items and services on an outpatient, rather than an inpatient, basis, the hospital ends up receiving little if any reimbursement for reasonable and medically necessary items and services provided. The RACs fare significantly better: They keep a contingency percentage—9% to 12.5%—of the entire Part A payment.

43. Thus, for example, imagine a situation where a physician decides that a patient needs to be admitted to the hospital for a surgical procedure, and the cost of care provided to the

patient—surgery, drugs, and the like—amounts to \$20,000. CMS reimburses the hospital under Part A. Two years later, a RAC employee reviewing hospital records overrules the physician’s judgment and decides the patient should have received basically the same care, but on an outpatient basis. That decision, taken together with CMS’s Payment Denial Policy, means the hospital will end up receiving essentially no payment for the surgery and other care it provided. The RAC, by contrast, will receive approximately \$2,000 for that one case alone.

44. The only justification CMS has *ever* cited for refusing to reimburse hospitals under Part B for reasonable and medically necessary items and services provided in such cases is Medicare Benefits Policy Manual (MBPM) Chapter 6 § 10. This manual provision, promulgated by CMS without any explanation (much less notice and comment), provides:

Payment may be made under Part B for . . . medical and other health services listed below when furnished by a participating hospital (either directly or under arrangements) to an inpatient of the hospital, but only if payment for these services cannot be made under Part A.

The services “listed below” include only ancillary services like diagnostic tests, surgical dressings, splints and casts, outpatient physical therapy, and vaccines. The services listed *do not* include the emergency room services, drugs, and surgical procedures that often comprise the bulk of the care.

45. Upon information and belief, CMS has never articulated a reason for reimbursing the ancillary items and services listed in MBPM Chapter 6 § 10, but refusing to reimburse the items and services not on the list. Nor has CMS articulated a reason why it refuses to reimburse hospitals for items and services everyone agrees were reasonable and medically necessary.

46. All agree that keeping the Medicare trust funds solvent is an important and laudable goal. But that goal can be accomplished only in a manner that is consistent with the

Medicare Act and other federal statutes and that ensures that care for the intended beneficiaries of the trust fund—Medicare patients—will be provided in the most appropriate setting.

C. Administrative Appeals

47. RAC decisions are subject to administrative review. A provider can ask for redetermination of a RAC's findings by a Medicare claims processing contractor (known as a fiscal intermediary or Medicare Administrative Contractor (MAC)). If unsatisfied, a provider can seek reconsideration from a Qualified Independent Contractor (QIC), which includes an independent record review by a panel of physicians or other healthcare professionals. The next step is review by an Administrative Law Judge (ALJ). An ALJ's decision, in turn can be reviewed by the Departmental Appeals Board Medicare Appeals Council (DAB). 42 C.F.R. §§ 405.940–405.1130.

48. Only the DAB decision qualifies as the “final” decision of the Secretary for judicial review purposes. 42 U.S.C. § 1395ff(f)(2)(A)(iv).

49. Hospitals have responded to Part A claim denials and CMS's demand for repayment by taking the position Plaintiffs advance here: Even assuming that the patient could have been treated on an outpatient basis, the hospital is entitled to Part B payment for reasonable and medically necessary items and services provided. The DAB at least four times has agreed, holding that Part B payment was available to hospitals that provided reasonable and medically necessary services on an inpatient basis when the patient could have been treated in the outpatient setting. *In re: Missouri Baptist Hospital of Sullivan* (DAB Oct. 23, 2012); *In re: Montefiore Medical Center* (DAB May 10, 2011); *In re: O'Connor Hospital* (DAB Feb. 1, 2012); *In re: UMDNJ-University Hospital* (DAB Mar. 14, 2005).

50. Despite these DAB decisions, CMS continues to adhere to the Payment Denial Policy set forth in MBPM Chapter 6 § 10. In other words, it continues to tell hospitals and CMS

contractors that Part B payment is not permitted after a Part A denial other than for the small subset of ancillary items listed in MBPM Chapter 6 § 10.

51. Upon information and belief, CMS has never provided a reasoned analysis indicating why it has disavowed these DAB decisions.

D. Harms Suffered By Plaintiffs

52. CMS's Payment Denial Policy has harmed each of the Plaintiff hospitals.

Missouri Baptist Sullivan

53. In March 2010, a 67-year-old Medicare beneficiary arrived at Missouri Baptist to have his gallbladder removed. (The patient's name, and those of the other patients discussed below, are omitted to protect patient confidentiality.) He was admitted as an inpatient and spent one night in the hospital. Missouri Baptist submitted a request for Part A reimbursement on the patient's behalf. A CMS contractor approved the Part A claim and paid the hospital \$5,591.01 for the items and services it provided to the patient.

54. About eleven months later, without ever meeting or speaking to the patient or his physicians, the RAC determined that he should have been treated on an outpatient basis. No one disputed that the patient needed to have his gallbladder removed or that the hospital provided only medically necessary items and services while caring for him. And yet the RAC demanded that Missouri Baptist repay the entire \$5,591.01.

55. Missouri Baptist has exhausted its administrative appeals for the case just described. It appealed to the MAC, QIC, and ALJ, and received adverse decisions from each. Missouri Baptist then appealed to the DAB on July 20, 2012, seeking a declaratory ruling that CMS's Payment Denial Policy is unlawful. On October 23, 2012, the DAB issued a decision

authorizing Part B Payment for Missouri Baptist but ignoring Missouri Baptist's request for a declaratory ruling. Missouri Baptist's administrative appeals were exhausted as of that date.

56. The RAC audit and lengthy administrative process described above was far from unusual. Since January 30, 2010, the RAC has asked Missouri Baptist to turn over 418 patient records so the RAC could examine whether the decision to admit the patient as an inpatient was medically necessary. Of those 418 requests for medical records, the RAC determined, based on review of a cold paper record years after the fact, that 98 patients should not have been admitted as inpatients. These RAC denials have required Missouri Baptist— a hospital with fewer than 26 acute care beds—to repay Medicare \$226,501, resulting in a payment of approximately \$21,495 to the RAC itself based on its 9.49 percent contingency-fee rate.

57. The RAC's record requests, and subsequent appeals from RAC decisions, place a heavy burden on Missouri Baptist. Missouri Baptist has strained to respond to medical records requests while fulfilling patient care needs. It also has hired an external professional review company to pre-review all short-stay decisions. Missouri Baptist Sullivan could have used the resources spent on these activities for direct patient care, but instead had to devote them to RAC requests and appeals.

Munson Medical Center

58. In August 2010, a 68-year-old Medicare beneficiary went to Munson Medical Center for a cardiac catheterization. He was admitted as an inpatient and spent one night in the hospital. Because he was a Medicare beneficiary, Munson submitted a request for Part A reimbursement on his behalf. A CMS contractor approved the Part A claim and paid Munson \$11,628.93 for the items and services it provided to the patient.

59. A little more than a year later, after reviewing the patient's medical records, the RAC determined that he should have been treated as a hospital outpatient, rather than an inpatient. The RAC demanded that Munson repay the entire \$11,628.93. At no point before, during, or after the RAC review has anyone disputed that the patient needed the cardiac catheterization or that the hospital had provided only medically necessary items and services.

60. The RAC has demanded this sort of repayment from Munson hundreds of times. Between July 1, 2007 and October 22, 2012, the RAC asked Munson to turn over 1,526 patient records to examine whether the decision to admit the patient as an inpatient was medically necessary. Of those 1,526 requests, the RAC determined, based on review of a cold paper record years after the fact, that 844 patients should not have been admitted as inpatients. In only 453 cases has the RAC determined that the patient was properly admitted as an inpatient. (229 cases remain pending.) The RAC, in other words, has demanded that Munson return all payment—for care that everyone agrees was medically necessary—in two-thirds of the cases it has reviewed.

61. These RAC denials have required Munson to repay Medicare \$6,485,000, resulting in payments of approximately \$810,625 to the RAC itself based on its 12.5 percent contingency-fee rate.

62. For each of those Part A denials, Munson has eventually received only a small percentage—if anything at all—of the full Part B payment for the care it provided. That is so despite the fact that the RAC regularly concludes that the care rendered to the patient was medically necessary. The RAC's objection is only that the patient should have been treated on an outpatient, rather than an inpatient, basis.

63. The RAC's record requests, and subsequent appeals from RAC decisions, place a massive burden on Munson. Munson has spent hundreds of thousands of dollars handling RAC requests and appealing RAC denials. Much of that spending involves hiring new staff just to comply with RAC demands. Munson has hired 4.5 additional staff members to respond to RAC audits—one person dedicated to coordinating the RAC appeals process, two billing employees, and one full-time and one part-time employee to handle medical records requests. It also is seeking to hire two registered nurses to assist with the process. And it has spent more than \$165,000 on technology upgrades and license fees so that it can track the status of RAC records requests, audits, and appeals.

64. When Munson chooses to appeal a RAC denial, it wins about 50 percent of the time. When the case reaches the ALJ level, Munson achieves full reversals on 58 percent of its appeals. That said, Munson often does not appeal, in part because of the cost of the appeal.

65. The resources Munson has dedicated to responding to RAC audits and pursuing successful appeals could have used for patient-care related activities. The substantial time lag between delivering care, initiation of the RAC audit, and completion of appeals also hinders Munson's ability to budget and invest in improvements to patient care by creating uncertainty about reimbursement.

Lancaster General Hospital

66. In March 2008, a 71-year-old Medicare beneficiary went to Lancaster General Hospital to have spinal surgery. His surgery was invasive, removing portions of his vertebrae to stop them from causing nerve damage and pain. He was admitted as an inpatient and spent one night in the hospital.

67. Lancaster General submitted a request for Part A reimbursement on the patient's behalf. A CMS contractor approved the Part A claim and paid Lancaster General \$4,636.99 for the items and services it provided to the patient.

68. More than three years later, after reviewing the patient's medical records but without speaking to anyone involved in his care, the RAC determined that he should have been treated as an outpatient, rather than as an inpatient. It demanded that Lancaster repay the entire \$4,636.99, despite the fact that no one disputed that the care Lancaster provided was medically necessary.

69. As with the other plaintiff hospitals, this sort of RAC demand is a common occurrence for Lancaster General. Since April 2011, the RAC has asked Lancaster General to turn over 4,089 patient records, many to examine whether the decision to admit the patient as an inpatient was medically necessary. The RAC has determined, based on review of those paper records years after the fact, that 645 patients should not have been admitted as inpatients. These RAC denials have required Lancaster General to repay Medicare \$3.8 million, resulting in more than \$480,000 in payments to the RAC itself based on its 12.5 percent contingency-fee rate.

70. For all of those Part A denials, Lancaster General has not received any Part B payments, despite the fact that the RAC nearly always concludes that the care provided was medically necessary.

71. Lancaster General, too, spends hundreds of thousands of dollars a year on RAC-related compliance and appeals. The hospital has six staff members who work full- or part-time responding to RAC requests and appeals. Lancaster General also has hired a vendor to respond to medical records requests at a cost of more than \$100,000 per year. And it has hired an

external physician consulting company to handle medical necessity appeals. Moreover, it spends \$150,000 per year on software to track the status of RAC requests and appeals.

72. Because of these increased costs, Lancaster has had to reallocate resources that could have been used for patient care and staff education and training.

73. When Lancaster General chooses to appeal a complex RAC denial, it wins 86 *percent* of the time. That said, Lancaster General does not always choose to appeal, in part because of the cost of the appeal.

Trinity Health

74. In December 2009, a 66-year-old Medicare beneficiary went to a Trinity Health hospital to have a transobturator sling placed to treat stress urinary incontinence. She was admitted as an inpatient and spent one night in the hospital. The Trinity Health Hospital submitted a request for Part A reimbursement on her behalf. A CMS contractor approved the Part A claim and paid the hospital \$4,291.84 for the items and services it provided.

75. About a year and a half later, after reviewing the patient's medical records, the RAC determined that she should not have been admitted as an inpatient; instead, she should have been an outpatient during the procedure and her recovery. The RAC demanded that the Trinity Health Hospital repay the entire \$4,291.84, despite the fact that no one disputed that the care provided to the patient was medically necessary.

76. Again, this is a common occurrence for Trinity Health and its hospitals. Since January 2010, the RAC has asked Trinity Health to turn over 27,402 patient records from 28 hospitals to examine whether payment was appropriate, including whether the decision to admit the patient as an inpatient was medically necessary. Of those 27,402 requests for medical records, the RAC determined, based on review of cold records, that 8,015 Medicare beneficiaries

should not have been admitted as inpatients. Thus far, Trinity Health has had to repay Medicare \$33,628,176.

77. Like the other plaintiff hospitals, Trinity Health now must devote substantial staff and financial resources to handling RAC requests and appeals. Since January 2010, Trinity Health has spent \$8,423,264 handling RAC requests and appealing RAC denials. The home office appeal department added 11 full-time equivalent staff, each Trinity Health hospital has had to hire a RAC coordinator, and the hospitals' staffs spend substantial time on RAC issues. Trinity Health also has hired an external firm to respond to medical records requests at a cost to date of more than \$500,000, and has spent more than \$10,000 on project management/tracking systems.

78. When Trinity Health chooses to appeal the RAC denials, it wins *87 percent* of the time. But as with the other plaintiff hospitals, each appeal is expensive. Trinity Health therefore does not always choose to appeal.

Harms Nationwide

79. CMS's Payment Denial Policy is inflicting similar harms on hospitals across the nation.

80. Plaintiff AHA collects data and anecdotal evidence from member hospitals regarding the RAC program and its effects. Those data show the following: More than 95 percent of the general medical-surgical hospitals that provided information to the AHA have been targeted by RACs. The RACs have demanded more than a half-million medical records to audit. Many of those audits result in RAC determinations of "overpayment." And of those overpayment determinations, more than 60 percent relate to one- to two-day inpatient admissions that RACs deem medically unnecessary.

81. Hospitals thus have been required to give back hundreds of millions of dollars per year due to RAC determinations that services should have been provided in an outpatient, rather than inpatient, setting. In the first quarter of 2012 alone, information provided to the AHA by hospitals shows that they were forced to repay *\$236 million* for medically necessary items and services that RACs deemed should have been provided on an outpatient, rather than an inpatient, basis. And this amount does not include the millions of dollars recovered from hospitals that did not report data to the AHA.

82. Due to the Payment Denial Policy, hospitals that repaid these amounts were not eligible to be reimbursed under Part B, except for a few ancillary services. They accordingly provided many hundreds of millions of dollars' worth of concededly reasonable and medically necessary care for which they will never be compensated.

83. Advocates for Medicare patients have expressed worry that the Payment Denial Policy has led and will lead physicians and hospitals to refrain from admitting patients, opting instead to treat patients on an outpatient basis to ensure Medicare reimbursement.

84. CMS has expressed the same disquiet. In July 2010, CMS Acting Administrator Marilyn Tavenner reported "a modest trend toward proportionally more observation services" and specifically told hospitals that CMS is concerned about hospitals not admitting Medicare beneficiaries as inpatients, but instead treating them as outpatients. *See* Letter from Marilyn Tavenner to Richard Umbdenstock (July 7, 2010). Tellingly, though, CMS understands that the trend has its roots in hospitals' belief—supported by hospital experience with RACs—that hospitals face a "greater risk" that they will not receive Medicare payment "in cases where it is not immediately clear whether a patient should be admitted to the hospital as an inpatient or whether they should remain an outpatient." *Id.* at 2.

E. Applicable Federal Law

85. The majority of dollars recouped by CMS for “improper” inpatient admissions should have been repaid to the hospitals under Medicare Part B to cover the cost of providing reasonable and medically necessary items and services.

86. The Medicare Act requires this result. The Act “entitle[s]” hospitals to payment for all reasonable and necessary “medical and other health services” provided to beneficiaries, 42 U.S.C. § 1395k(a)(2), except for services the statute specifically excludes, *see id.* § 1395y. The services at issue in these RAC cases—emergency room services, drugs, surgical procedures, and the like—are covered under those definitions. The services are “medical and other health services” under 42 U.S.C. § 1395x(s)(2), which defines that term to include hospital services. The services do not fall within the exclusions listed in § 1395y. And in fact CMS pays for these very services in millions of cases per year. CMS accordingly must pay for them here.

87. From an administrative perspective, Part B payment following a Part A denial could occur in at least two ways. Hospitals could simply amend or supplement their initial requests for reimbursement to make clear that they now seek Part B payment, furnishing additional information about the items and services provided if needed. Congress has recognized some claims for payment may need to be supplemented with additional information before they are paid, *see* 42 U.S.C. §§ 1395g(a), 1395l(e); 42 C.F.R. § 424.5(a)(6), and that not all claims will be “clean claims” that will be paid promptly as billed, *see* 42 U.S.C. §§ 1395h(c), 1395u(c). To address such circumstances, CMS has issued regulations and policy statements allowing for claim adjustment by Medicare claims processing contractors and providers alike, *e.g.*, 42 C.F.R. § 421.100(a)(2); Medical Financial Management Manual, CMS Pub. 100-06 Ch. 3 § 170. Amending or supplementing an initial reimbursement request would not require the hospital to

submit a new claim, and thus would not run afoul of the general requirement that hospitals submit reimbursement requests within one year of the date the services were provided. *See id.* §§ 1395n(a)(1), 1395u(b)(3)(B).

88. Alternatively, if CMS preferred hospitals seeking Part B payment to submit different reimbursement requests for Part B payment, the Secretary could waive the one-year timely filing requirement. *See id.* §§ 1395n(a)(1), 1395u(b)(3)(B) (Secretary may “specify exceptions to the 1 calendar year period.”).

89. In short, neither the Medicare Act nor its implementing regulations erect any administrative barriers to full Part B payment following a Part A denial.

90. Put simply, the Medicare program commands CMS to pay for medically necessary services provided to beneficiaries unless there is some authorization in the statute not to pay for them. There is no such statutory authorization in this case. CMS’s refusal to pay for these services is unlawful, and it is hurting hospitals and patients alike.

COUNT I

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT The CMS Policy Is Not in Accordance with the Medicare Act

91. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

92. The Administrative Procedure Act prohibits Defendant from implementing the Medicare Act in a manner that is not in accordance with law. 5 U.S.C. § 706(2)(A).

93. The Medicare Act “entitle[s]” hospitals to payment for all reasonable and necessary “medical and other health services” provided to beneficiaries, 42 U.S.C. § 1395k(a)(2), except for services the statute specifically excludes, *see id.* § 1395y.

94. The services provided by plaintiffs in this case are reasonable and medically necessary medical and other health services that do not fall within a statutory exclusion.

95. CMS's policy prohibiting Part B payment for reasonable and medically necessary items and services is invalid under the APA because it violates the Medicare Act.

96. The Secretary must direct CMS to reimburse hospitals under Part B for the medically necessary and reasonable care they provide. If the Secretary prefers hospitals to submit new claims for Part B reimbursement, rather than amend or supplement their original claims, the Secretary must waive the one-year timely filing requirement.

COUNT II

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT The CMS Policy Is Arbitrary and Capricious

97. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

98. The APA prohibits Defendant from implementing the Medicare Act via actions, findings, or conclusions that are arbitrary and capricious. 5 U.S.C. § 706(2)(A).

99. Plaintiffs do not believe it is possible for CMS to articulate a satisfactory explanation for the Payment Denial Policy. Nonetheless, CMS's failure to articulate *any* explanation for refusing to reimburse hospitals for items and services that all agree are reasonable and medically necessary renders the Payment Denial Policy arbitrary and capricious and thus invalid under the APA.

100. CMS's failure to articulate a satisfactory explanation—or any explanation—for reimbursing hospitals for a few ancillary services after a Part A denial, but refusing to reimburse them for services that make up the bulk of the bill, renders CMS's Payment Denial Policy arbitrary and capricious and thus invalid under the APA.

COUNT III

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT CMS's Failure to Follow Precedent Is Arbitrary and Capricious

101. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

102. The APA prohibits Defendant from implementing the Medicare Act via actions, findings, or conclusions that are arbitrary and capricious. 5 U.S.C. § 706(2)(A).

103. An agency action is arbitrary and capricious if it departs from agency precedent without explanation.

104. Defendant continues to enforce the Payment Denial Policy even though she repeatedly has found that Part B payment is warranted for reasonable and medically necessary items and services provided in these Part A denial cases.

105. By continuing to enforce the Payment Denial Policy, Defendant has acted arbitrarily and capriciously in violation of the APA.

COUNT IV

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT

The CMS Policy Is Invalid for Failure to Undergo Notice and Comment Rulemaking

106. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

107. The APA prohibits Defendant from implementing the Medicare Act via actions, findings, or conclusions accomplished without observing the procedures required by law. 5 U.S.C. § 706(2)(A).

108. The APA requires agencies to afford notice of a proposed rulemaking and an opportunity for public comment prior to a rule's promulgation, amendment, modification, or repeal. *Id.* § 553.

109. The APA's notice-and-comment requirements do not apply to certain interpretive rules, general statements of policy, or rules of general agency organization, procedure or practice. *See id.* The Payment Denial Policy does not fall within any of those categories. Nor has Defendant articulated good cause for failing to submit the Payment Denial Policy to notice and public comment.

110. To comport with the mandates of the APA, Defendant therefore must have subjected the Payment Denial Policy to notice and comment procedures.

111. Defendant did not subject the Payment Denial Policy to notice and comment procedures.

112. Defendant's failure to do so violates the APA.

113. This failure constitutes a separate reason why the Payment Denial Policy is invalid. To be clear: The policy would be unlawful no matter the procedures used to promulgate it because it conflicts with the Medicare statute and because it is arbitrary and capricious. But even setting aside these fatal problems, the Payment Denial Policy cannot stand under the APA.

COUNT V

VIOLATION OF MEDICARE ACT

The CMS Policy Is Invalid Because It Was Not Promulgated as a Regulation

114. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

115. The Medicare Act requires that all rules, requirements, and statements of policy that establish or change a substantive legal standard governing the scope of benefits or payment for services be promulgated via regulation. 42 U.S.C. § 1395hh(a).

116. CMS's Payment Denial Policy establishes a substantive legal standard governing the scope of Part B benefits and payment for items and services.

117. Defendant did not promulgate the Payment Denial Policy as a regulation.

118. Defendant's failure to do so violated the Medicare Act.

119. The Payment Denial Policy would be invalid even if promulgated as a regulation, because it cannot be reconciled with the Medicare statute and because it is arbitrary and capricious. The failure to promulgate the Policy as a regulation nonetheless constitutes an additional independent reason why the Policy cannot stand.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court issue judgment in its favor and against Defendant and issue the following relief:

- A. A declaratory judgment that CMS's Payment Denial Policy is invalid because it violates the language and purpose of the Medicare Act;
- B. A declaratory judgment that CMS's Payment Denial Policy is arbitrary and capricious because (1) Defendant has not articulated a satisfactory explanation for refusing to reimburse providers for reasonable and medically necessary services provided and (2) Defendant has not articulated a satisfactory explanation for providing reimbursement for only a limited subset of services, rather than all reasonable and medically necessary services;
- C. A declaratory judgment that CMS's Payment Denial Policy is invalid under the APA for failure to undergo notice and comment rulemaking;
- D. A declaratory judgment that CMS's Payment Denial Policy is invalid under the Medicare Act because it was not promulgated as a regulation;
- E. A declaratory judgment that CMS's Payment Denial Policy is arbitrary and capricious because Defendant has not provided an explanation for departing from, and refusing to adhere to, her final decisions in prior appeals awarding Part B payment after a Part A denial based upon the wrong setting of care;
- F. An order vacating or setting aside CMS's Payment Denial Policy;
- G. An order that the Plaintiff hospitals be paid full Part B reimbursement for the appeals at issue;

H. An order that *all* hospitals that have received Part A denials based upon the wrong setting of care be paid full Part B reimbursement ; and

I. An award of such other temporary and permanent relief as this Court may deem just and proper.

Dated: November 1, 2012

Respectfully submitted,

/s/ Catherine E. Stetson
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