UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
325 Seventh Street, NW, Suite 700
Washington, DC 20004;

BANNER HEALTH,
1441 N. 12th Street
Phoenix, AZ 85006;

THE MOUNT SINAI HOSPITAL,
One Gustave L. Levy Place
New York, NY 10029;

EINSTEIN HEALTHCARE NETWORK,
5501 Old York Road
Philadelphia, PA 19141;

WAKE FOREST BAPTIST MEDICAL CENTER,
1 Medical Center Boulevard
Winston-Salem, NC 27103;

GREATER NEW YORK HOSPITAL ASSOCIATION,
555 West 57th Street, #1500
New York, NY 10019;

HEALTHCARE ASSOCIATION OF NEW YORK STATE,
One Empire Drive
Rensselaer, NY 12144;

NEW JERSEY HOSPITAL ASSOCIATION,
760 Alexander Road
P.O. Box 1
Princeton, NJ 08534-0001; and

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA,
4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600,

Plaintiffs,

Case No. _____

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20204,

Defendant.

COMPLAINT

Plaintiffs the American Hospital Association, Banner Health, Mount Sinai Hospital, Albert Einstein Healthcare Network, Wake Forest University Baptist Medical Center, Greater New York Hospital Association, Healthcare Association of New York State, New Jersey Hospital Association, and The Hospital & Healthsystem Association of Pennsylvania bring this action to challenge three unlawful Medicare policies. As described below, these policies burden hospitals with arbitrary standards and documentation requirements and deprive hospitals of Medicare reimbursement to which they are entitled. The policies should be invalidated.

INTRODUCTION

1. The federal government pays for "inpatient hospital services" for Medicare beneficiaries under what is known as Medicare Part A. The Medicare Act, however, has never included a definition of what it means to be an "inpatient." Instead, for more than 50 years, the Secretary of the U.S. Department of Health & Human Services, acting through the Centers for Medicare & Medicaid Services ("CMS") to administer the program, has committed the decision whether to admit a patient to the hospital to the expert judgment of the treating physician.

2. CMS has long recognized that the decision to admit a patient to the hospital is a "complex judgment" call that involves consideration of various factors. CMS, Medicare Benefit

Policy Manual ("MBPM") Ch. 1 § 10. CMS has instructed hospitals and physicians that "generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least *overnight* and occupy a bed, even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a bed *overnight*." *Id.* (emphasis added). CMS thus stated that a physician or other practitioner should "use a 24-hour period as a benchmark, i.e., [physicians] should order admission for patients who are expected to need hospital care for 24 hours or more." *Id*. But at the same time, CMS has recognized that the decision to admit a patient to the hospital is a fact-sensitive, "complex medical judgment" that "can be made only after the physician has considered a number of factors," including "the patient's medical history and current medical needs," "the severity of the signs and symptoms exhibited by the patient," "the types of facilities available," "the hospital's by-laws and admissions policies," the "medical predictability of something adverse happening to the patient," and "the relative appropriateness of treatment" in the inpatient versus outpatient setting. *Id.*

3. In short, the question whether to admit a patient as an inpatient is fact-sensitive and a matter of judgment. Nevertheless, in August 2013 CMS adopted a new test for determining when a patient is an "inpatient" for purposes of Medicare reimbursement. The new rule provides that a Medicare beneficiary is not an "inpatient" unless the admitting physician expects that beneficiary to need care in the hospital for a period spanning two midnights—i.e., a patient who arrives on Day 1 will stay in the hospital all that day and night, all through the next day, and into the next night, and will not be discharged until Day 3. This rule applies regardless of the "level of care" the physician expects the patient to need. And it means that if a physician

admits a patient who is not expected to stay until Day 3, and the hospital bills for that patient's care under Medicare Part A, CMS will refuse to pay for that inpatient stay.

4. CMS's newly-minted "two-midnights" rule has deprived and will deprive hospitals of Medicare reimbursement for reasonable, medically necessary care they provide to patients. And the rule is arbitrary and capricious: It undoes decades of Medicare policy. It unwisely permits the government to supplant treating physicians' judgment. And most important, it defies common sense. The word "inpatient" simply doesn't mean "a person who stays in the hospital until Day 3," and CMS is not at liberty to change the meaning of words to save money. The rule cannot withstand scrutiny under the Administrative Procedure Act ("APA").

5. CMS also adopted two other new requirements related to inpatient admissions that are equally flawed under the APA. First, CMS devised a way to avoid reimbursing hospitals for medically necessary care provided to Medicare beneficiaries. It did so in the context of Medicare review contractors, including in particular "Recovery Audit Contractors" or RACs: When a Medicare beneficiary is admitted to the hospital as an inpatient, the hospital seeks payment under Medicare Part A. In some cases, however, a RAC later reviews the cold paper record and overrules the physician's judgment, determining in hindsight that the patient should have been an outpatient instead. In such cases, CMS claws back the Part A payment. And even CMS has agreed that, when that happens, the hospital has a statutory entitlement to be paid under Medicare Part B, which covers outpatient services. And yet CMS now has made it impossible for hospitals to obtain that Part B payment in practically every case. It has done so by deciding to apply a one-year time limit to such Part B payment requests, running from the date when care was provided, *even though RACs almost never begin their review process until at least one year after the date of care*. In other words, the time limit has already expired on the first day a

hospital could seek payment. CMS does not have to apply that time limit, as described below. And yet it has done so in a way that ensures hospitals will receive no payment whatsoever for millions of dollars' worth of care that everyone agrees was reasonable and medically necessary. That choice is arbitrary and capricious.

6. Second, CMS now purports to require a written physician order as a condition of Medicare payment for every inpatient stay. That is directly contrary to the Medicare statute. The statute requires certification only for *extended* hospital stays. Moreover, Congress specifically amended the statute in 1967 to make clear that a physician order is not required for Part A payment for *short-term* hospital stays. The requirement is contrary to federal law and therefore invalid under both the Medicare Act and the APA.

7. These three policies deprive hospitals of reimbursement to which they are entitled. They also have forced and are forcing hospitals to spend hundreds of thousands of dollars, and hundreds of hours of personnel time, to change their medical records systems, admissions policies and procedures, and documentation protocols, harming hospitals and consuming resources that instead could be invested in patient care.

8. In this Complaint, Plaintiffs ask the Court to set aside all three unlawful policies. The Plaintiff hospitals also seek a reversal of any and all denials of their claims based on any of these three requirements and an order that the hospitals be reimbursed for those claims.

PARTIES

9. Plaintiff the American Hospital Association ("AHA") is a national not-for-profit organization that represents and serves nearly 5,000 hospitals, health care systems, and networks, plus 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and related

organizations that are accountable to the community and committed to health improvement. The AHA provides extensive education for health care leaders and is a source of valuable information on health care issues and trends. It also ensures that members' perspectives and needs are heard in national health policy development, legislative and regulatory debates, and judicial matters.

10. Plaintiff Banner Health is one of the nation's largest not-for-profit health care systems. Based in Phoenix, Arizona, Banner Health delivers high-quality, efficient care at twenty-four hospitals and other health care facilities across seven states. These include sixteen acute care hospitals, three of which are "Sole Community Hospitals"—a Medicare designation for certain hospitals that fill an important medical need in their rural communities—located in Fairbanks, Alaska; Sterling, Colorado; and Fallon, Nevada.

11. Plaintiff Mount Sinai Hospital is a 1,171-bed, not-for-profit, tertiary-care teaching facility in New York City. Mount Sinai Hospital is part of a large academic medical center that provides numerous specialty services on its campus and serves as the teaching hospital to the Icahn School of Medicine at Mount Sinai.

12. Plaintiff Einstein Healthcare Network ("Einstein") is a private, not-for-profit organization committed to providing compassionate, high-quality health care to the greater Philadelphia, Pennsylvania region. Einstein operates several major facilities, including Einstein Medical Center, a tertiary-care teaching hospital in Philadelphia, and Einstein Medical Center Montgomery, a new hospital that opened in 2012, as well as many outpatient centers.

13. Plaintiff Wake Forest University Baptist Medical Center ("Wake Forest") is a fully integrated, not-for-profit, academic medical center and health care delivery system. It operates 1,004 acute care, rehabilitation, and psychiatric care beds as well as outpatient and community health clinics and information centers in Winston-Salem, North Carolina. Wake

Forest also operates Lexington Medical Center in Lexington, North Carolina, and Davie Medical Center, which has facilities in Bermuda Run and Mocksville, North Carolina.

14. Plaintiff Greater New York Hospital Association ("GNYHA") is a regional, not-for-profit trade association that represents nearly 150 hospitals in New York, New Jersey, Connecticut, and Rhode Island. GNYHA 's core mission is to help hospitals deliver the finest patient care in the most cost-effective way. To do so, GNYHA engages in a wide range of educational activities, such as helping its members implement safety initiatives and sharing information about health care finance, health insurance, and graduate medical education. GNYHA also educates policymakers and State and Federal legislators on the complexities and constraints hospitals face in delivering care.

15. Plaintiff Healthcare Association of New York State ("HANYS") is a not-for-profit statewide organization that represents and advocates at the state and federal levels on behalf of all New York State hospitals and health systems. HANYS also provides its members with data and intelligence on health care policy and operations, and has created a Data Academy to provide training in the tactical and strategic application of health care data.

16. Plaintiff New Jersey Hospital Association ("NHJA") is New Jersey's oldest and largest not-for-profit trade association dedicated to hospitals and their patients. NJHA is a community for healthcare, representing nearly 400 healthcare organizations from hospitals to nursing homes to healthcare-related business and educational institutions. NHJA provides educational programming on diverse, substantive topics. Through the NJHA Institute for Quality and Patient Safety, NHJA unites healthcare providers and engages experts in collaborative efforts to improve healthcare quality. In 2010, NHJA's Institute was designated a "patient safety organization" by the U.S. Agency for Healthcare Research and Quality.

17. Plaintiff The Hospital & Healthsystem Association of Pennsylvania ("HAP") is a statewide not-for-profit organization that advocates at the state and federal level for nearly 240 Pennsylvania health care providers and the communities they serve. HAP provides services to the hospital community beyond traditional issue advocacy, including public-private partnerships and strategic planning. For example, HAP develops resources to help not-for-profit hospitals complete community health assessments, works with the Department of Health to enhance emergency preparedness and response efforts statewide, and assists hospitals and stakeholders in implementing health information technology that will improve patient quality and reduce health care errors and costs.

18. Defendant Kathleen Sebelius is the Secretary of Health and Human Services (the "Secretary"). In that capacity, she is responsible for the conduct and policies of HHS, including the conduct and policies of CMS. The Secretary resides in the District of Columbia and is sued in her official capacity only.

JURISDICTION AND VENUE

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

20. 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).

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

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

STATUTORY AND REGULATORY BACKGROUND

A. Medicare Act

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

24. The Medicare program is divided into four parts, A through D. Parts A and B are the only parts relevant here. Part A pays for "inpatient hospital services." 42 U.S.C. §§ 1395c–1395i-5. Part B pays for various "medical and other health services" not covered by Part A, including physician services and hospital outpatient services. *Id.* §§ 1395k(a); 1395j–1395w-4j. Thus, for an individual treated for a condition on an outpatient basis, payment to the hospital may be made under Part B, while for an individual whose risk factors support treating the same condition on an inpatient basis, payment to the hospital may be made under Part A.

25. Whether a patient is treated on an "inpatient" or an "outpatient" basis has cost implications. Part A and Part B are funded separately and use different formulae to calculate the reimbursement rates paid to hospitals. Generally, a hospital paid under Part A for treating a patient will receive a larger payment than if it had been paid under Part B for treating that patient.

26. To be covered by 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." 42 U.S.C. § 1395y(a).

27. To participate in the Medicare program, hospitals must enter into a provider agreement with CMS and comply with specific "Conditions of Participation." *See* 42 U.S.C. § 1395x(e); 42 C.F.R. § 482.1. To be reimbursed by Medicare for the services that they provide,

hospitals also must comply with many complex documentation requirements, including those described in the Medicare Act and CMS's regulations as "Conditions of Payment." *See generally* 42 U.S.C. § 1395f; 42 C.F.R. §§ 424.1, .5. As the name suggests, Conditions of Payment must be satisfied before the government will pay a Medicare claim.

B. The Recovery Audit Contractor Program and CMS's Previous Unlawful Payment Policy

28. 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 has long recognized, the decision to admit a patient is a "complex medical judgment which can be made only after the physician has considered a number of factors." MBPM Ch. 1 § 10. Those factors are set forth above at paragraph 2.

29. But in recent years, CMS has employed private third parties as a variety of Medicare review contractors, including in particular contractors known as RACs, to engage in wide-ranging review of physicians' decisions to admit patients. RACs are paid based on the amount of Medicare reimbursement they can "claw back" from hospitals. And though they operate with just a cold paper record, they now regularly overrule physicians' expert judgments long after the fact, determining that particular Medicare patients 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.

30. In particular, RACs have focused their reviews on situations where, according to the RACs, hospitals could have provided services on an outpatient rather than inpatient basis.

31. For example, take a 70-year-old Medicare beneficiary with high blood pressure and high cholesterol who comes the emergency room after experiencing dizziness and chest pain. A physician evaluates the patient and based on her medical history, the severity of her symptoms,

the need for diagnostic tests, and the risk of an adverse event such as a heart attack, decides the patient should be admitted as an inpatient. The hospital (after completing its own utilization review to confirm inpatient admission is appropriate) will care for the beneficiary on an inpatient basis and submit a bill for reimbursement under Medicare Part A. CMS pays the hospital. But then—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 as a result, CMS will take back the entire Part A payment amount.

32. The RACs are not alone. Other Medicare contractors also have focused on these types of cases, and hospitals have spent tens or hundreds of thousands of dollars managing these review processes.

33. The Medicare statute provides that hospitals are entitled to be paid for the reasonable and necessary care that they provide on an outpatient basis under Medicare Part B. *See* 42 U.S.C. § 1395k(a). And yet for many years, CMS took the position that after a Part A denial based on the level of care provided, the hospital could not request Part B payment other than for a small subset of ancillary items and services, such as splints, casts, and vaccines. MBPM Ch. 6 § 10 (Sept. 12, 2005). It adhered to that policy even though, in most Part A denial cases, no one disputes that the care the hospital provided was reasonable and necessary.

34. On March 13, 2013, CMS repudiated its unlawful policy. CMS simultaneously issued two documents. The first, CMS Ruling 1455-R, was an interim policy to handle rebilling after Part A denials, effective until CMS promulgated a new rule. The second was a proposed rule to address these types of claims going forward. *See* Medicare Program; Part B Inpatient Billing in Hospitals, 78 Fed. Reg. 16,632 (proposed Mar. 18, 2013).

35. CMS effectively conceded in these documents that its longstanding prior policy was unlawful. It wrote in the proposed rule:

> Having reviewed the statutory and regulatory basis of our current Part B inpatient payment policy, we believe that, *under section 1832 of the [Social Security] Act, Medicare should pay all Part B services that would have been reasonable and necessary (except for services that require an outpatient status) if the hospital had treated the beneficiary as a hospital outpatient rather than treating the beneficiary as an inpatient*, when Part A payment cannot be made for a hospital inpatient claim because the inpatient admission is determined not reasonable and necessary under section 1862(a)(1)(A) of the Act. [78 Fed. Reg. at 16,636 (emphasis added)].

36. Despite this statement, however, CMS proposed a new approach that in fact would *not* "pay all Part B services that would have been reasonable and necessary . . . if the hospital had treated the beneficiary as a hospital outpatient[.]" *Id.* Instead, CMS proposed to treat requests for Part B payment in these circumstances as brand-new claims—even though the hospital is seeking reimbursement for the treatment of the exact same patient billed on the original Part A claim—and apply a one-year time limit to those claims. CMS thus would require that the rebilled claims be filed within one year of the date when the hospital provided care to the patient. 78 Fed. Reg. at 16,639–40.

37. In May 2013, CMS also proposed to adopt two other new, and related, policies.

38. First, CMS proposed a time-based rule for determining whether a patient is an "inpatient" for purposes of Part A payment. Specifically, CMS instructed physicians that they "should order admission if [they] expect[ ] that the beneficiary's length of stay will exceed a 2-midnight threshold or if the beneficiary requires a procedure specified as inpatient-only under 42 CFR 419.22." Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates, 78 Fed. Reg. 27,486, 27,648 (proposed May 10, 2013). Conversely, if the physician expects to keep

the patient in the hospital for a period that does not cross two midnights, "the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used the bed." *Id.*

39. Second, CMS announced that hospitals cannot obtain payment under Part A unless the patient's medical record contains a physician's order admitting the patient as an inpatient. *Id.* at 27,646.

C. The IPPS Final Rule

40. CMS published its final rules governing hospital inpatient prospective payment system (IPPS) payments for federal fiscal year 2014 in the Federal Register on August 19, 2013 ("IPPS Final Rule"), adopting with few changes the proposed policies described above. *See* 78 Fed. Reg. 50,496, 50,505–06 (Aug. 19, 2013). We discuss each of those policies in more detail below.

41. On September 18, 2013, the AHA sent a letter to CMS calling for the agency to issue more detailed guidance regarding the new requirements. Letter from Linda Fishman to Jonathan Blum (Sept. 18, 2013), http://www.aha.org/advocacy-issues/letter/2013/130918-cl-2midnight.pdf. The AHA called for CMS to delay enforcement of the two-midnights rule and the physician order rule until after CMS had issued additional guidance on these topics. *Id.* at 3.

42. In response, CMS refused to delay enforcement of any of the new requirements. Letter from Marilyn Tavenner to Richard Umbdenstock (Sept. 26, 2013). Hospitals must comply with them now; if, according to CMS's Medicare Administrative Contractors, a hospital's claims do not meet those requirements, the claims are denied. At the same time, CMS has instructed its contractors to review a small sample of each hospital's inpatient claims spanning less than two midnights during a "probe & educate" period that CMS has extended several times.

D. The "Two-Midnights" Rule

43. CMS's "two-midnights" rule limits when a Medicare beneficiary is an inpatient for Part A purposes. Specifically, a beneficiary is an "inpatient" only when the physician expects the patient to require a stay that crosses "2 midnights"—that is, when the patient was admitted prior to midnight and stayed in the hospital that night, the next day, and the next evening until at least midnight. 78 Fed. Reg. at 50,908, 50,949, 50,965 (codified at 42 C.F.R. § 412.3(e)(1)).

44. CMS stated that the physician's expectation should be based on "such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event." 42 C.F.R. § 412.3(e)(1). And yet, throughout the preamble to the IPPS Final Rule and in its subsequent guidance, CMS has made clear that it is the expected amount of time—*not* the level of care—that should be the driving factor in the physician's admission decision. *See, e.g.*, 78 Fed. Reg. at 50,947, 50,950; CMS, *Reviewing Hospital Claims for Patient Status: Admissions On or After October 1, 2013* (Mar. 12, 2014).[1]

45. Under CMS's new rule, patients often will not be "inpatients" unless they are expected to stay in the hospital into the beginning of a third day. Take, for example, a Medicare beneficiary who arrives at the emergency room at 6 a.m. on Tuesday and is found to need surgery. After the procedure, she is given a bed in a hospital room, spends that night and all of the next day at the hospital recovering, is closely monitored by nurses, receives three or four meals during that time, and is discharged at 8 p.m. on Wednesday. If her length of stay matches up with what the physician who admitted her expected, she would not be an "inpatient."

46. That definition of "inpatient" is arbitrary and capricious because it bears no resemblance to the word's actual meaning, and CMS made no attempt to explain why it adopted

[1] *Available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/ReviewingHospitalClaimsforAdmissionforPosting03122014.pdf.

such a counterintuitive definition. *Every* available definitional source—from dictionaries, to scores of judicial decisions, to the regulations of other agencies, to CMS's own longstanding guidance—expresses the same understanding of "inpatient": a person who spends *a night* in the hospital (or who spends even less time but needs intensive treatment). And yet CMS now says the word inpatient is limited to people who spend *two* nights in the hospital.

47. That surprising assertion will save the agency millions of dollars because it will convert tens of thousands of inpatient cases, reimbursed under Part A, into outpatient cases, reimbursed under Part B. CMS's hospital claims data show that a variety of diseases and conditions, such as heart attacks, atherosclerosis, circulatory system problems, concussions or even comas without complications, are routinely treated on an inpatient basis for a period lasting less than two midnights. Similarly, many surgeries, such as appendectomies and mastectomies, routinely are performed on an inpatient basis for a period lasting less than two midnights. In many of these cases, physicians for decades have determined in their expert judgment that the patients should be admitted as inpatients. And CMS has agreed, creating Medicare Severity – Diagnosis-Related Group ("MS-DRG") codes that authorize inpatient payment. And yet these patients will no longer be "inpatients" under CMS's counterintuitive rule. Hospitals will be forced to bill Medicare as if these individuals were outpatients.

48. That will cost hospitals millions of dollars to which they are entitled. Worse still, it has the potential to undercut appropriate patient care. A physician who is uncertain about how to diagnose or treat a patient's symptoms and the level of severity of those systems, and thus the length of time a patient should be expected to stay in the hospital for treatment, will order that patient receive observation services as an outpatient. But CMS has acknowledged that it "do[es] not consider observation services and inpatient care to be the same level of care and, therefore,

they would not be interchangeable and appropriate for the same clinical scenario." 72 Fed. Reg. 66,579, 66,814 (Nov. 27, 2007). Many commenters expressed exactly that concern in the rulemaking in this case, explaining that "there are many beneficiaries who stay in a hospital for less than 2 midnights but still require an inpatient level of care." 78 Fed. Reg. at 50,945.

49. CMS dismissed those concerns and expressly rejected suggestions that it should create any exceptions to the time-based rule according to the level of care that the *physician* determines that the patient needs—*even in cases in which the physician finds the beneficiary needs to be treated in an intensive care unit*. *See id.* at 50,946.

50. CMS's two-midnights rule is arbitrary and capricious. CMS is not at liberty to redefine commonly-understood terms to save money. At the least, if CMS seeks to deviate from common meaning in this way, it is obliged to explain why that makes sense. It did not do so here.

E. The One-Year Filing Rule

51. CMS's imposition of a one-year filing limit on hospitals' requests for Part B payment after a Part A denial likewise is arbitrary and capricious. On information and belief, nearly all RAC Part A denials are issued more than a year after the date the service was provided because the RACs typically select claims for review that are several *years* old. Thus under CMS's approach hospitals could almost never rebill under Part B after a Part A denial. Their Part B claims would be untimely even if filed on the very same day that the contractor issued its Part A denial.

52. CMS thus (i) squarely recognized that Medicare *must* pay hospitals under Part B after a Part A denial by a RAC, *see supra* ¶ 35, and then (ii) made it impossible for hospitals to obtain that payment.

53. In these circumstances, it is arbitrary and capricious for CMS to apply the one-year time limit. That is so because CMS has other choices that would not create the absurdity just described.

54. First, CMS easily can convert the original Part A claim to a request for Part B payment without deeming the rebilling a "new claim" and triggering the time limit. In fact, CMS has done just that as recently as last year. *See* 78 Fed. Reg. at 50,924. And it makes sense to do so: Requests for Part B payment in these cases simply require hospitals to supplement the information on the originally submitted Part A claim; they are not new claims.

55. Second, and in any event, application of the one-year time limit in these circumstances is arbitrary and capricious because CMS has the authority to create exceptions to that time limit, 42 U.S.C. § 1395n(a)(1), and it has done so before in analogous circumstances.

56. CMS has created exceptions "where providers, suppliers, and beneficiaries, through no fault of their own, would be disadvantaged through strict application of the 1-calendar year timely filing requirements." 78 Fed. Reg. at 50,924. That rationale applies with equal force to these circumstances because hospitals cannot avoid Part A denials under CMS's unworkable standard: Since the outset of the RAC program, RACs regularly have denied claims where they simply disagreed with the physician's judgment about the care the patient should have been expected to need to receive at the hospital. There is no reason to believe that will change now that physicians have to predict whether a beneficiary will need to be in the hospital for "two midnights," instead of 24 hours. If anything, the problem will be worse, as physicians are required to predict events further into the future. Moreover, the RACs have strong financial incentives to construe the documentation in the medical record in the manner the least favorable

to the hospital because the RACs are paid a contingency fee that is a percentage of each clawed back Part A payment.

57. CMS acknowledged that "[o]ver 300 commenters" objected to applying the one-year time limit to rebilled Part B claims, while only "[o]ne commenter supported the proposal." 78 Fed. Reg. at 50,922. Yet, CMS sided with the one over the 300. And CMS did not offer any adequate rationale for doing so. That arbitrary decision cannot stand under the APA.

F. The Physician Order Rule

58. Although the Medicare Conditions of Participation have long required each inpatient's record include a physician order admitting the patient as an inpatient, CMS nevertheless added a new, and redundant requirement that makes such written physicians orders a condition of Part A payment. The new order must be in the medical record and must be supported by the physician's admission and progress notes. 78 Fed. Reg. at 50,965 (codified in 42 C.F.R. § 412.3(a)-(c)).

59. The order must adhere to specific requirements regarding the practitioner who signs it and the order must contain fairly specific language related to the admission decision. CMS requires the order to "specify the admitting practitioner's recommendation to admit 'to inpatient,' 'as an inpatient,' 'for inpatient services,' or similar language specifying his or her recommendation for inpatient care." *Id.* It is not sufficient for physicians to refer to inpatient units within the hospital, such as "Admit to Tower 7." 78 Fed. Reg. at 50,942.

60. CMS advised in subsequent guidance that if the order is not "properly" documented, "the hospital should not submit a claim for Part A payment[.]" CMS, *Hospital Inpatient Admission Order and Certification* (Jan. 30, 2014).[2]

[2] *Available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/IP-Certification-and-Order-01-30-14.pdf.

61. The physician order requirement is unlawful because it is directly contrary to the language and the legislative history of the Medicare Act.

62. CMS relied on 42 U.S.C. § 1395f(a)(3) as authority for the rule. 78 Fed. Reg. at 50,965. Section 1395f establishes a limited basis for requiring "certification" for inpatient services other than psychiatric inpatient services. CMS has described the physician order as an element of the physician certification.

63. The statutory provision upon which CMS relies, however, forecloses the requirement.

64. Subsection 1395f(a)(3) provides that payment for services furnished may be made only to an eligible provider and only if:

> with respect to inpatient hospital services (other than inpatient psychiatric hospital services) ***which are furnished over a period of time***, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose[.]

65. The italicized language is critical.

66. When Medicare was enacted in 1965, 42 U.S.C. § 1395f(a)(2)(A) stated that an eligible provider could be paid for inpatient hospital services only if a physician certifies that "such services are or were required to be given on an inpatient basis for such individual's medical treatment[.]" Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 294.

67. Two years later, however, Congress amended the statute: It struck the language just quoted and inserted the current paragraph (3), which limits the certification requirement by adding the "over a period of time" qualifier. *See* Pub. L. No. 90-248, § 126(a), 81 Stat. 821, 846.

68. The legislative reports on that amendment explained, in no uncertain terms, why Congress made this change: to *eliminate* the requirement that a physician order appear in the files in every case. *See* H.R. Rep. No. 90-544, at 149 (1967); S. Rep. No. 90-744, at 239 (1967).

69. Both the House and Senate reports state that the effect of the change was to "*eliminate the hospital insurance program requirement that there be a physician's certification of medical necessity with respect to each admission to a general hospital, and to require such a certification only in cases of hospital stays of extended duration*[.]" *Id.* (emphasis added).

70. The House report further explains the rationale for the amendment: "[A]dmissions to general hospitals are almost always medically necessary and the requirement for a physician's certification of this fact results in largely unnecessary paperwork." H.R. Rep. No. 90-544, at 38 (1967).

71. The legislative history also makes clear that the language "furnished over a period of time" was designed to limit the physician order requirement to extended stays.

72. CMS does not have the authority to re-impose a requirement that Congress affirmatively—and deliberately—chose to delete.

73. In any event, CMS has not provided any justification for creating such a requirement now. It certainly is not necessary to protect patient health or safety; regulations already require that the inpatient admission decision be made upon the "recommendation" of a physician, 42 C.F.R. § 482.12(c)(2), and that the patient's medical record "contain information to justify admission and continued hospitalization," *id.* § 482.24(c).

74. The new requirement serves only to give CMS a reason to deny otherwise valid Part A claims—a "gotcha" for those hospitals that fail to use the specific language mandated in the rule.

75. On the flip side, there is a good reason *not* to require physician orders as a Condition of Payment: Such a requirement may increase the incidence of long observation stays as is explained below.

76. Taken together, CMS's two-midnights and physician order rules require physicians to predict a stay of more than two midnights, and *certify* that expectation, to justify admission. 42 C.F.R. § 412.3(c), (e). Given the many factors that affect length of stay, it often is impossible to make that prediction with confidence. Even CMS acknowledges "long-term predictions are inherently more difficult than short-term predictions." 78 Fed. Reg. at 50,945.

77. Faced with the uncertainty inherent in making a longer-term prediction and the burden of Medicare review contractors' widespread practice of second-guessing physician judgments, the message to physicians is clear: order outpatient observation services for as long as necessary to be certain that the patient will in fact be in the hospital for a period spanning two midnights, even if that means the patient spends 24 hours or more under observation.

78. This pressure is heightened by the risk that whistleblowers or government lawyers will use the new certification requirement to spin theories of fraud or False Claims Act ("FCA") liability. To be sure, one incorrect prediction likely will not, in practice, give rise to an FCA claim. But doctors must make these decisions many times a day. An aggressive relator surely could attack a physician for multiple certified predictions that did not come to fruition.

79. Physicians and hospitals strive to get it right the first time. But fear of audits and FCA liability may influence even a well-intentioned physician to order observation services instead of admission to the hospital. Thus, the physician order rule also undermines CMS's own stated intent to reduce the occurrence of long observation stays. *See id.* at 50,906-07.

G. Plaintiffs' Protests Regarding Final Rule

80. On at least three different occasions, the AHA, on behalf of its members including the Plaintiff hospitals, informed CMS that the two-midnights rule, the one-year time limit and the physician order requirement were arbitrary and capricious and therefore unlawful. On June 19, 2013, the AHA submitted comments in response to the IPPS Proposed Rule, opposing all three proposals and urging CMS not to adopt them. The AHA submitted similar comments on September 18, 2013, specifically requesting CMS to issue subregulatory guidance on the agency's inpatient admissions and review criteria that were finalized in the IPPS Final Rule. *See supra* ¶ 41. Finally, on April 7, 2014, the AHA sent yet another letter on behalf of its members, including the Plaintiff hospitals, together with GNYHA, HANYS, NJHA and HAP, calling for CMS to revise the three rules and informing CMS that the AHA would seek relief from a federal court if the agency did not change those policies.

THE PLAINTIFFS HAVE SUFFERED HARM

81. The AHA and its member hospitals, including the Plaintiff hospitals, have been harmed in several ways by the three unlawful rules set forth above.

82. First and foremost, they have already lost Medicare reimbursement to which they are entitled—a problem they expect will increase dramatically as CMS continues implementing the new rules. For example, Mount Sinai Hospital expects to lose tens of millions of dollars in Medicare reimbursement in federal fiscal year 2014 alone as a result of the two-midnights rule.

83. Since October 1, 2013, the respective Medicare contractors for Banner Health's hospitals have asked Banner Health to turn over more than 167 patient records for inpatient stays, or approximately 15 records per hospital, to determine whether the decision to admit the patient as an inpatient in those cases complied with the two-midnights rule and the physician order rule.

84. That process already has led to claim denials. For example, Banner Boswell Medical Center produced the medical records related to 10 inpatient stays for which the patient was discharged after October 1, 2013 to its Medicare contractor, Noridian Healthcare Solutions. Of those 10 medical records, the contractor denied 7 on the ground that they did not comply with the two-midnights rule and instructed the hospital to bill Medicare Part B for the care that it provided as though the care had been delivered on an outpatient basis.

85. On April 11, 2014 Banner Health appealed five of the claims that the contractor had determined did not comply with the two-midnights rule. Banner Health argued that the rule is arbitrary and capricious and therefore is invalid.

86. Meanwhile, Mount Sinai Hospital, for example, filed a claim for Part A payment "under protest." It added notations to the claim to explain that although the technical requirements of the two-midnights rule and the physician order rule were not satisfied in that isolated case, Part A payment nevertheless is appropriate because the two policies are unlawful.

87. Upon information and belief, even after the Plaintiff hospitals appeal their denials, they cannot obtain a hearing at the Administrative Law Judge ("ALJ") level of administrative review because the Office of Medicare Hearings and Appeals has announced a more than two-year moratorium on assigning new claims appeals to ALJs. *See* Office of Medicare Hearings and Appeals, http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html (last visited Apr. 14, 2014).

88. The Plaintiffs also are being harmed in other ways by the new rules. Hospitals are spending tens of thousands of dollars revising their records systems, training their physicians and other practitioners, and hiring additional billing and compliance staff, and reallocating other limited resources to meet the new requirements.

89. For example, even before CMS published the IPPS Final Rule on August 19, 2013, Mount Sinai Hospital started the time- and resource-intensive process of modifying its electronic medical records systems, training physicians and other members of the medical staff, and revising all of its medical record documentation policies and procedures to comply with the new time-based test for inpatient admissions and the physician order requirement.

90. Mount Sinai Hospital has provided hours of training to its physician and medical staff regarding the two-midnights requirements and the physician order rule. The hospital added one and a half full-time positions to review these claims, in addition to its case management review team. And the hospital has spent more than 50 hours updating its medical records system to include a new physician certification regarding the expected length of stay and to allow a physician to countersign his or her own verbal order for admission or a written order for admission signed by a medical resident. The hospital will continue to incur additional costs for training, systems updates, and new staff as long as it is required to comply with the new rules.

91. The costs incurred by Mount Sinai are not unique. Wake Forest also has spent a tremendous number of hours and resources revising its records systems, training its physicians, and revising workflow processes to meet the new requirements. For example, Wake Forest University Baptist Medical Center's senior clinical and information technology leadership personnel have met weekly since August 2013 to develop policies and workflow processes to ensure compliance with the two-midnights rule.

92. All of the Plaintiff hospitals have undertaken similarly expensive changes to comply. These resources could have been used to enhance patient care instead.

93. The AHA also has been forced to devote significant time and money to responding to these rules, thereby diverting resources from its educational programs.

94. NJHA and its 71 acute care hospital members have suffered harm and will continue to suffer harm as a result of the three unlawful policies. NJHA member hospitals have suffered tens of thousands of dollars in lost Medicare reimbursement. NJHA also has been forced to devote significant time and money to responding to these rules, thereby diverting resources from its educational activities.

95. GNYHA and its 150 voluntary and public hospital members have suffered harm and will continue to suffer harm as a result of the three unlawful policies. GNYHA member hospitals have suffered tens of thousands of dollars in lost Medicare reimbursement. GNYHA also has been forced to devote significant time and money to responding to these rules, thereby diverting resources from its advocacy and other initiatives, such as working with members to improve the quality of care they deliver and to help them develop systems for ensuring continuous care improvement and safety, and providing technical assistance on delivery system reform initiatives.

96. HAP and its nearly 240 members have suffered harm and will continue to suffer harm as a result of the three unlawful policies. HAP member hospitals have suffered tens of thousands of dollars in lost Medicare reimbursement. HAP also has been forced to devote significant time and money to responding to these rules, thereby diverting resources from its educational activities.

COUNT I

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT
The Two-Midnights Rule 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. Under the two-midnights rule, patients often will not be "inpatients" unless they are expected to stay in the hospital into the beginning of a third day. That definition of "inpatient" is arbitrary and capricious because it bears no resemblance to the word's actual meaning, and CMS made no attempt to explain why it adopted such a counterintuitive definition.

100. CMS is not at liberty to reinvent the meaning of terms used in the Medicare Act simply because doing so will save it money. At the very least, if it seeks to deviate from plain meaning and its historic interpretation, it must explain why it has chosen that course.

101. CMS's interpretation of the term "inpatient" via the two-midnights rule is arbitrary and capricious and therefore invalid under the APA.

COUNT II

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT
The Application of the One Year Time Limit Is Arbitrary and Capricious

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

103. 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).

104. CMS has determined to apply the one-year time limit in situations where (i) a Medicare contractor has clawed back a Part A payment on the basis that treatment should have been provided on an outpatient basis and (ii) the hospital has sought to rebill for Part B payment.

105. CMS has acknowledged that it should pay hospitals under Part B in these circumstances. And yet it knows full well that application of the one-year time limit means hospitals will almost never be paid, because contractors like the RACs almost never even *begin* reviewing claims until more than a year has elapsed.

106. CMS's decision to nonetheless apply the one-year time limit is arbitrary and capricious because CMS has two other options, both of which would avoid placing hospitals in

such an impossible position.

107. First, CMS is empowered to treat requests for Part B payment as adjustment bills that do not trigger the time limit. CMS did not provide a reasoned explanation to justify its refusal to treat requests for Part B payment as adjustment bills.

108. Second, CMS is empowered to make exceptions to the time limit and has done so in analogous circumstances. CMS failed to provide an adequate explanation to justify its refusal to create an exception here.

109. Applying the one-year time limit to bar claims rebilled under Part B, without an adequate rationale for doing so, is arbitrary and capricious and therefore invalid under the APA.

COUNT III

VIOLATION OF THE MEDICARE ACT
The Physician Order Rule Is Contrary to the Medicare Act

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

111. CMS has created a requirement that all short-stay inpatient admissions be supported by a physician order mandating the inpatient admission.

112. That requirement is contrary to the language, intent, and history of 42 U.S.C. § 1395(f)(a)(3).

113. Because CMS does not have statutory authority to impose the physician order requirement, the requirement is unlawful under the Medicare Act and cannot stand.

COUNT IV

VIOLATION OF ADMINISTRATIVE PROCEDURE ACT
The Physician Order Rule Is Contrary to Law

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

115. 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).

116. The physician order rule violates the Medicare Act for the reasons set forth in Count III.

117. The physician order rule thus also is invalid under the APA. That constitutes an additional, independent reason why the rule must be set aside.

COUNT V

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT
The Physician Order Rule Is Arbitrary and Capricious

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

119. 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).

120. Since the Social Security Amendments of 1967, CMS has not required, as a Condition of Payment, a physician admission order for inpatient services except in long-stay cases.

121. CMS failed to provide any justification for creating the physician order rule now, despite sound reasons *not* to implement this new requirement.

122. CMS's failure to provide any justification for this new requirement renders the physician order rule arbitrary and capricious and thus invalid under the APA.

PRAYER FOR RELIEF

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

A. A declaratory judgment that the two-midnights rule is arbitrary and capricious;

B. A declaratory judgment that the application of the one-year time limit is arbitrary and capricious;

C. A declaratory judgment that requiring a written physician order for all inpatient admissions, including short acute care inpatient stays, is arbitrary and capricious;

D. A declaratory judgment that requiring a written physician order for all inpatient admissions, including short acute care inpatient stays, violates the Medicare Act;

E. A declaratory judgment that the physician order policy is invalid under the APA because it is contrary to law;

F. An order vacating or setting aside the two-midnights policy, the one-year time limit policy, and the physician order policy;

G. An order that the Plaintiff hospitals be reimbursed for the reasonable and necessary care they provided in the appeals at issue;

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

Dated: April 14, 2014

Respectfully submitted,

/s/

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