IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, MISSOURI BAPTIST SULLIVAN HOSPITAL, MUNSON MEDICAL CENTER, LANCASTER GENERAL HOSPITAL, TRINITY HEALTH CORPORATION, and DIGNITY HEALTH, *Plaintiffs*, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, *Defendant*.	Case No. 1:12-cv-1770 (CKK)

PLAINTIFFS' PROPOSED MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES:

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

ADMINISTRATIVE CASES:

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

STATUTES:

TABLE OF AUTHORITIES—Continued

Page

REGULATIONS:

RULE:

ADMINISTRATIVE MATERIAL:

OTHER AUTHORITIES:

TABLE OF AUTHORITIES—Continued

Page

[*] *Authorities on which we principally rely are marked with asterisks*

INTRODUCTION

Plaintiffs bring this action to end an unlawful and unfair government practice: The Centers for Medicare & Medicaid Services (CMS) has been refusing to pay the nation's hospitals for hundreds of millions of dollars' worth of care provided to Medicare patients, even though all agree that the care at issue is medically necessary and covered by Medicare. CMS's refusal to pay for this care is intolerable. And it has absolutely no basis in law. This Court should declare CMS's policy unlawful and should order the agency to make hospitals whole.

As it comes to this Court, the dispute has its roots in the distinction between "inpatient" and "outpatient" hospital treatment. When an individual goes to a hospital, the attending physician must decide whether he or she should be admitted. If so, the patient is treated on an "inpatient" basis; if not, he or she is treated on an "outpatient" basis. Many of the same services—for example, numerous surgeries—can be provided to a patient regardless of his or her status as an inpatient or outpatient. But the distinction is important in the Medicare context, because Medicare is divided into two main parts: Part A, which covers inpatient services, and Part B, which covers outpatient services. Whether a hospital seeks payment under Part A or Part B depends on whether the patient was admitted.

As CMS has long acknowledged, "the decision to admit a patient is a complex medical judgment" that requires a physician to consider multiple factors. Medicare Benefit Policy Manual (MBPM) Ch. 1, § 10.[1] That is why the decision traditionally has been committed to the attending physician's expert judgment. But in recent years, the Secretary of Health and Human Services (HHS) acting through CMS has employed private third parties—known as Recovery Audit Contractors, or RACs—to review physicians' decisions to admit patients. These contractors are paid based on the amount of Medicare reimbursement they can "claw back" from

[1] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c01.pdf.

hospitals. Operating with nothing but a cold paper record, RACs can (and regularly do) overrule physicians' expert medical judgments long after the fact, determining that particular Medicare patients they have never seen should not have been admitted as inpatients, but should have been treated as outpatients. In such cases, CMS's contractors typically do not dispute that the care the hospital provided was appropriate. They nonetheless demand that all Medicare reimbursement be returned on the ground that payment should not have been made under Medicare Part A.

The RAC review process is deeply problematic; as we discuss below, RACs are often wrong, and hospitals spend millions fighting to correct their mistakes. But RAC decisions retroactively denying Part A payments are not the focus of Plaintiffs' complaint. Plaintiffs' complaint, instead, is with what happens after the Part A claim is denied: CMS takes back *all* the payments it made to the hospital and then—even though its own contractor has determined the patient should have been treated as an outpatient—CMS *refuses to pay the hospital under Part B for the care it provided*. Specifically, CMS has told its contractors to follow a policy (the "Payment Denial Policy") that allows Part B reimbursement for only "a limited list" of services in situations where a Part A claim has been denied. CMS, *Memorandum re: Administrative Law Judge Decisions* 2 (July 13, 2012) ("*Tavenner Memorandum*").[2] That list is "limited" indeed: Under the Payment Denial Policy, CMS will pay for only ancillary, typically inexpensive, items and services, such as splints and casts. MBPM Ch. 6, § 10.[3] It will not pay for the emergency room services, drugs, and surgical procedures that typically comprise the bulk of the care. That means hospitals that have had Part A payment "clawed back" by the RAC will *never* be paid for those services, even though all agree the patient needed the services and even though CMS pays for the same services in millions of cases per year.

[2] *Available at* http://www.bkd.com/docs/pdf/cms_memorandum_re_effectuating_part_b_reimbursement.pdf.

[3] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c06.pdf.

CMS, in short, simply refuses to pay hospitals for covered, medically necessary care. Its policy is costing hospitals hundreds of millions of dollars per year and stripping them of revenues they desperately need. And it is unlawful. This Court can and should invalidate it on any of five different grounds.

First and foremost, CMS's Payment Denial Policy runs headlong into the Medicare Act. The Act "entitle[s]" hospitals to payment for reasonable and necessary "medical and other health services" provided to beneficiaries, 42 U.S.C. § 1395k(a)(2), except for services the Act excludes, *see id.* § 1395y. The services at issue in these RAC cases are "medical and other health services" under 42 U.S.C. § 1395x(s)(2). They do not fall within Section 1395y's exclusions. And they are concededly reasonable and necessary. CMS accordingly must pay for them. Its contrary policy "conflicts with [its] own statute" and thus is invalid under the Administrative Procedure Act (APA). *NextWave Personal Commc'ns, Inc.* v. *FCC*, 254 F.3d 130, 149 (D.C. Cir. 2001).

Second, the Payment Denial Policy is arbitrary and capricious under the APA because CMS has never made *any* attempt to explain or justify it. That is no hyperbole; CMS literally appears never to have said a word about why it deigns to pay for a few "ancillary" services or about how it draws the line between the two categories. That is fatal to its policy, for "a conclusion supported with no explanation is the epitome of arbitrary and capricious decisionmaking." *Columbia Gas Transmission Corp.* v. *FERC*, 448 F.3d 382, 387 (D.C. Cir. 2006) (emphasis and quotation marks omitted).

Third, the Payment Denial Policy is arbitrary and capricious for a separate reason too: In at least 16 recent cases, the Secretary's *own administrative adjudicators* have agreed that hospitals in these circumstances are entitled to Part B payment, *see infra* at 14, and yet the agency continues to hew to its contrary policy. That leaves hospitals in the absurd position of

having to give back all of their Medicare payments in each RAC-clawback case, knowing all the while that—if they are willing to commit the substantial resources necessary to appeal every denied Part A claim—they may eventually obtain Part B payment due to the agency's internal divide on the issue. This is not how federal agencies are supposed to work. CMS's continued adherence to the Payment Denial Policy in this circumstance is fundamentally unfair, and moreover it represents an agency failure to "either conform to its own precedents or explain its departure from them." *International Union* v. *NLRB*, 459 F.2d 1329, 1341 (D.C. Cir. 1972). It is invalid for both reasons.

Fourth, the Payment Denial Policy is invalid because CMS never subjected it to notice-and-comment rulemaking. The APA requires notice-and-comment procedures before agencies may enact "legislative rules"—*i.e.*, rules of "general . . . applicability" that have "future effect" and that define the rights and obligations of members of the regulated community. 5 U.S.C. § 551(4); *Industrial Safety Equipment Ass'n* v. *EPA*, 837 F.2d 1115, 1120 (D.C. Cir. 1988); *Batterton* v. *Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980). That well describes the Payment Denial Policy, which CMS purports to apply generally to all hospitals and which constrains hospitals' rights to payment. Notice-and-comment rulemaking was required.

Fifth, the Payment Denial Policy is invalid because the Medicare Act separately provides that all requirements establishing substantive legal standards that govern payment for services must be promulgated by regulation. 42 U.S.C. § 1395hh(a). For this reason, too, CMS's failure to promulgate the Payment Denial Policy as a formal rule renders it invalid.

Finally, even if the Payment Denial Policy were valid, the Plaintiff hospitals would be entitled to payment in this case. That is so because the Medicare Act states that where "a determination is made" that "payment may not be made under part A or part B," the provider

nonetheless is entitled to payment if it "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B[.]" 42 U.S.C. § 1395pp(a). That provision applies here, and entitles the hospitals to payment, for two reasons. First, CMS's inpatient-outpatient guidance is so sparse that the hospitals could not have known that their Part A claims would be denied. And second, in light of the unbroken string of administrative decisions granting hospitals Part B payment in these circumstances, *no* hospital could reasonably be expected to have known "that payment would not be made." *Id.* Quite the contrary, for some time now hospitals have reasonably expected that payment *will* be made—if only after they spend thousands making their way through an unnecessary appeals process.

The motion for summary judgment should be granted.

BACKGROUND

A. Medicare.

Medicare, established in 1965, provides health insurance to individuals over age 65 or who otherwise qualify because they are disabled or have end-stage renal disease. *See Heckler* v. *Ringer*, 466 U.S. 602, 605 (1984). The program's operative statute, housed in Title XVIII of the Social Security Act, is commonly known as the Medicare Act. *See* 42 U.S.C. §§ 1395 *et seq.* The Medicare program "is administered by the Centers for Medicare and Medicaid Services, a subunit of HHS." *Wilson ex rel. Estate of Wilson* v. *United States*, 405 F.3d 1002, 1005 (Fed. Cir. 2005).

Medicare reimburses providers for items and services they supply to eligible patients. The Act—and the program generally—is divided into five "Parts," two of them relevant here. Part A pays for institutional care provided primarily on an inpatient basis. *See* 42

U.S.C. §§ 1395c to 1395i-5. Part B is an optional supplemental insurance program that "provides the disabled and elderly with outpatient items and services" not covered by Part A. *Hays* v. *Sebelius*, 589 F.3d 1279, 1280 (D.C. Cir. 2009); *see* 42 U.S.C. §§ 1395j to 1395w-4. Anyone covered by Part A may purchase Part B insurance by paying a monthly premium. 42 U.S.C. §§ 1395j, 1395o.

The Medicare Act defines the reach of Part B's coverage. The first substantive provision under Part B states that "[t]he benefits provided to an individual by the insurance program established by this part shall consist of," among other things, "entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services[.]" *Id.* § 1395k(a). The term "medical and other health services," in turn, is defined to include "hospital services . . . incident to physicians' services rendered to outpatients[.]" *Id.* § 1395x(s); *accord* 42 C.F.R. § 410.10(c). The statute includes one additional limitation: "[N]o payment may be made under part A or part B of this subchapter for any expenses incurred for items or services" which "are not 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). Taken together, these provisions establish a legal entitlement: "Under Part B of Medicare, providers of 'medical and other health services' . . . are entitled to reimbursement for . . . providing such services," so long as the services are reasonable and medically necessary. *United States* v. *Weiss*, 914 F.2d 1514, 1515-16 (2d Cir. 1990).

B. Inpatients Versus Outpatients.

Hospitals do not bill CMS directly when they treat Medicare patients. Instead, they "receive reimbursement under Part A or Part B (or both) from a fiscal intermediary"—now known in Medicare parlance as a Medicare Administrative Contractor, or MAC—"that functions

as the Secretary's agent in making payment on covered claims." *Irvine Med. Ctr*. v. *Thompson*, 275 F.3d 823, 826 (9th Cir. 2002). But whether a hospital will seek payment under Part A or Part B depends, in most cases, on whether the Medicare recipient was admitted as an inpatient.

That decision whether to admit a patient, in turn, is complex and requires the exercise of medical judgment. The Medicare Benefit Policy Manual—a CMS policy manual discussed further below—explains as much. It states that "[g]enerally, a patient is considered an inpatient if formally admitted as [an] inpatient with the expectation that he or she will remain at least overnight and occupy a bed" even if it later turns out that an overnight stay is not required. MBPM Ch. 1, § 10. It says physicians should use 24 hours as a "benchmark," admitting patients who are expected to need hospital care for that amount of time or more. *Id.* But, the manual concedes, "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, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting." *Id.* It then lists "[f]actors to be considered when making the decision to admit." *Id.* They include "[t]he severity of the signs and symptoms exhibited by the patient," "[t]he medical predictability of something adverse happening to the patient," "[t]he need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted," and "[t]he availability of diagnostic procedures at the time when and at the location where the patient presents." *Id.*

Importantly, the services provided to inpatients and outpatients can in many circumstances be identical, and Medicare will cover those services whether provided on an

inpatient or outpatient basis. *See, e.g.*, CMS, *Are You A Hospital Inpatient or Outpatient?* (Feb. 2011) (stating that "Medicare Part B covers outpatient hospital services," including "emergency room visit[s]" and "surgery");[4] MedPac, *Report to the Congress: Medicare Payment Policy* 72 (Mar. 2004) (same).[5] For example, a young, healthy patient may be a good candidate to have a surgery in an outpatient setting, while an older patient with a higher risk of complications should have the same surgery on an inpatient basis. The difference between the inpatient and outpatient setting will determine the channel of reimbursement: For an individual who receives a 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 may be made under Part A. *See, e.g., In re L.B.*, No. M-11-1559, 2011 WL 7177068 (DAB Dec. 7, 2011). Although the difference in settings may affect the amount of payment for a given treatment, because Part A and Part B use somewhat different payment systems, *see id.*, in many cases the payment under Part A and Part B is the same. For example, Part A payment for an average surgical admission is the same as full Part B payment for the identical procedure. Steinberg Decl. at ¶ 14. And the actual medical care provided rarely, if ever, differs at all. As CMS's appeals tribunal has explained, "Medicare's inpatient vs. outpatient distinction primarily relates to the amount of payment and coverage under the inpatient and outpatient prospective payment systems, and not to the type of care required and received." *In re L.B.*, 2011 WL 7177068.

C. The RAC Program.

1. RACs. Concerned with identifying and correcting improper Medicare payments, Congress in 2003 enacted a new statutory provision—Section 306 of the Medicare

[4] *Available at* http://www.medicare.gov/Pubs/pdf/11435.pdf.

[5] *Available at* http://www.medpac.gov/publications/congressional_reports/Mar04_Ch3A.pdf.

Modernization Act, Pub. L. No. 108-173, § 206, 117 Stat. 2066, 2256-57—that tasked the Secretary with addressing the problem. Section 306 instructed the Secretary to experiment with the use of "RACs"—independent organizations that contract with the government to audit Medicare over- and under-payments. CMS, *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration* 1, 31 (June 2008) ("*Project Evaluation*").[6] Specifically, the statute "authorized CMS to complete a demonstration project to determine whether RACs could be utilized efficiently and effectively in Medicare when tasked with identifying Medicare overpayments and underpayments and recouping." *Id.* at 7.

The Secretary launched the demonstration project in 2005 with three RACs. Each RAC received payment for its auditing services on a contingent basis; the more money recovered from providers, the more the RACs stood to benefit. *Id.* And because they were paid on contingency, the RACs established their claim-review strategies to focus on high-dollar payments—such as the inpatient hospital claims at issue here. *Id.* at 18. During the demonstration project, the RACs found that thousands of inpatient hospital claims were invalid. In 41 percent of those cases, the RACs so found because, in their judgment, medical services had been provided in a "medically unnecessary" setting. *Id.* That often meant—according to the RACs—that "the beneficiary needed care but did not need to be admitted to the hospital to receive that care." *Id.* In such cases CMS's contractors concluded that payment under Part A was improper. Providers then were required to refund all Part A payments for that care.

During the three-year RAC demonstration, the RACs identified more than $1.03 billion in "improper" payments, 96 percent of which were overpayments. *Id.* at 2. The Project proved

[6] *Available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/RACEvaluationReport.pdf.

highly "cost effective" from CMS's point of view. *Id.* at 14. CMS reported that factoring in underpayments and costs, the Project returned $693.6 million to the Medicare coffers. *Id.* at 2.

Congress made the RAC program permanent in 2006. *See* Pub. L. No. 109-432, 120 Stat. 292 (2006), *codified at* 42 U.S.C. § 1395ddd. In the years since, RAC review of inpatient hospital claims has exploded. RACs are authorized to scrutinize hospital records and examine claims for up to three years after CMS paid the provider. *See Final RAC Statement of Work* 10 (Sept. 2011).[7] According to data collected by Plaintiff American Hospital Association (AHA), the RACs have demanded more than a half-million medical records to audit. Steinberg Decl. at ¶ 7. They have identified purported overpayments in tens of thousands of those cases. *Id.* And more than 60 percent of those purported overpayments have involved a finding that the *treatment* was appropriate but that the *setting* was incorrect because the patient should have been treated as an outpatient. *Id.* at ¶ 8.

Those determinations have forced hospitals to return hundreds of millions of dollars. From the beginning of the RAC program through the first half of 2012, information provided to the AHA by hospitals shows that hospitals were forced to repay *$267 million* for medically necessary items and services that RACs deemed should have been provided on an outpatient basis. *Id.* at ¶ 10. And the figure does not even include the many millions of dollars recovered from the 74 percent of hospitals that did not report data to the AHA. *Id.*

2. RAC Error Rates And Appeals. Unsurprisingly, given the medical expertise involved in physicians' admissions decisions, the RACs' attempts to second-guess those decisions are quite frequently wrong. Indeed, hospitals report that when they pursue appeals

[7] *Available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/090111RACFinSOW.pdf.

through CMS's administrative appeals process, they are successful in overturning RAC denials *75 percent* of the time. *Id.* at ¶ 15.

And yet many hospitals lack the resources to pursue those appeals through the long, cumbersome, multi-layer administrative process—a process that can require an investment of resources equal to or greater than a particular claim's value. By regulation, RAC decisions are subject to four tiers of administrative appeal. A provider that disagrees with the RAC's assessment can first seek redetermination by a Medicare claims processing contractor, typically referred to as a MAC. 42 C.F.R. §§ 405.940-405.958. If unsatisfied, the provider can seek reconsideration by a contractor, known as a QIC, that CMS hires to process second-level appeals. *Id.* §§ 405.960-405.978. The third level of appeal is review by an Administrative Law Judge (ALJ), who can conduct a hearing or rule on the record alone. *Id.* §§ 405.1000-405.1054. The ALJ's decision, in turn, can be reviewed by the Medicare Appeals Council Departmental Appeals Board (DAB), an appeals board housed in the Office of the Secretary and empowered to issue the Secretary's final decision. *Id.* §§ 405.1100-405.1130. Navigating all four levels of review can cost a hospital thousands of dollars. Steinberg Decl. at ¶ 16.

D. The Payment Denial Policy.

The RACs' sustained, and often erroneous, attacks on short-term hospital admissions would be highly burdensome to hospitals in any circumstance. But the impact would be much less devastating if, once CMS determines that a hospital should have treated a patient on an outpatient basis, the agency did what it *should* do under the statute: pay the hospital under Part B for the care it provided. That is the result the Medicare Act requires. After all, as set forth *supra* at 6, the Act "entitle[s]" providers to reimbursement when (i) they provide medical and other health services and (ii) those services are reasonable and medically necessary. 42 U.S.C.

§§ 1395k(a), 1395y(a). The care provided in the typical RAC short-term admission cases—emergency room services, drugs, surgical procedures, and the like—meets both descriptions. It constitutes medical and other health services because it consists of hospital services that CMS pays for in millions of cases each year. *See* CMS, *Are You A Hospital Inpatient or Outpatient?*, *supra* at 7. And there is no question that it is reasonable and medically necessary; the RACs and agency adjudicators typically say as much. *See, e.g.*, *In re St. Mary's Medical Center*, No. M-12-1428, 2012 WL 3303208 (DAB June 11, 2012) ("While the ALJ denied Medicare Part A coverage for the inpatient hospital stay, the ALJ determined that the 'underlying care was medically reasonable and necessary' for the purposes of reimbursement under Medicare Part B[.]"). CMS accordingly must pay.

But that is not the approach CMS has taken. Instead, it has hewed to the Payment Denial Policy, insisting—and instructing its contractors—that once a Part A claim is denied, hospitals cannot receive Medicare Part B payment except for a few ancillary services.

The only basis CMS has ever cited for its Payment Denial Policy is a passage in the Medical Benefit Policy Manual, one of several manuals CMS issues to guide implementation of the Medicare program. The passage states:

> Payment may be made under Part B for physician services *and for the nonphysician 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.
>
> In PPS hospitals, this means that Part B payment could be made for these services if: . . .
>
> - *The admission was disapproved as not reasonable and necessary* (and waiver of liability payment was not made)[.]

MBPM Ch. 6, § 10 (emphases added). The "medical and other health services listed below," however, are sharply limited. They do not include emergency room services, surgical procedures, or the other costly services often provided in short-term admission cases. Instead, they include a list of ancillary, less-expensive services: "surgical dressings," "splints," "casts," "vaccines," and similar items. *Id.* In CMS's own words, "[i]n these cases . . . hospitals may rebill . . . for only a limited set of Part B services." 77 Fed. Reg. 45061, 45155 (July 30, 2012) ("*OPPS Rule*").

That "limited set" typically amounts to a very small portion—10 percent or less—of the total cost of services provided. Steinberg Decl. at ¶ 14. Take, for example, a hypothetical case where a physician decides a patient needs to be admitted to the hospital for a surgical procedure, and the cost of care—surgery, drugs, and the like—amounts to $20,000. CMS reimburses the hospital under Part A.[8] 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 payment for some of its ancillary costs of care—surgical dressings, say—but no payment for the surgery itself, or for the drugs provided to that patient, despite the fact that all agree the hospital provided reasonable, medically necessary treatment. The RAC will fare significantly better: It keeps a contingency percentage—9 to 12.5 percent—of the entire Part A payment, and it accordingly would receive approximately $2,000 for that one case alone.

The MBPM, like all of CMS's policy manuals, was not subjected to notice-and-comment rulemaking and generally does not have the force of law. *See Catholic Health Initiatives* v. *Sebelius*, 617 F.3d 490, 491 (D.C. Cir. 2010); *National Med. Enters.* v. *Bowen*, 851 F.2d 291, 293 (9th Cir. 1988) ("The [Medicare] Manual is a guide for intermediaries in applying the

[8] The hospital is not paid for the physician's services; under Medicare, the physician bills CMS separately.

Medicare statute and reimbursement regulations and does not have the binding effect of law or regulation.") (quotation marks omitted). Notably, however, CMS has chosen to make the manual binding on its contractors. *See, e.g.*, *Catholic Health*, 617 F.3d at 491 (CMS manual "does bind Medicare's 'fiscal intermediaries'—private firms under contract with the Secretary to review provider reimbursement claims and determine the amount due."); NHIC Corp., *Recovery Audit Contractor/Comprehensive Error Rate Testing Programs*, at 16 (Aug. 2009) (contractor asserting that RACs "are bound by . . . manual instructions").[9] And CMS has specifically instructed its contractors to apply the Payment Denial Policy in evaluating claims. *See Tavenner Memorandum, supra*, at 2.

E. Agency Confusion Over The Payment Denial Policy.

Hospitals in many cases have responded to Part A denials by appealing on the ground that the contractor was wrong and that the admission, and Part A payment, were proper. *See supra* at 10. In other cases, however, they have argued on appeal the position Plaintiffs advance here: that even assuming the patient should have been treated on an outpatient basis, the hospital is entitled to Part B payment. And in case after case, *the Secretary herself has agreed.* The Secretary's designated appellate tribunal, the DAB, has held in at least 16 cases that even where a Part A denial was correct, "otherwise-covered and medically reasonable services must be covered and paid in the manner they would have been had they been claimed under Medicare Part B." Ex. A, *In re: Missouri Baptist Hospital of Sullivan*, No. M-12-2368 (DAB Oct. 23, 2012).[10]

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[9] *Available at* http://www.medicarenhic.com/PA/seminars/RAC_CERT%20Presentation%208-13.pdf.

[10] *Accord In re: Virtua-West Jersey Hosp.*, No. M-11-1291, 2012 WL 4294308 (DAB Aug. 1, 2012); *In re: Providence Health Ctr.*, No. M-11-1462, 2012 WL 3805722 (DAB July 18, 2012); *In re: Cent. Iowa Hosp. Corp.*, No. M-12-1280, 2012 WL 3805727 (DAB July 18, 2012); *In re: Providence Health Ctr.*, No. M-11-1217, 2012 WL 3780378 (DAB July 13, 2012); *In re: Providence Health Ctr.*, No. M-12-809, 2012 WL 3637361 (DAB June 29, 2012); *In re: St. Mary's Med. Ctr.*, No. M-12-1428, 2012 WL 3303208 (DAB June 11,

Yet even in the face of the DAB's persistent refusal to apply the Payment Denial Policy, CMS has continued to assert that the policy applies. *See, e.g.*, *OPPS Rule*, 77 Fed. Reg. at 45155 (reaffirming policy); CMS, *Part A to Part B Rebilling Demonstration* (Dec. 8, 2011) (explaining that providers can re-bill "for Inpatient Part B services, also known as ancillary services, but only for the services on the list in the Benefit Policy Manual");[11] CMS, *Frequently Asked Questions #2519* (same).[12] And it has continued to instruct its contractors that the policy—whose basis CMS has never explained—applies. *See Tavenner Memorandum*, *supra*, at 2.

That bizarre state of affairs has left hospitals in an untenable bind. If they invest the time and resources to proceed all the way through the administrative appeals process in every case, they have a chance to secure Part B payment. And yet they have no choice but to keep appealing, each and every time, at a substantial cost in every case. That is so because the CMS contractors, bound by the Payment Denial Policy, continue to claw back every penny of Part A payment the hospital received without any offset for the Part B payment that is due.

F. Harms Suffered By Plaintiffs And Other Hospitals.

CMS's Payment Denial Policy has inflicted, and continues to inflict, substantial harms on hospitals across the country. From the beginning of the RAC program through the first half of 2012, hospitals were forced to repay at least $267 million in Part A denial cases. Steinberg Decl.

2012); *In re: Yale-New Haven Hosp.*, No. M-12-877, 2012 WL 3091657 (DAB May 24. 2012); *In re: Indiana Univ. Health Methodist Hosp.*, No. M-12-872, 2012 WL 3262931 (DAB May 17, 2012); *In re: Maine Gen. Med. Ctr.*, No. M-12-571, 2012 WL 2491654 (DAB May 11, 2012); *In re: Maine Gen. Med. Ctr.*, No. M-12-719, 2012 WL 2491634 (DAB May 7, 2012); *In re: Hendrick Med. Ctr.*, M-11-410, 2012 WL 2324891 (DAB Apr. 23, 2012); *In re: Montefiore Med. Ctr.*, No. M-10-1121, 2011 WL 6960290 (DAB May 18, 2011); *In re: Montefiore Med. Ctr.*, No. M-10-1171, 2011 WL 6960263 (DAB May 10, 2011); *In re: O'Connor Hosp.*, 2010 WL 425107 (DAB Feb. 1, 2010); *In re: UMDNJ-Univ. Hosp.*, 2005 WL 6290383 (DAB Mar. 14, 2005). Some of these cases involve Part A payment followed by RAC clawbacks. Others involve situations where a CMS contractor denied the Part A payment in the first instance.

[11] *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/downloads/AB_QA_12811.pdf.

[12] *Available at* https://questions.cms.gov/faq.php?id=5005&faqId=2519.

at ¶ 10. They accordingly provided many hundreds of millions of dollars' worth of concededly reasonable and medically necessary care for which they will never be compensated. And hospitals have spent millions more navigating the administrative appeals process in an attempt to overturn those decisions. *Id.* at ¶ 17.

Nor can losses of this magnitude simply be absorbed by hospitals without adverse effects. Plaintiff Missouri Baptist provides an illustrative example. Missouri Baptist is a small facility that CMS designated as a "critical access hospital," *i.e.*, a hospital with no more than 25 acute care beds that provides crucial services to a typically rural community. *See* CMS, *Critical Access Hospitals* (Jan. 2012) (explaining the critical-access designation).[13] As a critical-access hospital, Missouri Baptist by definition is quite small; it is prohibited from having more than 25 acute-care beds. *See id.* And yet 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. Steinberg Decl. at ¶ 19. 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. *Id.* These RAC denials have required Missouri Baptist to repay Medicare $226,501—an amount that would have been sufficient to hire several additional employees. *Id.* at ¶ 20. Moreover, the RAC's record requests themselves, and subsequent appeals from RAC decisions, place a heavy burden on Missouri Baptist; the hospital has had to commit its own scarce resources to respond to RAC requests and has had to hire an external professional review company to pre-review all short-stay decisions. *Id.* at ¶ 21. Spending resources on RAC-related activities has meant there is less available to spend on direct patient care.

[13] *Available at* http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CritAccessHospfctsht.pdf.

Missouri Baptist appeals a substantial number of these RAC Part A denials, despite the burden. The hospital's participation in this case arises out of one such claim. In 2010, a 67-year-old Medicare beneficiary arrived at Missouri Baptist to have his gallbladder removed. *See* Ex. A, *In re: Missouri Baptist*, *supra*, at A-10. He was admitted as an inpatient and spent one night in the hospital. *Id*. 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. Ex. A, *HealthDataInsights Demand Letter*, at A-51. Almost a year later, the RAC determined that the patient should have been treated on an outpatient basis. No one disputed that he 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. *Id*.

Missouri Baptist appealed to the MAC, QIC, and ALJ, and received adverse decisions from each. Ex. A, *Medicare Appeal Decision from WPS*, at A-46; Ex. A, *Medicare Appeals Decision from MAXIMUS Federal Services*, at A-55; Ex. A, *ALJ Notice of Decision*, at A-63. 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. Ex. A, *In re: Missouri Baptist*, *supra*, at A-16. That result ensures that Missouri Baptist's administrative odyssey will do it no good in future cases. The next time a RAC retroactively denies a Part A claim, the Payment Denial Policy will still be in place, and the CMS contractors accordingly will seek to claw back the entirety of Medicare's payment to Missouri Baptist. The hospital's only hope for obtaining the payment to which it is entitled will

be to appeal from the RAC's decision and proceed through four layers of administrative review, again and again.

G. Hospitals' Separate Efforts To Obtain Payment Under Section 1879.

Some hospitals faced with this dilemma have raised a second, separate argument when they appeal RAC denials: They have argued that they are entitled to payment pursuant to Medicare Act Section 1879, codified as 42 U.S.C. § 1395pp(a).

Section 1879 is designed to ensure that beneficiaries and providers do not lose out on reimbursement when they had no reason to know that their payment request would be denied. It provides that where "a determination is made" that "payment may not be made under part A or part B," the provider nonetheless is entitled to payment if it "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B[.]" 42 U.S.C. § 1395pp(a). Some hospitals appealing from RAC denials have argued that that provision applies—and requires that they be paid for the services they provided—because given the lack of agency guidance about when patients should be admitted, they could not reasonably be expected to know that a RAC would apply the CMS guidance differently and claw back their payments. *See, e.g.*, *Indiana University Methodist Hospital*, *supra*, at HHS 9 (DAB May 17, 2012); *Montefiore Medical Center*, No. M-10-1171, *supra*, at HHS 3, 19-21.

Agency adjudicators generally have rejected these claims. But instead of examining what the appellant hospital reasonably should have known based on CMS's minimal guidance, as the statute requires, they have simply rejected the Section 1879 claims on the basis that—in the opinion of the RAC and adjudicator—Part A payment was not appropriate. *See Yale-New Haven Hospital*, *supra*, at HHS 10-12; *Providence Health Center*, No. M-12-809, *supra*, at HHS 11; Ex.

B, *Dignity Health Notice of ALJ Decision*, at B-10. In other words, they have treated the Section 1879 inquiry as if it were identical to the question whether the RAC got it right.

H. CMS's Rebilling Demonstration Project.

CMS plainly recognizes the problems its Payment Denial Policy creates for hospitals—and the degree to which it creates an adverse incentive for hospitals to keep patients under outpatient observation care. Late last year, CMS announced a three-year demonstration project that effectively lifts the Payment Denial Policy, and permits partial Part B billing after a Part A denial, for participating hospitals. *See OPPS Rule*, 77 Fed. Reg. at 45,156. CMS limited the program to 380 hospitals, however. *See id.* It also structured the program so that even those hospitals do not receive complete relief: Participating hospitals receive only 90 percent of the Part B payment when they rebill, and they are required to give up all appeal rights in exchange for participating in the demonstration. *See id.* And there is no guarantee the demonstration project will become a permanent program or that it will be expanded to include the many thousands of hospitals that cannot participate. In the meantime, the Payment Denial Policy continues to harm hospitals across the country every day.

SUMMARY OF ARGUMENT

CMS's Payment Denial Policy is unlawful five times over and should be invalidated. First, it violates the Medicare Act, which entitles beneficiaries to payment for reasonable and necessary medical services. Second, it is also arbitrary in the most basic sense of the word: CMS has never explained why it refuses to pay for most Part B services after a Part A denial and has never offered even a whisper of justification for the line it draws between "ancillary" and other services. Third, CMS's internal divide over Part B reimbursement—the agency's adjudicators regularly grant it, and yet the agency continues to instruct its contractors *not* to grant

it—is quintessential arbitrary and capricious agency action. Fourth, CMS was required to—but did not—subject its policy to notice-and-comment rulemaking under the APA. Fifth, the Medicare Act itself required CMS to promulgate its policy as a rule, and CMS did not do so. Finally, and in any event, the Plaintiff hospitals were entitled to payment under Section 1879.

The Payment Denial Policy is utterly arbitrary. And it is costing America's hospitals hundreds of thousands of dollars (or more) *per day*, and many millions per year. This Court can, and should, invalidate the policy on any or all of the grounds set forth above and should order CMS to make hospitals whole.

STANDARD OF REVIEW

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "In a case involving review of a final agency action" under the APA, however, "the standard set forth in Rule 56[ ] does not apply because of the limited role of a court in reviewing the administrative record." *Sierra Club* v. *Mainella*, 459 F. Supp. 2d 76, 89 (D.D.C. 2006); *see also Charter Operators of Alaska* v. *Blank*, 844 F. Supp. 2d 122, 126-127 (D.D.C. 2012). In an APA case, "[s]ummary judgment . . . serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Id.* at 90.

ARGUMENT

I. CMS's PAYMENT DENIAL POLICY VIOLATES THE MEDICARE ACT.

The Payment Denial Policy is unlawful, first and foremost, because it cannot be reconciled with CMS's governing statute: That statute entitles providers to payment for the care at issue here, and CMS refuses to provide it.

A. The Medicare Act Entitles Hospitals To Payment For Reasonable And Necessary Medical Services Provided To Beneficiaries.

The Medicare Act is notoriously complex, but on the particular issue presented here—whether CMS must pay for the hospital services provided by the Plaintiffs—it is straightforward. Part B states that "[t]he benefits provided to an individual by the insurance program established by this part shall consist of . . . *entitlement* to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services[.]" 42 U.S.C. § 1395k(a) (emphasis added). "Medical and other health services" is defined to include "hospital services . . . incident to physicians' services rendered to outpatients[.]" *Id.* § 1395x(s); *accord* 42 C.F.R. § 410.10(c). And Section 1395y, in turn, provides that "no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services" which "are not 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).

Taken together, these provisions entitle beneficiaries—or in this case, the providers that treated them—to payment for reasonable, necessary medical services. The federal courts have confirmed exactly that. The Second Circuit, for example, has explained that "[u]nder Part B of Medicare, providers of 'medical and other health services' . . . are entitled to reimbursement for . . . providing such services." *Weiss*, 914 F.2d at 1515-16; *accord Charpentier* v. *Kizer*, 1990 WL 252191, at *3 (E.D. Cal. Nov. 19, 1990) ("Medicare beneficiaries are entitled to have

Medicare payments made on their behalf" for medical and other health services) (citing 42 U.S.C. § 1395k(a)); *Bohlen* v. *Richardson*, 345 F. Supp. 124, 131 (D.C. Pa. 1972) ("Congress has stated that if the requirements are met, an individual is eligible for enrollment and once enrolled is *entitled* to payment for 'medical and other health benefits.' "). The Sixth Circuit, likewise, has explained that under the Medicare Act "the legal question . . . is one of entitlement, and that entitlement to reimbursement is triggered when the Government announces that a medical procedure is 'reasonable and necessary.' " *Guzzo* v. *Thompson*, 393 F.3d 652, 654 (6th Cir. 2004). And the Third Circuit has squarely rejected the argument that reasonable, medically necessary services are "excluded from coverage" merely because "the Secretary determines that it was not reasonable and necessary to render those services in a hospital[.]" *Hultzman* v. *Weinberger*, 495 F.2d 1276, 1282 (3d Cir. 1974).

B. The Payment Denial Policy Cannot Be Reconciled With The Act.

The Payment Denial Policy cannot be reconciled with that statutory framework. The policy as memorialized in the Medicare Benefit Policy Manual authorizes Part B payment after an "admission was disapproved," but only for "the nonphysician medical and other health services listed below." MBPM Ch. 6, § 10. The "services listed below" do not include the most expensive hospital services *usually* covered by Part B, including surgery and drugs. *See id.* And yet there is no question in these cases that the care the hospital provided was reasonable and medically necessary; indeed, CMS's adjudicators often concede as much. *See* Ex. A, *ALJ Notice of Decision*, at A-77.

The bottom line: CMS flatly refuses to cover a wide range of concededly reasonable, necessary medical and other health services—precisely the opposite of what the statute commands. That is unlawful. Under the APA, courts must "hold unlawful and set aside agency

action . . . found to be . . . not in accordance with law [or] . . . in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2). That provision "requires [courts] to invalidate agency action . . . if it conflicts with [the] agency's own statute." *NextWave*, 254 F.3d at 149; *accord National Treasury Employees Union* v. *Chertoff*, 452 F.3d 839, 864 (D.C. Cir. 2006) (agency rule "cannot survive judicial review" if it "reflects an action that is inconsistent with the agency's authority."); *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians* v. *Patchak*, 132 S. Ct. 2199, 2208 (2012) (assertion that agency action "violates a federal statute" is a "garden-variety APA claim"). Here such a conflict is apparent: The Medicare Act "entitles" providers to be compensated under Part B for reasonable and medically necessary "medical and other health services" provided to beneficiaries, and yet CMS has declined to provide that compensation. CMS cannot just refuse to cover services that its own governing statute says it covers. Its Payment Denial Policy accordingly should be struck down.[14]

II. THE PAYMENT DENIAL POLICY IS ARBITRARY AND CAPRICIOUS BECAUSE CMS HAS MADE NO ATTEMPT TO JUSTIFY IT.

The Payment Denial Policy is unlawful under the APA for a second reason too: Even if CMS enjoyed discretion to adopt an ancillary-services-only approach—which it did not—its policy would be arbitrary and capricious because the agency failed to explain its choice.

1. Under the APA, an agency must "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). That means the

[14] The Payment Denial Policy is entitled to no deference because it does not purport to interpret the Medicare Act at all. *See Public Citizen, Inc.* v. *U.S. Dep't of Health & Human Servs.*, 332 F.3d 654, 661 (D.C. Cir. 2003) (even if Court were prepared to accord deference to HHS manual, "that document contains no interpretation of [the statute] to which we might defer"). And even if it did purport to interpret the Act, the policy would be entitle only to minimal deference. "[I]nterpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law . . . do not warrant *Chevron*-style deference." *Christensen* v. *Harris County*, 529 U.S. 576, 587 (2000)). And "an agency action that is not entitled to *Chevron* deference 'is entitled to respect' only to the extent it has the 'power to persuade.' " *Fox* v. *Clinton*, 684 F.3d 67, 76 (D.C. Cir. 2012) (quoting *Gonzales* v. *Oregon*, 546 U.S. 243, 256 (2006)).

agency "must cogently explain why it has exercised its discretion in a given manner." *Id.* at 48; *accord A.L. Pharma, Inc.* v. *Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995); *Allina Health Servs.* v. *Sebelius*, --- F.Supp.2d ---, 2012 WL 5565453, at *16 (D.D.C. Nov. 15, 2012) (Collyer, J.). In the context of rules of general applicability, the agency must "explain the logic and the policies underlying any legislative choice." *United Steelworkers of Am.* v. *Marshall*, 647 F.2d 1189, 1207 (D.C. Cir. 1980); *accord Lead Indus. Ass'n* v. *EPA*, 647 F.2d 1130, 1162 (D.C. Cir. 1980) (choice between two policy approaches must be explained); *Industrial Union Dep't, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 476 (D.C. Cir. 1974) ("when [an agency administrator] is obliged to make policy judgments . . . he should so state and go on to identify the considerations he found persuasive").

The logical corollary, of course, is that an agency judgment "supported with no explanation is the epitome of arbitrary and capricious decisionmaking" and cannot survive APA review. *Columbia Gas*, 448 F.3d at 387 (emphasis and quotation marks omitted). Such an agency judgment fails entirely to "explain the logic and the policies underlying any legislative choice." *United Steelworkers*, 647 F.2d at 1207. Moreover, it makes judicial review impossible because "an agency's order must be upheld, if at all, 'on the same basis articulated in the order by the agency itself.' " *LePage's 2000, Inc.* v. *Postal Regulatory Comm'n*, 642 F.3d 225, 231 (D.C. Cir. 2011) (quoting *Federal Power Comm'n* v. *Texaco Inc.*, 417 U.S. 380, 397 (1974)).

2. The Payment Denial Policy cannot stand under this precedent because CMS has offered no explanation whatsoever for its counterintuitive policy choices. Why should hospitals that provided reasonable, necessary medical services be denied payment for most of those services? Why should they be *granted* payment for a small—and, from all that appears, totally arbitrary—subset of those services? How did the agency draw the line between the two

categories? How do any of these choices conform to the statutory commands discussed above? There is no way for the Court to know. CMS accordingly has neither "articulate[d] a satisfactory explanation for its action" nor "cogently explain[ed] why it has exercised its discretion in a given manner." *State Farm*, 463 U.S. at 43, 48. Its Payment Denial Policy should be vacated.

III. CMS's CONTINUED, UNEXPLAINED ENFORCEMENT OF THE PAYMENT DENIAL POLICY IN THE FACE OF ADVERSE DAB DECISIONS IS ARBITRARY AND CAPRICIOUS.

The Payment Denial Policy is arbitrary and capricious for an additional reason: CMS has continued to enforce its Policy despite more than a dozen DAB decisions rejecting the Policy's logic and requiring CMS to make Part B payments following Part A denials. This leaves hospitals in an absurd position: If a RAC has denied a Part A claim, the hospital must give back all of its payment, knowing full well that if it is willing to spend the time and money appealing the RAC decision through the Secretary's own administrative process, it may obtain Part B payment for the medically necessary services it provided. Hospitals, in short, are being whipsawed. In that circumstance, CMS's continued adherence to the Payment Denial Policy without providing an explanation for that adherence, even in light of the agency's contrary precedents, is arbitrary and capricious.

1. Just as the policymaking divisions within CMS derive their authority from the Secretary of Health and Human Services, so too does the DAB. *See* 42 C.F.R. § 50.403. DAB opinions qualify as the Secretary's final decisions. 42 U.S.C. § 1395ff(f)(2)(A)(iv). And to Plaintiffs' knowledge, each and every time the DAB has been called upon to render a decision regarding whether Part B payment can be made following a Part A denial, it has concluded that Part B payment is indeed appropriate for the medically necessary services a hospital provided.

The DAB first reached that conclusion while the RAC program was still in its demonstration phase. In *In re: O'Connor Hospital*, 2010 WL 425107, at HHS 1 (DAB Feb. 1, 2010), a RAC denied a hospital Part A payment for services it had provided to a beneficiary more than three years earlier. The CMS contractor argued that because the beneficiary's inpatient admission was not medically necessary, it needed to reimburse the hospital only for the items and services on the ancillary services list. The DAB rejected that approach. Though it did not explicitly purport to overrule or invalidate the Payment Denial Policy, it held that the contractor had to issue Part B payment for *all* medically necessary services the hospital provided to the beneficiary. According to the DAB, various CMS manual provisions, read together, require (i) that Medicare pay for covered services even if the claim in question also contained a request for payment for non-covered services and (ii) that providers be allowed to correct improperly submitted claims. *Id.* at HHS 3-5. Thus even though the hospital could not receive payment for any services covered only under Part A, it could receive Part B payment for services typically covered under Part B. *Id.* at HHS 6-7.

The DAB has reached the same result every time it has considered the question, adopting nearly identical reasoning each time. *See supra* at 14 (collecting cases). In *In re: Montefiore Medical Center*, No. M-10-1121, 2011 WL 6960290 (DAB May 18, 2011), for example, the DAB expressly relied on *O'Connor Hospital* to hold again that "Part B payment may be made if Part A payment is denied." *Id.* at HHS 16. And in *In re: Missouri Baptist Hospital of Sullivan*, *supra*—the case involving Plaintiff Missouri Baptist—the DAB wrote that "the appellant is entitled to payment for otherwise-covered medically reasonable and necessary services under Medicare Part B." *Id.* at HHS 12 (emphasis omitted). The DAB added:

> The Council does not specify the manner in which the Medicare Administrative Contractor should facilitate such process, *e.g.*, whether the

> contractor should direct the appellant to re-file the claim under Part B with an itemized list of services, whether the contractor is able to make payment based on the current claim as filed, or by other manner. *The Council simply finds that the otherwise-covered and medically reasonable services must be covered* and paid in the manner they would have been had they been claimed under Medicare Part B.

Id. (emphasis added).

2. Despite these clear pronouncements, none of the DAB decisions—16 in all—has prompted CMS to reconsider its Payment Denial Policy, to hew to the DAB's interpretation of Medicare's requirements, or to formally articulate any reason why it refuses to do so. Quite the contrary. On July 13, 2012, amid a flurry of DAB and ALJ decisions relying on *O'Connor Hospital* to award Part B payment, CMS sent a memorandum to its contractors reaffirming that they must continue to follow the Payment Denial Policy. *See Tavenner Memorandum, supra*. CMS acknowledged that the ALJ decisions requiring Part B payment were "in conflict with Chapter 6, section 10 . . . of the Medicare Benefits Policy Manual." *Id.* at 1-2. And while CMS instructed the contractors to comply with each ALJ and DAB decision *in the particular case in which it was rendered*, the agency emphasized that that instruction "should not be construed or interpreted as a change in the policy." *Id.* at 3. Instead "[c]ontractors should continue to follow existing policy and practices in all situations where there is not a conflicting ALJ order." *Id.*

CMS, in short, has shunted providers into an endless loop: Contractors will refuse to make Part B payment to hospitals after a Part A denial every time; the agency's adjudicators will overturn those decisions; and yet the contractors will stick to their guns in subsequent cases and keep on denying payment, knowing full well they will later be overturned. Providers thus cannot obtain the Part B payment to which they are entitled unless they are willing to navigate a time-consuming, expensive, four-stage appeal process in *every* case.

3. That is the very definition of arbitrary agency behavior, as the D.C. Circuit and other courts have recognized. *See, e.g.*, *Johnson* v. *U.S. R.R. Retirement Bd.*, 969 F.2d 1082 (D.C. Cir. 1992); *Continental Can Co.* v. *Marshall*, 603 F.2d 590, 597 (7th Cir. 1979); *Jones* v. *Califano*, 576 F.2d 12 (2d Cir. 1978). In *Johnson*, the D.C. Circuit faced an agency's refusal to acquiesce to a series of court of appeals decisions striking down an agency policy. Again and again, courts had declined to follow the agency's rule. And yet the agency continued to "put claimants to further expense and meaningless appeals by forcing them to exhaust their administrative remedies before they can receive benefits." 969 F.2d at 1091. The D.C. Circuit criticized that approach as "grossly unjust," "prejudicial," and "unfair." *Id.* at 1090, 1093. It explained that the agency's approach "results in very different treatment for those who seek and who do not seek judicial review": Those who possess "the determination and the financial and physical strength . . . to make it through the administrative process" get paid, and all others do not. *Id.* at 1092 (citation omitted). Wrote the Court:

> It is a peculiar view of fairness . . . that treats all claimants equally poorly by depriving them of benefits they will eventually receive if they have the fortitude to run an administrative gauntlet. This looks uncomfortably like the frivolous and obstructionistic litigation that the Supreme Court has severely criticized in the context of habeas corpus.

Id. at 1093 (citing *McCleskey* v. *Zant*, 499 U.S. 467 (1991)).

In *Jones*, meanwhile, the Second Circuit faced a circumstance even closer to that here: the Secretary of Health, Education, and Welfare had "declin[ed] to alter his [Social Security] regulations in spite of successive decisions by the Appeals Council" refusing to follow them, and as a result the Secretary was "forcing claimants to proceed by the tedious method of adjudicating their claims on an individual basis, even though eligibility is conceded." 576 F.2d at 19. Addressing that approach in the context of administrative exhaustion, the Second Circuit deemed

it indefensible because it treated those with the resources to hurdle the administrative process better than those without them, even though the agency knew full well that *all* claimants would prevail if they could only appeal to the end. *Id.* at 20. "Such a result would scarcely comport with the 'basic human claim that the law should provide like treatment under like circumstances,' " the Court explained. *Id.* (citing H. Friendly, *Federal Administrative Agencies* 19 (1962)). "Although agencies are not inflexibly bound by the rule of stare decisis, neither is their discretion unlimited. Thus, courts have imposed a duty of consistency toward similarly situated taxpayers, and have held that agencies may not treat similar situations in dissimilar ways." *Id.* (quotation marks & citations omitted). This was such a case, the Court held. After all, "[a] fundamental of justice is equality of treatment," and an agency that provides benefits only to claimants with the resources to continually appeal is not providing equal treatment. *Id.* *See also Continental Can*, 603 F.2d at 597 (requiring regulated entity to relitigate an issue "over and over in an untold number of hearings . . . is harassment of a capricious kind"); *Duggan* v. *Bowen*, 691 F. Supp. 1487, 1507 (D.D.C. 1988) (criticizing Secretary for forcing Medicare claimants onto a "merry-go-round" of pointless administrative appeals).

The courts, in sum, have deemed the exact approach the agency is taking here—refusal to award benefits that it knows would eventually be awarded after appeal, and insistence on a demonstrably pointless administrative process—"grossly unjust," "prejudicial," "unfair," "frivolous," "obstructionistic," "tedious," and contrary to "a fundamental of justice." They are right. And that makes the agency's approach arbitrary and capricious for three separate reasons.

First, "[n]otwithstanding [an agency's] reasoned justification," a policy is "arbitrary and capricious if . . . it is sufficiently unfair." *U.S. AirWaves, Inc.* v. *FCC*, 232 F.3d 227, 235 (D.C. Cir. 2000). If any agency action meets that description, it is the Secretary's "grossly unjust"

approach to these cases, *Johnson*, 969 F.2d at 1090—an approach that forces cash-strapped hospitals to spend precious resources and dollars on administrative appeals that the agency knows the hospitals will win.

Second, "[a] long line of precedent has established that an agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently." *Transactive Corp.* v. *United States*, 91 F.3d 232, 237 (D.C. Cir. 1996). This is just such a case, for the reasons explained by the Second Circuit in *Jones*: hospitals claimants situated like Plaintiffs here are all entitled to Part B payment under the DAB's consistent approach, and the only difference among them is their resources to appeal in every case—hardly a legitimate distinguishing factor.

Third, agencies must "do more than simply ignore" contrary precedent, *LeMoyne-Owen College* v. *NLRB*, 357 F.3d 55, 61 (D.C. Cir. 2004), and their "failure to come to grips with conflicting precedent constitutes 'an inexcusable departure from the essential requirement of reasoned decision making.' " *Ramaprakash* v. *FAA*, 346 F.3d 1121, 1125 (D.C. Cir. 2003) (quoting *Columbia Broad. Sys.* v. *FCC*, 454 F.2d 1018, 1027 (D.C. Cir. 1971)). As the D.C. Circuit has said: "It is an elementary tenet of administrative law that the agency must either conform to its own precedents or explain its departure from them." *International Union*, 459 F.2d at 1333. CMS has done neither. The DAB's decisions are final decisions of the Secretary, and CMS has neither conformed to them nor formally explained why it has not done so.

The agency's left hand is ignoring what its right hand is doing. And hospitals are caught in the middle. In this circumstance CMS cannot just allow its internally divided process to continue apace. Plaintiffs are entitled to summary judgment on Count III of their Complaint.

IV. THE PAYMENT DENIAL POLICY IS INVALID FOR LACK OF NOTICE-AND-COMMENT RULEMAKING.

The Payment Denial Policy is also invalid because CMS never subjected it to notice-and-comment rulemaking, as the APA requires.

A. Substantive Rules Require Notice-And-Comment Procedures.

Sections 553 of the APA "generally require[s] an agency to publish notice of a proposed rule in the Federal Register and to solicit and consider public comments upon its proposal." *Electronic Privacy Info. Ctr.* v. *U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 5 (D.C. Cir. 2011). The APA specifies the notice-and-comment procedures an agency must undertake prior to a rule's promulgation. *See* 5 U.S.C. § 553. Rules "not promulgated in accordance with notice and comment rulemaking proceedings are invalid and will not be enforced." *Beverly Health & Rehab. Servs., Inc.* v. *Thompson*, 223 F. Supp. 2d 73, 98-99 (D.D.C. 2002); *see also Electronic Privacy Info. Ctr.*, 653 F.3d at 8 (striking down rule where agency "advanced no justification for having failed to conduct a notice-and-comment rulemaking").

The APA, however, "does provide certain exceptions to this standard procedure." *Id.* at 5. "[I]n particular . . . the notice and comment requirements do not apply 'to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.' " *Id.* (quoting 5 U.S.C. § 553(b)(3)(A)). Congress intended these exceptions to be narrow. *Asiana Airlines* v. *FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998). Notice-and-comment rulemaking, after all, serves important purposes: It "reintroduce[s] public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies," *Batterton*, 648 F.2d at 703, and it "assures that the agency will have before it the facts and information relevant to a particular administrative problem, as well as suggestions for alternative solutions," *Guardian Fed. Sav. & Loan Ins. Corp.* v. *FSLIC*, 589 F.2d 658, 662 (D.C. Cir. 1978).

Rules falling within these narrow exceptions need not undergo notice-and-comment rulemaking. All other rules, however, must. Courts refer to this latter category as "substantive" or "legislative" rules. As the D.C. Circuit has explained: " '[W]hen agencies base rules on arbitrary choices they are legislating, and so these rules are legislative or substantive and require notice and comment rulemaking.' " *Catholic Health*, 617 F.3d at 495 (quoting *Hoctor* v. *USDA*, 82 F.3d 165, 170-171 (7th Cir. 1996)).

B. The Payment Denial Policy Is A Substantive Rule.

The Payment Denial Policy is a substantive rule, and accordingly CMS's failure to subject it to notice-and-comment rulemaking renders it "invalid." *Beverly Health*, 223 F. Supp. 2d at 98-99.

1. "[A]n agency performs a legislative function when it makes 'reasonable but arbitrary (not in the arbitrary or capricious sense) rules' " that are "not derived" from the statute or regulation under which they are promulgated in the sense that " 'they represent an arbitrary choice among methods of implementation.' " *Catholic Health*, 617 F.3d at 495 (quoting *Hoctor*, 82 F.3d at 170-171). That describes the Payment Denial Policy perfectly. Even if its line-drawing were permissible under the statute—which it is not—it clearly would "represent an arbitrary choice among methods of implementation." *Id.* Nothing in the Medicare Act requires CMS to draw the line where it has. Its policy accordingly amounts to a substantive rule.

Indeed, this Court has held that Medicare policies amount to substantive rules, and has struck them down for failure to undergo notice and comment, in situations very similar to this one. In *Duggan*, 691 F. Supp. 1487, for example, the Court (per Judge Sporkin) faced a challenge to a Medicare policy that limited coverage for home health care. *Id.* at 1490. Plaintiffs alleged that the policy was contrary to the statute because it denied payment for what should be

covered care. *Id.* Plaintiffs also alleged that the agency's own adjudicators consistently refused to apply the unlawful policy but that the agency persisted in hewing to the policy anyway, thus placing beneficiaries on a "merry-go-round" of pointless administrative appeals. *Id.* at 1507. And plaintiffs alleged that the Medicare policy was arbitrary and capricious because it had not undergone notice-and-comment rulemaking. *Id.* at 1514.

The Court agreed on all three points. *Id.* at 1508-14. As to the last, it explained that the challenged policy "effectively circumscribes administrative discretion and is determinative of issues or rights to which it is addressed," and that "Medicare Fiscal intermediaries are bound by defendants' policy." *Id.* For both reasons, the policy amounted to a "substantive" or "legislative" rule, not merely an interpretation. *Id.* at 1514 n.44. And yet the policy had not been subjected to notice-and-comment rulemaking. The Court explained that that sufficed to render the rule invalid: "The promulgation of a 'rule' requires adherence to the notice-and-comment procedures of the APA, which were not followed in this case." *Id.* at 1514. Just so here.

2. CMS presumably will argue that its policy falls within the notice-and-comment exceptions for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(3)(A). That argument should be rejected. None of the exceptions applies.

Interpretive Rule. The Payment Denial Policy is not an interpretive rule. "To fall within the category of interpretive, the rule must derive a proposition from an existing document whose meaning compels or logically justifies the proposition. The substance of the derived proposition must flow fairly from the substance of the existing document." *Catholic Health*, 617 F.3d at 494 (quotation marks omitted). The Payment Denial Policy cannot be described in these terms. It

does not "derive a proposition from an existing document whose meaning compels or logically justifies the proposition," *id.*, because the distinctions it draws—no Part B payment after a Part A denial, except for ancillary services—spring from nowhere. No statute or regulation of which we are aware compels any such line-drawing. The policy accordingly is not interpretive. As the D.C. Circuit put it, where "the rule cannot fairly be seen as interpreting a statute or a regulation," it is " 'not an interpretive rule exempt from notice-and-comment rulemaking.' " *Id.* (quoting *Central Tex. Tel. Coop.* v. *FCC*, 402 F.3d 205, 212 (D.C. Cir. 2005)).

General Statement of Policy. The Payment Denial Policy likewise cannot fall within the "general statement of policy" exception (notwithstanding the exception's name). A general statement of policy " 'is not finally determinative of the issues or rights to which it is addressed. . . . [It] announces the agency's tentative intentions for the future." *Panhandle Eastern Pipe Line Co.* v. FERC, 198 F.3d 266, 269 (D.C. Cir. 1999) (quoting *Pacific Gas & Electric Co.* v. *Federal Power Comm'n*, 506 F.2d 33, 38-39 (D.C. Cir. 1974)). Thus where the rule "grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests," it is not a general statement of policy. *Troy Corp.* v. *Browner*, 120 F.3d 277, 287 (D.C. Cir. 1997) (quotation marks omitted); *accord National Ass'n of Broadcasters* v. *FCC*, 569 F.3d 416, 426 (D.C. Cir. 2009). The Payment Denial Policy clearly is not a general statement of policy under these definitions. Far from announcing "tentative intentions for the future," it provides a hard-and-fast rule, binding on CMS contractors, that forbids Part B reimbursement for hospitals nationwide.

Rule of Agency Organization, Procedure, or Practice. Nor can the Payment Denial Policy fit within the final notice-and-comment exception. The "critical fact" for determining whether a rule is procedural or substantive is whether it alters the "substantive standards" by

which the agency evaluates a request. *JEM Broad. Co.* v. *FCC*, 22 F.3d 320, 327 (D.C. Cir. 1994); *Aulenback, Inc.* v. *Fed. Highway Admin.*, 103 F.3d 156, 169 (D.C. Cir. 1997). Because the Payment Denial Policy sets forth a substantive standard—delineating which services are reimbursable—it is not merely a procedural rule.[15]

For all of these reasons, CMS was required to subject the Payment Denial Policy to notice-and-comment rulemaking, and it did not do so. The policy is invalid because it was promulgated "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). This Court should grant Plaintiffs summary judgment on Count IV of the Complaint.

V. THE PAYMENT DENIAL POLICY IS INVALID BECAUSE IT WAS NOT PROMULGATED AS A REGULATION.

Just as the Payment Denial Policy is invalid under the APA because it did not undergo notice-and-comment rulemaking, it is also invalid under the Medicare Act itself. 42 U.S.C. § 1395hh(a)(2) expressly forbids the Secretary from promulgating any "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 subchapter . . . unless it is promulgated by the Secretary" as a regulation—*i.e.*, through notice-and-comment rulemaking.

Many circuits have held that this provision "imposes no standards greater than those established by the APA." *Baptist Health* v. *Thompson*, 458 F.3d 768, 776 n.8 (8th Cir. 2006);

[15] The APA has a separate exception for situations where it would be "impracticable, unnecessary, or contrary to the public interest" to engage in notice-and-comment rulemaking. 5 U.S.C. § 553(b). This exception is clearly inapplicable. It "excuses notice and comment in emergency situations," *Jifry* v. *FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004), and with respect to "routine determination[s], insignificant in nature and impact, and inconsequential to the industry and to the public." *Utility Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2010). This case fits neither description. It is not an emergency, and the Payment Denial Policy's rule of denying hospitals the bulk of their Part B payments in Part A-denial cases is far from inconsequential. *See supra* at 10.

see also Yale-New Haven Hosp. v. *Leavitt*, 470 F.3d 71, 75 (2d Cir. 2006) (calling § 1395hh(a) a "reframing of settled law under the Administrative Procedure Act"); *Erringer* v. *Thompson*, 371 F.3d 625, 633 (9th Cir. 2004) (rejecting an argument that § 1395hh(a)(2) "creates a requirement for promulgation by regulation broader than that of the APA"). But neither does it lower the rulemaking bar in any substantial way. While the D.C. Circuit has thus far declined to determine with certainty whether Section 1395hh(a)(2) "creates a more stringent obligation" than the APA or "whether it somehow changes the dividing line between legislative and interpretive rules," *Monmouth Med. Ctr.* v. *Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001), it has made clear that the provision "adopted an exemption at least *similar* in scope to that of the APA." *Id.* (emphasis in original). That is so because "the Medicare Act was drafted after the APA" and because Section 1395hh "reference[s] to interpretive rules without any further definition." *Id.*; *accord Warder* v. *Shalala*, 149 F.3d 73, 79 n.4 (1st Cir. 1998) (adopting similar approach).

The Medicare Act's rulemaking requirements, in short, are at least akin to those of the APA. And so, because the Payment Denial Policy is neither an interpretive rule, nor a procedural rule, nor a general policy statement, *see supra* at 33-34, it amounts to a "substantive legal standard" subject to § 1395hh(a)'s notice-and-comment requirements. *See Monmouth Med. Ctr.*, 257 F.3d at 814. Just as Plaintiffs are entitled to judgment as a matter of law on Count IV of their Complaint, they are entitled to judgment on Count V, too.

VI. EVEN IF THE PAYMENT DENIAL POLICY WERE VALID, PLAINTIFFS WOULD BE ENTITLED TO PAYMENT UNDER SECTION 1879.

Finally, even if the Payment Denial Policy were valid, the Plaintiff hospitals would be entitled to payment in this case under Section 1879, codified as 42 U.S.C. § 1395pp(a). Under Section 1879, where "a determination is made" that "payment may not be made under part A or part B," the provider nonetheless is entitled to payment if it "did not know, and could not

reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B[.]" 42 U.S.C. § 1395pp(a). The provision applies here, and entitles the hospitals to payment, for two reasons.

1. First, CMS's inpatient-admission guidelines give hospitals so little guidance that Plaintiff hospitals cannot be said to have been on notice that their claims would later be denied. The ALJ in Dignity's case reached a contrary conclusion, rejecting Dignity's Section 1879 claims on the ground that CMS's "inpatient hospital admission criteria" provided the requisite notice. Ex. B, *ALJ Notice of Decision*, at B-10. But that is clearly not so. The CMS "criteria" to which the ALJ is referring concede on their face that "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*, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting." MBPM Ch. 1, § 10 (emphasis added). The manual then lists a non-exclusive set of factors—"[t]he severity of the signs and symptoms exhibited by the patient," "[t]he medical predictability of something adverse happening to the patient," etc.—with no guidance about how to balance them in any particular case. *Id.* That tells hospitals next to nothing about how to treat particular cases.

Indeed, CMS has come close to admitting as much. The agency wrote in a recent proposed rule that it was seeking to "improve clarity and consensus among providers, Medicare, and other stakeholders" regarding "when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient." *OPPS Rule*, 77 Fed. Reg. at 45,155. To that end, it wrote, it was "interested in receiving public comments and suggestions regarding whether and how we might improve our current instructions" on inpatient admissions, "*keeping in mind the challenges of*

implementing national standards that are broad enough to contemplate the range of clinical scenarios but prescriptive enough to provide greater clarity." *Id.* at 45,157 (emphasis added).

In plaintiff Dignity's case, its attending physician admitted a 79-year-old patient with a heart rhythm disorder who came to the hospital to have a pacemaker permanently implanted. Ex. B, at B-3. Nothing in CMS's inpatient admissions criteria offered Dignity any guidance on how to handle that particular case, or any reason to believe a RAC would overrule its attending physician's considered judgment that the woman should be admitted as an inpatient. The ALJ's contrary conclusion was erroneous.

2. Second, Dignity and the rest of the Plaintiff hospitals are entitled to payment under Section 1879 in light of the unbroken string of favorable DAB decisions discussed *supra* at 26-30. The provision entitles hospitals to payment so long as they "*did not know*, and could not reasonably have been expected to know, *that payment would not be made* for such items or services under such part A or part B[.]" 42 U.S.C. § 1395pp(a) (emphases added). That well describes the state of hospitals' knowledge in every short-term-admission denial case since the DAB began issuing its string of decisions granting providers Part B payment. After all, hospitals know, and have known for some time now, that payment *will* be made—if they persevere all the way through the laborious administrative process. They accordingly "did not know, and could not reasonably have been expected to know, that payment would *not* be made." *Id.* (emphasis added). Section 1879 applies by its terms.

CONCLUSION

Medicare "is, to put it mildly, a complex program with reams of statutory provisions and regulations." *Allina*, 2012 WL 5565453, at *1. The Secretary in past cases has "[b]ank[ed] on this complexity to execute a fancy two-step," trying to convince this Court to "excuse[ ] a lack of

proper rulemaking" and lack of explanation for the Secretary's statutory interpretations. *Id.* The Court has rejected such attempts before, *see id.*, and it should reject them again here. Plaintiffs' Motion for Summary Judgment should be granted.

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Respectfully submitted,

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