

Plaintiffs' claims are grounded in facts conclusively established by the administrative record, or lack thereof; no genuine issues of material fact prevent the Court from granting Plaintiffs summary judgment as a matter of law. *See* Fed. R. Civ. P. 56(c).

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INTRODUCTION

Plaintiffs bring this action to challenge an unlawful Medicare policy: The Centers for Medicare & Medicaid Services (“CMS”) has slashed Medicare payments to hospitals across the board by 0.2 percent, and it has done so without any basis in law. A 0.2 percent cut may sound small, but it is not—it will deprive the nation’s hospitals of more than \$200 million, by CMS’s own estimation. The payment cut should be vacated as arbitrary, capricious, and otherwise unlawful.

As described below, CMS imposed the cut to address changes in Medicare payment patterns arising from a new definition of what constitutes an “inpatient.” When a patient comes to a hospital for treatment, the attending physician must decide whether to admit the individual as an inpatient or provide treatment on an outpatient basis. The classification has financial ramifications: Under federal law, Medicare typically must pay a hospital that cares for a Medicare patient on an *inpatient* basis more than it would if the hospital cared for the patient on an *outpatient* basis.

Obviously, then, the definition of the term “inpatient” helps determine how much Medicare pays. And that definition recently changed. CMS long instructed that patients generally are inpatients if they are expected to be in the hospital overnight. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates, 78 Fed. Reg. 27,486, 27,645 (proposed May 10, 2013) (attached hereto as Ex. A). Thus, CMS told physicians to “use a 24-hour period as a benchmark.” *Id.* Last year, however, CMS changed that guidance: It adopted a new policy under which a Medicare patient must be expected to need hospitalization for at least *two* midnights—that is, a day and night, a second day, and a second night until at least

midnight—before the patient can be admitted as, and billed to Medicare as, an inpatient.

Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates, 78 Fed. Reg. 50,496, 50,944 (Aug. 19, 2013) (attached hereto as Ex. B). Put another way, patients often must be in the hospital for anywhere from 36 to 48 hours before they are “inpatients,” instead of 24 hours as before.

That new definition makes it more difficult to categorize patients as “inpatients.” And since Medicare generally pays more for hospitals to treat inpatients as opposed to outpatients, the logical result should be that the new policy drives Medicare payments to hospitals *down*. Yet, in the same rulemaking in which it adopted the new definition of inpatient, CMS somehow concluded that the new definition will drive Medicare payments to hospitals *up*. Specifically, CMS concluded that there will be a net increase in inpatient stays and that CMS will be required to pay hospitals an additional \$220 million over a one-year time period. For this reason, it slashed reimbursement rates by \$220 million—or 0.2 percent across almost all of our nation’s hospitals—to offset the supposed additional cost (the “0.2 Percent Payment Cut”).

CMS’s decision to impose the 0.2 Percent Payment Cut defies common sense. But more to the point, it is arbitrary and capricious and in violation of the Medicare Act, 42 U.S.C. §§ 1395 *et seq.*, and the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 551 *et seq.*, for a host of reasons. Each provides an independent basis on which the Court can and should conclude that the 0.2 Percent Payment Cut is invalid and must be vacated.

First, in the proposed rule, CMS failed to reveal any of the assumptions or methodology that led it to conclude that its new definition of “inpatient” will somehow lead to *more* Medicare spending. Instead, it simply announced its conclusion that more cases would shift from

outpatient to inpatient than vice versa, with no further details. That failure to explain violated the APA's notice-and-comment procedures. *See* 5 U.S.C. § 553(b)(3). Agencies have a duty to make available to the public their data and reasoning in proposed rules. CMS's failure to do so precluded hospitals and other interested parties from engaging in any meaningful notice-and-comment process.

Second, even after numerous commenters complained about the proposed rule's failure to explain the rationale for the 0.2 Percent Payment Cut, and alerted CMS that they could not replicate its results, CMS *still* failed to explain its calculations in the final rule. Keeping all the details under wraps, CMS instead made matters worse by belatedly acknowledging two major, and previously undisclosed, assumptions behind its still-unexplained calculations—assumptions that, had they been revealed in the proposed rule, would have drawn heavy criticism. That combination of silence and belated revelations not only underscores CMS's violation of notice-and-comment procedures, but it also amounts to a classic APA violation in its own right. To satisfy the arbitrary-and-capricious standard, an agency must “articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’ ” *American Trucking Ass'ns, Inc. v. FMCSA*, 724 F.3d 243, 246 (D.C. Cir. 2013) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). That means courts “cannot uphold a rule based on a [statistical] model when an important aspect of its methodology was wholly unexplained.” *Id.* That is this case. Moreover, as part of their duty to provide a reasoned explanation, agencies must “respond to relevant and significant public comments.” *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 212 (D.C. Cir. 2011). CMS failed in that respect too.

The 0.2 Percent Payment Cut is also arbitrary and capricious because when CMS finally revealed a few of its assumptions in the final rule, those assumptions proved indefensible. As described below, they caused CMS both to undercount the volume of cases that would shift from inpatient to outpatient and overestimate the number of cases that would shift from outpatient to inpatient. For that reason, too, the 0.2 Percent Payment Cut must be invalidated. When an agency adopts a methodology that appears arbitrary on its face and “generate[s] seemingly implausible results,” its rule cannot withstand judicial review—at least not where, as here, it fails to explain away the facial implausibility. *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1035 (D.C. Cir. 2001).

Third, the policy violates both the Medicare Act and the APA because CMS failed to promulgate the 0.2 Percent Payment Cut as a regulation, as required by 42 U.S.C. § 1395hh(a) and § 1395ww(d)(5)(I)(i). Rather than codifying the policy in the Code of Federal Regulations, CMS only described the reduction in the preamble to the final rule. This simply does not suffice because it is well-established that a preamble is not a regulation. This procedural flaw provides yet another reason why the 0.2 Percent Payment Cut cannot stand.

For these reasons, this Court should grant Plaintiffs’ motion for summary judgment and vacate the 0.2 Percent Payment Cut.

FACTUAL BACKGROUND¹

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).

The Medicare program is divided into four parts, A through D. Parts A and B are the only parts relevant to this proceeding. Part A, the hospital insurance program, provides for reimbursement of inpatient hospital services. 42 U.S.C. §§ 1395c-1395i-5. Part B, the supplemental medical insurance program, pays for various “medical and other health services” not covered by Part A, including physician services and hospital outpatient services. *Id.* § 1395k(a); *id.* §§ 1395j-1395w-4j. Not surprisingly, the amount of Part A reimbursement a hospital receives for treating a patient on an inpatient basis is typically higher than the amount of

¹ Pursuant to Local Rule 7(h)(2), Plaintiffs have not attached a separate statement of undisputed facts because “[i]n cases where judicial review is based solely on the administrative record, however, a Statement of Undisputed Facts is not required.” *See Grunewalv v. Jarvis*, 930 F. Supp. 2d 73, 81 n.2 (D.D.C. 2013). Rather, in cases involving judicial review of agency actions, the parties cite to the administrative record. *See Deppenbrook v. Pension Ben. Guar. Corp.*, 950 F. Supp. 2d 68, 71 n.2 (D.D.C. 2013) (Walton, J.). Because Defendant has not yet filed the administrative record in this case, Plaintiffs cite to administrative-record documents directly by citation and exhibits. For the convenience of the Court, Plaintiffs have attached the relevant pages from the Federal Register publication of the proposed rule as Exhibit A and the final rule as Exhibit B. Plaintiffs also have attached a document from the administrative record, The Moran Company, *Two Midnights: Implausible Assumptions and Lack of Detail Lead to Problems in Analysis* (2014), as Exhibit C. Plaintiffs recognize that the Court may want them to re-file this memorandum with AR citations once the administrative record is filed.

reimbursement the hospital would receive under Part B for treating the person on an outpatient basis. *See* 78 Fed. Reg. at 50,953.

The Plaintiff hospitals are reimbursed on a prospective basis for the inpatient care they provide to Medicare beneficiaries according to a detailed formula that is prescribed by the Medicare Act. *See* 42 U.S.C. § 1395ww(d)(5). CMS implements this formula to calculate the prospective payment amount paid for each Medicare discharge, which is based on the Medicare Severity Diagnosis-Related Group (“MS-DRG”) that corresponds to the beneficiary’s clinical condition and treatment provided. *See id.* § 1395ww(d); 42 C.F.R. §§ 412.60, 412.64, 412.100-.374. The specific algorithm for calculating the MS-DRG payment for each Medicare discharge varies depending on the characteristics of the particular hospital, market conditions in the hospital’s location, and the beneficiary’s clinical condition. *See, e.g.*, 42 C.F.R §§ 412.90(a), 412.92(d), 412.60, 412.64(c). If the Secretary wishes to make “exceptions or adjustments” to those prospective payment amounts, she “shall” do so “by regulation.” 42 U.S.C. § 1395ww(d)(5)(I)(i); *see also* 42 U.S.C. § 1395hh(a)(1) (“No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, [or] the payment for services, . . . shall take effect unless it is promulgated by the Secretary by regulation . . .”).

B. The Proposed Rule

On May 10, 2013, CMS published a proposed rule governing Medicare payment policy under the inpatient prospective payment system (“IPPS”) for federal fiscal year 2014 (“IPPS Proposed Rule”). Among other things, the IPPS Proposed Rule introduced significant changes to CMS’s guidelines about when a Medicare beneficiary should be admitted to the hospital as an inpatient. 78 Fed. Reg. at 27,648.

CMS has long recognized that the decision to admit a patient is a “complex medical judgment” that involves the consideration of many factors. *Id.* at 27,645. CMS has instructed hospitals and physicians that “generally, a beneficiary is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight, whether or not the beneficiary is later discharged or transferred and is not present overnight.” *Id.* Thus, according to CMS, a physician or other practitioner should “use a 24-hour period as a benchmark, that is, [physicians] should order admission for patients who are expected to need hospital care for 24 hours or more[.]” *Id.*

But in the IPPS Proposed Rule, CMS proposed to establish a presumption, whereby admission is “generally appropriate” when the physician expects the patient to receive care in the hospital for a period spanning two midnights—i.e., always more than 24 hours, and depending on the time the patient arrives at the hospital, in some cases nearly 48 hours. Conversely, CMS wrote that hospital admission is “generally inappropriate” when the physician expects the patient to require care for less than two midnights. *Id.* at 27,648.

As already discussed, that change logically should result in *fewer* inpatient admissions—many thousands of patients who are expected to be in the hospital for somewhere between 24 and 48 hours will now be outpatients, instead of inpatients—and thus reduce Medicare spending, as Medicare will reimburse hospitals at the lower outpatient payment rates. And yet CMS predicted exactly the opposite in the IPPS Proposed Rule: It wrote that it thought the new definition would produce a net *increase* of 40,000 inpatient stays. Here is its explanation of how it derived that figure, set forth in its entirety:

[CMS foresees] an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the [prospective payment amounts paid to hospitals for outpatients under the outpatient prospective payment system (OPPS)], and some encounters of less

than 2 midnights moving from the IPPS to the OPSS. Specifically, our actuaries examined FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters and estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters.

78 Fed. Reg. at 27,649. CMS did not explain how its actuaries arrived at these estimates, what criteria they used to determine the cases that would “shift,” what universe of cases they examined, or anything else about their calculation or methodology. Instead, having announced its bare-bones numerical conclusion, CMS asserted that the “net shift of 40,000 encounters” would cost Medicare “approximately \$220 million.” *Id.* CMS announced that it therefore was proposing to use its statutory adjustment authority to offset the loss by cutting IPPS payment amounts by 0.2 percent for all hospitals. *Id.* at 27,650.

C. Hospital Comments and the Final Rule

Hospitals and other commenters quickly reacted by pointing out that CMS’s proposed payment cut was wholly unexplained, making it impossible for them to critique the agency’s methodology. As CMS itself acknowledged when it described those comments in its Final Rule, the commenters told CMS that its proposed payment cut “was unsupported and insufficiently explained to allow for meaningful comment.” 78 Fed. Reg. at 50,508 (“IPPS Final Rule”). In particular, hospitals and other commenters—including many of the Plaintiffs in this case—asked CMS to explain how a policy that makes it *harder* to justify inpatient treatment and requires an inpatient stay to last longer could result in *more* inpatient cases. They noted that CMS had not revealed its data, methodology, or assumptions underlying the payment cut, and they asked CMS to reveal that information so they could provide informed comments. *See id.* At least one commenter also noted that it had attempted to replicate CMS’s conclusion about the net shift of patient encounters using publicly available data and it could not do so. Letter from Adventist

Health System/Sunbelt, Inc. et al. to CMS Administrator Marilyn Tavenner Regarding CMS Proposed Rule CMS-1599-P, at 10 (June 25, 2013) (“IPPS Comment Letter”).²

In response, CMS kept mum. The agency published the IPPS Final Rule in the Federal Register on August 19, 2013. The preamble to that rule adopted the 0.2 Percent Payment Cut. 78 Fed. Reg. at 50,953. And CMS once again refused to reveal most details of its methodology or calculations. Nor did it engage with the commenters’ critiques of its model. Instead, CMS wrote that it “disagreed” with commenters who said it had failed to explain its methodology in arriving at a 40,000 net shift from outpatient to inpatient in the IPPS Proposed Rule. *Id.* But as proof that it had revealed sufficient methodological detail to allow for meaningful comment, all CMS could offer was the same conclusory description it had included in the proposed rule itself—a description that revealed nothing of substance about its methodology:

In the . . . proposed rule (78 FR 27649), we specifically discussed the methodology used and the components of the estimate. Our actuaries examined FY 2009 to FY 2011 claims data. Based on this examination, we stated the number of encounters our actuaries estimated would shift from inpatient to outpatient (360,000) and the number of encounters they estimated would shift from outpatient to inpatient (400,000).

Id.

CMS did, however, belatedly identify at least *some* of its actuaries’ assumptions in the IPPS Final Rule. First, CMS wrote that “[i]n determining the estimate of the number of encounters that would shift from outpatient to inpatient, our actuaries examined outpatient claims for observation or a major procedure. Claims not containing observation or a major procedure were excluded.” *Id.* Second, CMS stated that “[i]n determining the estimate of the number of encounters that would shift from inpatient to outpatient, our actuaries examined inpatient claims containing a surgical MS–DRG. Claims containing medical MS–DRGs were excluded.” *Id.* In

² Available at <http://www.regulations.gov/#!documentDetail;D=CMS-2013-0084-0450>.

other words, CMS categorically excluded medical MS-DRGs when calculating the shift from inpatient to outpatient, but included observation cases (cases involving not-yet-diagnosed conditions that are most like the medical MS-DRGs) when calculating the shift from outpatient to inpatient. CMS did not explain why its actuaries had excluded a vast swath of cases—the hundreds of thousands of inpatient claims containing medical MS-DRGs—from their calculation of how many cases would shift to outpatient, or the effect that analytical limitation had on their results.

D. Plaintiffs' Efforts to Seek Relief from Substantial Harm

As of October 1, 2103, the 0.2 Percent Payment Cut, began reducing reimbursement to hospitals caring for Medicare patients. The cut has inflicted, and continues to inflict, substantial harms on hospitals across the country.

In an effort to seek relief from this policy, on January 23, 2014, each Plaintiff hospital timely requested a group or individual hearing by the Provider Reimbursement Review Board (PRRB), seeking expedited judicial review pursuant to 42 U.S.C. § 1395oo(f)(1). *See* Compl. at 69-88, *AHA et al. v. Sebelius*, Case No. 1:14-cv-00607 (D.D.C. Apr. 14, 2014), ECF No. 1. On March 20, 2014, the PRRB granted the Plaintiff hospitals' requests for expedited judicial review. *Id.* That PRRB ruling gave Plaintiffs statutory authorization to challenge the 0.2 Percent Payment Cut in federal court, and gave this Court jurisdiction to adjudicate that challenge. *See* 42 U.S.C. § 1395oo(f)(1).

SUMMARY OF ARGUMENT

CMS's 0.2 Percent Payment Cut is based on the premise that a policy that makes it *more difficult* for a Medicare beneficiary to qualify as an inpatient will produce an *increase* in the number of inpatient cases. That premise is both highly implausible and wholly unexplained.

And the resulting policy is unlawful for at least three separate reasons. First, CMS failed in the IPPS Proposed Rule to reveal *anything* about its methodology or calculations, thus precluding hospitals from engaging in meaningful notice and comment. Second, in the IPPS Final Rule CMS failed to explain its assumptions and methodology in anything approaching enough detail to allow for meaningful judicial review, and similarly failed to respond to commenters who challenged its model—both textbook APA violations. Even setting aside its failures to explain itself, CMS’s payment cut is still arbitrary and capricious because the agency relied on indefensible assumptions to reach its results. Finally, the payment cut violates the Medicare Act and the APA because CMS failed to promulgate the 0.2 Percent Payment Cut as a regulation, as required by 42 U.S.C. § 1395hh(a) and § 1395ww(d)(5)(I)(i).

This Court can, and should, invalidate the 0.2 Percent Payment Cut on any or all of these grounds and should order CMS to recalculate the Medicare IPPS payment amounts for federal fiscal year 2014 accordingly.

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.” *Hosp. of Univ. of Pa. v. Sebelius*, 847 F. Supp. 2d 125, 133 (D.D.C. 2012). Instead, in such a 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.*; see also *Kaiser Found. Hospitals v. Sebelius*, 828 F. Supp. 2d 193, 198 (D.D.C. 2011) *aff’d*, 708 F.3d 226 (D.C. Cir. 2013) (same).

Under the APA, courts must “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law,” or that are adopted “without observance of procedure required by law.” 5 U.S.C. § 706(2)(A), (D).

ARGUMENT

I. The 0.2 Percent Payment Cut Is Invalid Because CMS Failed to Provide Adequate Notice or a Meaningful Opportunity to Comment as Required by the APA.

The 0.2 Percent Payment Cut is invalid, first of all, because in its proposed rule CMS failed entirely to reveal the calculations or methodology underlying the proposed payment reduction. That failure violated the APA by preventing commenters from critiquing or otherwise joining issue with CMS’s proposal—in other words, by foreclosing meaningful notice and comment.

The APA requires an agency that undertakes rulemaking to provide notice of “either the terms or substance of the proposed rule” and an “opportunity to participate in the rule making through submission of written data, views, or arguments.” 5 U.S.C. § 553(b)(3),(c). The D.C. Circuit has explained that “[i]ntegral to the notice requirement is the agency’s duty ‘to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules.’ ” *Solite Corp. v. EPA*, 952 F.3d 473 (D.C. Cir. 1991) (citation omitted). Thus, it is black-letter law that “an agency cannot rest a rule on data ‘that, [in] critical degree, is known only to the agency.’ ” *Time Warner Entertainment Co., L.P. v. FCC*, 240 F.3d 1126, 1140 (D.C. Cir. 2001) (quoting *Community Nutrition Inst. v. Block*, 749 F.2d 50, 57 (D.C. Cir. 1984)); accord *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir.

2008); *Wisconsin Power & Light Co. v. F.E.R.C.*, 363 F.3d 453, 463 (D.C. Cir. 2004).

CMS's failure to identify or explain its actuaries' methodology or assumptions in the IPPS Proposed Rule plainly runs afoul of that APA requirement. CMS revealed only two points relevant to its key conclusion of a net outpatient-to-inpatient shift: that its actuaries looked at three years of claims data, and that they concluded based on those data that there would be a "net shift of 40,000 encounters." 78 Fed. Reg. at 27,649. That information falls laughably short of allowing meaningful rejoinders or critiques. Among other things, it does not tell regulated entities what specific claims data the actuaries included in their review, what data they excluded, what factors they thought relevant in identifying cases that might shift, or how they evaluated those factors. All of that basic information was "[in] critical degree . . . known only to the agency." *Time Warner*, 240 F.3d at 1140.

American Radio Relay is similar. In that case, the FCC refused to reveal, either in its notice of proposed rulemaking or its final rule, "five scientific studies consisting of empirical data gathered from field tests" on which it relied in arriving at its policy. 524 F.3d at 237. The FCC made portions of the studies available to the public in the rulemaking record, but redacted certain sections on the basis that " 'they represent preliminary or partial results or staff opinions that were part of the deliberate process, exempt from disclosure under . . . the [Freedom of Information Act].' " *Id.* (citation omitted). The D.C. Circuit rejected that argument and invalidated the rule. *Id.* It wrote: "Under APA notice and comment requirements, '[a]mong the information that must be revealed for public evaluation are the 'technical studies and data' upon which the agency relies [in its rulemaking].' " *Id.* at 235 (alteration in original; citation omitted). "By requiring the most critical factual material used by the agency be subjected to informed comment," the court explained, "the APA provides a procedural device to ensure that agency

regulations are tested through exposure to public comment, to afford affected parties an opportunity to present comment and evidence to support their positions, and thereby to enhance the quality of judicial review.” *Id.* at 236. It concluded: “It would appear to be a fairly obvious proposition that *studies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment.*” *Id.* at 237 (emphasis added).

Here, there is no doubt that the analysis performed by CMS’s actuaries was “critical factual material” on which CMS relied in crafting the 0.2 Percent Payment Cut. *See id.* at 239. Indeed, CMS’s proposal to enact the 0.2 Percent Payment Cut turned entirely on its actuaries’ predictions that the “two midnights” inpatient definition would cause a net shift of 40,000 patient encounters from outpatient to inpatient, and would in turn result in an estimated \$220 million increase in IPPS expenditures. 78 Fed. Reg. at 27,649. And yet CMS refused to disclose its actuaries’ assumptions, the factual basis for those assumptions, or any explanation for how the actuaries counted the cases that would shift in each direction. Without that information, hospitals and other stakeholders—including the Plaintiffs in this case—could not meaningfully critique the actuaries’ estimates or attempt to reproduce or assess the reliability of CMS’s results. *See* IPPS Comment Letter, *supra*. The two assumptions CMS belatedly revealed in the IPPS Final Rule, *see infra* at 15, are good examples. Had CMS revealed these assumptions earlier, it would not have cured CMS’s failure to provide adequate notice: too many other aspects of the actuaries’ methodology and calculations would have remained unexplained. But it at least would have allowed commenters to engage with the agency’s analysis in some respect and attempt to demonstrate that it was flawed. The failure to reveal those assumptions until the Final Rule made that impossible.

CMS, in short, failed to reveal any assumptions or calculations in the IPPS Proposed Rule, and the Plaintiffs, left unable to grapple with CMS's analysis, "suffered prejudice from the agency's failure to provide an opportunity for public comment." *See American Radio Relay*, 542 F.3d at 236, 238 (citation omitted).

That is exactly the type of hollow rulemaking process that the D.C. Circuit has condemned. *See Connecticut Light & Power Co.*, 673 F.2d 525, 530 (D.C. Cir. 1982) ("To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport."). This Court should set aside the 0.2 Percent Payment Cut under the APA.

II. The 0.2 Percent Payment Cut Is Arbitrary and Capricious Because CMS Did Not Provide a Reasoned Explanation of Its Methodology and Relied on Indefensible Assumptions.

The 0.2 Percent Payment Cut is also unlawful for a second reason: the Final Rule is arbitrary and capricious in several respects. First, CMS again failed to explain its actuaries' methodology or calculations in the IPPS Final Rule, and to the extent it finally revealed a few (though far from all) of the assumptions those actuaries adopted, it failed to explain *why* the actuaries adopted them. Second, CMS failed to respond with a detailed explanation when a commenter questioned its model. Third, the minimal information that CMS did reveal in the IPPS Final Rule shows that it made assumptions that appear indefensible. Each of these failures separately renders the 0.2 Percent Payment Cut arbitrary and capricious in violation of the APA.

A. CMS Failed to Provide a Reasoned Explanation of Its Methodology.

To satisfy the arbitrary-and-capricious standard, an agency must "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice

made.’ ” *American Trucking*, 724 F.3d at 246 (quoting *State Farm*, 463 U.S. at 43). That explanation must be “sufficient to enable [the court] to conclude that the [agency’s action] was the product of reasoned decisionmaking.” *Id.* (quoting *State Farm*, 463 U.S. at 52). The D.C. Circuit has explained exactly how that test applies to agency rules based on models or other data-driven analysis: Courts “cannot uphold a rule based on a [statistical] model when an important aspect of [the model’s] methodology was wholly unexplained,” or when the agency “failed to provide a reasoned explanation for a number of the methodology’s critical elements.” *Id.*; *see also Appalachian Power*, 251 F.3d at 1035 (stating that agency must “explain the assumptions and methodology used in preparing the model”); *Advanced Micro Devices v. C.A.B.*, 742 F.2d 1520, 1523 (D.C. Cir. 1984) (rejecting agency rate-approval order where agency failed to “advert to the data and methods of calculation it used in such a way as to allow rate opponents and reviewing courts to understand how the Board reached its conclusions”). As the D.C. Circuit wrote in *Appalachian Power*: “With its delicate balance of thorough record scrutiny and deference to agency expertise, judicial review can occur only when agencies explain their decisions with precision, for ‘it will not do for a court to be compelled to guess at the theory underlying the agency’s action[.]’ ” 251 F.3d at 1035 (citation omitted).

The 0.2 Percent Payment Cut is invalid under these precedents. In the IPPS Final Rule—much like the IPPS Proposed Rule—CMS revealed only that its actuaries had looked at three years of claims data and concluded that 400,000 cases would shift in one direction (outpatient to inpatient) and 360,000 would shift the other way. *See* 78 Fed. Reg. at 27,649. But that is a far cry from providing enough information “to allow . . . opponents and reviewing courts to understand how the [agency] reached its conclusions.” *Advanced Micro Devices*, 742 F.2d at 1523. How did CMS’s actuaries determine which cases might shift, and in which direction?

What criteria did they use? Were those criteria based on the type of treatment a patient received? Other factors? How were they weighed? There is no way for this Court to know. “[A]n important aspect of [the model’s] methodology” accordingly “was wholly unexplained,” *American Trucking*, 724 F.3d at 246, and the Court would be “compelled to guess at the theory underlying the agency’s action[.]” *Appalachian Power*, 251 F.3d at 1035.

To be sure, the agency did reveal two small components of its methodology in the Final Rule: that its actuaries “examined outpatient claims for observation or a major procedure” in deciding which claims would shift from outpatient to inpatient, and “examined inpatient claims containing a surgical MS–DRG,” but not a medical MS-DRG, in deciding which claims would shift the other way. But that late-breaking revelation does not help CMS for two reasons. First, it leaves the vast bulk of the actuaries’ methodology still unexplained and impossible to evaluate. And second, even as to the two assumptions CMS revealed, it failed to explain *why* the actuaries adopted those assumptions, and what effect it had on their results. Without that information, it remains impossible for the Court “to conclude that the [agency’s action] was the product of reasoned decisionmaking.” *American Trucking*, 724 F.3d at 246. The 0.2 Percent Payment Cut is arbitrary and capricious and must be vacated.

B. CMS Failed to Adequately Respond to Significant Comments Raised During the Rulemaking Process.

CMS’s failure of explanation also has a second aspect that independently renders the rule invalid: The agency failed to respond to major criticisms raised during the rulemaking process.

CMS was not free simply to ignore objections raised to its proposed 0.2 Percent Payment Cut. “The requirement that agency action not be arbitrary and capricious includes a requirement that the agency . . . respond to relevant and significant public comments.” *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 212 (D.C. Cir. 2011) (quoting *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186,

197 (D.C. Cir. 1993). Specifically, “when a model’s methodology is challenged” by a commenter, “*the agency must ‘provide a complete analytic defense.’*” *American Trucking*, 724 F.3d at 46 (quoting *U.S. Air Tour Ass’n v. FAA*, 298 F.3d 997, 1008 (D.C. Cir. 2002)) (emphasis added). The agency’s failure to respond to significant comments in this way generally “ ‘demonstrates that the agency’s decision was not based on a consideration of the relevant factors,’ ” *Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313 (D.C. Cir. 2014) (quoting *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984)), and that the decision thus was arbitrary and capricious.

CMS fell far short of this standard in the IPPS Final Rule. Despite the lack of information in the IPPS Proposed Rule regarding how CMS’s actuaries reached their conclusion, at least one commenter, writing on behalf of a number of hospitals and health systems, noted that he had attempted to replicate CMS’s conclusion about the net shift of patient encounters using publicly available data and he could not do so. IPPS Comment Letter, *supra*, at 10. In fact, the commenter wrote, the analysis showed the opposite result—an anticipated decrease in inpatient stays that was far greater than the outpatient stays that would shift to the inpatient setting—leading the commenter to conclude that either CMS’s conclusion was erroneous or not adequately explained. *Id.*

Numerous commenters also objected that CMS actuaries’ estimate was “unsupported and insufficiently explained to allow for meaningful comment.” *See* 78 Fed. Reg. at 50,953. In response, CMS said next to nothing. It wrote that it “disagreed” that it had provided inadequate information, but then it simply reiterated, almost verbatim, the inadequate information it had provided before. *See* 78 Fed. Reg. at 50,953. And it made no effort at all to engage with the comment letter saying an independent analysis had reached the opposite result; much less did it

“provide a complete analytic defense” of its model. *American Trucking*, 724 F.3d at 46. That bare-bones information will not do. For that reason, too, the lack of reasoned explanation in CMS’s IPPS Final Rule violates the APA.

C. CMS Relied on Indefensible Assumptions.

The 0.2 Percent Payment Cut also is arbitrary and capricious because, based on what little CMS *did* reveal about its actuaries assumptions in the IPPS Final Rule, those assumptions appear indefensible. And when an agency’s modeling and assumptions “appear arbitrary on their face,” *West Virginia v. EPA*, 362 F.3d 861, 866 (D.C. Cir. 2004), and “generate[] seemingly implausible results,” *Appalachian Power*, 251 F.3d at 1035, the agency action supported by that modeling is arbitrary and capricious—at least absent further agency explanation, which is sorely lacking here. For this reason, too, the 0.2 Percent Payment Cut should be vacated.

1. In the IPPS Final Rule, CMS revealed that its actuaries made at least two major assumptions in calculating the 40,000-encounter net inpatient shift—the quantitative basis for the 0.2 Percent Payment Cut. Most importantly, CMS explained that when its actuaries estimated how many encounters would shift from inpatient to outpatient, they examined only “claims containing a surgical MS-DRG. Claims containing medical MS-DRGs were excluded.” 78 Fed. Reg. at 50,953. In other words, CMS’s calculations ignored an *entire category of cases*—medical cases that do not involve a surgery.

That makes no sense. Perhaps CMS assumed that none of the medical cases would shift to the outpatient setting. But if so, CMS did not explain its thinking at all—and simple logic suggests that CMS could not defend its choice. After all, in surgical cases, it often is easier for a physician to predict how long a patient will be hospitalized and thus to meet the new CMS criterion that physicians may “order admission if [they] expect[] that the beneficiary’s length of

stay will exceed a 2-midnight benchmark.” 78 Fed. Reg. at 50,944. In cases involving medical DRGs, by contrast, the patient often is hospitalized with symptoms that have not yet been diagnosed; in such cases it frequently will be more difficult for a physician definitively to predict how long the patient needs to be hospitalized and thus decide that a patient should be admitted as an inpatient. For example, the treatment provided on an inpatient basis for conditions like heart attacks, circulatory system problems, and concussions and other hard-to-diagnose conditions often corresponds to a “medical” MS-DRG.³ Thus, if anything, the uncertainty involved in predicting the length of time a medical case will require hospitalization means that medical cases would be *more* likely to shift from inpatient to outpatient than surgical cases. There is good reason to believe CMS systematically undercounted the shifts from inpatient to outpatient by considering only surgical cases in its modeling.

Indeed, there is good reason to believe CMS’s undercounting was substantial. According to statistics on the CMS website, there was a total of 1,569,693 inpatient stays of one day or less in calendar year 2011. CMS has stated in guidance regarding the new two-midnights policy that it expects that a “*majority* of short (total of zero- or one-night) Medicare hospital stays will be provided as outpatient services.” CMS, FREQUENTLY ASKED QUESTIONS 2 *Midnight Inpatient Admission Guidance & Patient Status Reviews for Admission on or after October 2013*, Question 13 (emphasis added).⁴ Even assuming that CMS accounted for the discrete categories of short stay cases that will not shift under the new policy—those involving patient deaths, transfers, departures against medical advice, and inpatient only procedures—that should mean

³ See CMS, FY 2014 Final Rule Data Files, Table 5 File, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2014-IPPS-Final-Rule-Home-Page.html> (click on “FY 2014 Tables” and download the “Table 5 File”).

⁴ Available at http://cms.gov?Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting_110413-v2-CLEAN.pdf.

that the total number of cases shifting to outpatient status under the new policy would be far higher than the 360,000 figure CMS announced. This, in turn, would mean a net increase in *outpatient* cases, rather than an increase in *inpatient* cases as CMS claims. Moreover, half of the 1,569,693 short inpatient stays involve medical MS-DRGs.⁵ Indeed, five medical MS-DRGs alone (which correspond to treatment for atherosclerosis, cardiac arrhythmia, syncope, and chest pain) represent nearly 160,000 short stay cases. *Moran Report* at 6. Thus if CMS excluded cases involving medical MS-DRGs from its count, it failed to account for hundreds of thousands of cases that could potentially shift from inpatient to outpatient.

The bottom line: It is simply implausible on its face for CMS's actuaries to assume, as they appear to have done, that not one of these hundreds of thousands of medical cases will shift from the inpatient to the outpatient setting. And CMS's failure to include medical cases appears to have dramatically altered its calculations. By CMS's own logic, CMS should have increased IPPS rates, not decreased them.

2. There also is another obvious problem with CMS's analytical approach: CMS did not impose a similar surgical-cases-only limitation when it counted how many encounters would shift in the other direction, from outpatient to inpatient. Instead, CMS examined "outpatient claims for observation or a major procedure." 78 Fed. Reg. at 50,953. That approach does not track the approach CMS used in counting inpatient-to-outpatient shifts because it *includes* observation cases—cases involving not-yet-diagnosed conditions that are most like the medical MS-DRGs that were categorically *excluded* from the inpatient-to-outpatient count. That

⁵ See CMS, FY 2014 Final Rule Data Files, Table 5 File, *supra* note 3; CMS, FY 2014 Final Rule Data Files, AOR/BOR File, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2014-IPPS-Final-Rule-Home-Page.html> (click on "FY 2014 Data Files" and download the "AOR/BOR File"); The Moran Company, *Two Midnights: Implausible Assumptions and Lack of Detail Lead to Problems in Analysis* 6 (Jan. 22, 2014) ("*Moran Report*") (attached hereto as Ex. C).

disconnect is critical. After all, CMS's decision to impose a 0.2 percent reduction turns entirely on its conclusion that more encounters would shift from outpatient to inpatient than vice versa. *See id.* If CMS used a smaller bucket of cases when it counted the subset shifting one way than it did the subset shifting the other, then the underpinnings supporting the payment reduction simply collapse.

3. These apparent logical failures in CMS's methodology independently render the 0.2 Percent Payment Cut arbitrary and capricious, even setting aside its fatal failures of explanation. "[J]udicial deference to the agency's modeling cannot be utterly boundless; [courts] must reverse the agency's application of [its] model as arbitrary and capricious if there is simply no rational relationship between the model and the known behavior [of the situation being studied]." *Chem. Mfrs. Ass'n v. E.P.A.*, 28 F.3d 1259, 1265 (D.C. Cir. 1994). Moreover, courts need not look the other way when the agency's modeling and assumptions "appear arbitrary on their face," *West Virginia*, 362 F.3d at 866, and "generate[] seemingly implausible results," *Appalachian Power*, 251 F.3d at 1035. *Accord St. James Hosp. v. Heckler*, 760 F.2d 1460, 1468-69 (7th Cir. 1985) (Secretary of Health and Human Services "committed a clear error of judgment" in relying on a deeply flawed study as the "sole empirical basis" for policy related to Medicare reimbursement and that even if the study were valid, the failure to examine the assumptions underlying the rule rendered the rule arbitrary and capricious). That is the situation here. The two key actuarial assumptions revealed in the IPPS Final Rule bear no rational relationship to the facts before the agency, including CMS's own publicly available data about Medicare beneficiaries' hospital stays. The proper course in that circumstance is to vacate the agency action.

III. The 0.2 Percent Payment Cut Violates the Medicare Act and the APA Because the Policy Was Not Promulgated by Regulation.

Finally, the 0.2 Percent Payment Cut violates both the Medicare Act and the APA because CMS did not promulgate the policy as a “regulation,” codified in the Code of Federal Regulations.

A. The 0.2 Percent Payment Cut Violates the Plain Language of the Medicare Act.

The 0.2 Percent Payment Cut is invalid under the plain language of the Medicare Act. The Act specifically requires that all rules, requirements, and statements of policy that establish or change a substantive legal standard governing the scope of benefits or payment for services be promulgated “by regulation.” 42 U.S.C. § 1395hh(a)(2); *see also id.* § 1395ww(d)(5)(I)(i) (any time the Secretary makes “such other exceptions and adjustments” to the prospective payment amounts paid to most hospitals, including Plaintiffs, for inpatient care, she “shall” do so “by regulation”). CMS failed to promulgate the 0.2 Percent Payment Cut “by regulation” because it did not codify the cut in the Code of Federal Regulations. Instead, CMS only discussed the 0.2 Percent Payment Cut in the preamble to the IPPS Final Rule. *See* 78 Fed. Reg. at 50,953-54.

That is not sufficient. It is well-established that *preambles* to statutes or regulations are not in fact statutes or regulations themselves. *See Utah Power & Light Co. v. Sec’y of Labor*, 897 F.2d 447, 450 (10th Cir. 1990) (“[P]reamble to the regulations . . . is not part of the regulations as published in the Code of Federal Regulations.”); *see also, e.g., Hawaii v. Office of Hawaiian Affairs*, 556 U.S. 163, 175 (2009) (stating that “the preamble is no part of the act”); *Int’l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 68 Fed. Appx. 205, 206 (D.C. Cir. 2003) (unpublished; per curiam) (“[I]t is well-settled that preambles, though undoubtedly ‘contribut[ing] to a general understanding’ of statutes and regulations, are not

‘operative part[s]’ of statutes and regulations.” (quoting *Nat’l Wildlife Fed’n v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002)); *Peabody Coal Co. v. Dir., Office of Workers’ Comp. Programs*, No. 12-70535, 2014 WL 1282289, at *5 (9th Cir. Apr. 1, 2014) (“[T]he preamble is not legally binding.”). Moreover publication in the Federal Register simply does not suffice to create a “regulation”; instead, publication in the Code of Federal Regulations is required. *See Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538-39 (D.C. Cir. 1986) (“The real dividing point between regulations and general statements of policy is publication in the Code of Federal Regulations”).

CMS, in short, failed to enact the 0.2 Percent Payment Cut “by regulation,” as required by Section 1395hh(a)(2). And as this district has proclaimed, “[s]ubstantive rules not promulgated in accordance with [Section 1395hh(a)(2) and 5 U.S.C. § 553(b)] are invalid and will not be enforced.” *Vencor Nursing Centers, L.P. v. Shalala*, 63 F. Supp. 2d 1, 11 (D.D.C. 1999). Because the Medicare Act “explicitly prohibits the Secretary from making legislative rules not promulgated as regulations[.]” *Landers v. Leavitt*, CIV.A. 3:04-CV-1988, 2006 WL 2560297, *8 n.8 (D. Conn. Sept. 1, 2006) *aff’d sub nom. Estate of Landers v. Leavitt*, 545 F.3d 98 (2d Cir. 2008), the Court should set aside the 0.2 Percent Payment Cut.

B. The 0.2 Percent Payment Cut Violates the APA Because the Policy Was Not Adopted with the Procedures Required by Law.

CMS’s failure to codify the 0.2 Percent Payment Cut not only violates the Medicare Act, but also the APA. The APA mandates that courts must hold unlawful and set aside agency action, findings, and conclusions found to be “not in accordance with law[.]” 5 U.S.C. § 706(2)(A). Likewise, courts “shall” and do “hold unlawful and set aside agency action, findings, and conclusions” when they have been accomplished “without observance of procedure required by law.” *Id.* § 706(2)(D); *see, e.g., Gerber v. Norton*, 294 F.3d 173, 186 (D.C. Cir.

2002) (finding that the Fish and Wildlife Service acted “without observance of procedure required by law” and “otherwise not in accordance with law” where in the course of approving a permit, the Service violated two requirements of the Endangered Species Act); *Military Order of Purple Heart of USA v. Sec’y of Veterans Affairs*, 580 F.3d 1293, 1297-98 (Fed. Cir. 2009) (setting aside new procedure where it was not in accordance with governing regulations). For the reasons explained above, CMS’s failure to codify the 0.2 Percent Payment Cut violates the plain language of the Medicare Act. In violating the procedural requirements of the Medicare Act, CMS also violates the APA.

The 0.2 Percent Payment Cut would be invalid even if promulgated as a regulation because it is arbitrary and capricious and was adopted without the notice and comment procedure required by the APA. The failure to promulgate the 0.2 Percent Payment Cut as a regulation nonetheless constitutes an additional, independent reason why the policy cannot stand.

CONCLUSION

Without affording hospitals any opportunity to weigh in or providing any plausible explanation for its choice, CMS has elected to take \$220 million from the nation’s hospitals. In doing so, it has violated both the Medicare Act and the APA. Plaintiffs respectfully request that the Court grant its Motion for Summary Judgment and set aside the 0.2 Percent Payment Cut in its entirety.

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Respectfully Submitted,

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