UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SHANDS JACKSONVILLE MEDICAL CENTER, INC., *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, Defendant.	Case No. 1:14-cv-00263

AMERICAN HOSPITAL ASSOCIATION PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND MOTION TO DISMISS

Dated: October 31, 2014

Respectfully Submitted,

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INTRODUCTION

CMS's opposition and cross-motion for summary judgment serves only to underscore how badly its 0.2 percent payment cut flunks the requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 *et seq.*, and Medicare Act, 42 U.S.C. §§ 1395 *et seq*.

First, CMS fails to explain away the fact that its proposed rule did not give commenters the information they needed to permit meaningful comment on CMS's proposed cuts. Commenters did not have access to CMS's actuaries' analysis, did not know what assumptions underlay that analysis, and did not know what data the actuaries considered relevant and what data they did not. Without any—much less all—of that information, it was not possible for commenters to cogently critique CMS's analysis. CMS, lacking any way to defend that state of affairs, attempts to cobble together statements from *outside* the rulemaking to prove that commenters knew the data that went into the agency's calculations. That effort fails: There are plenty of data available in the world, to be sure, but commenters did not have any way to know which of those data CMS's *actuaries* were using, how they were using them, what assumptions they were using, and how their calculations worked. In short, the technical information supporting CMS's actuaries' analysis was completely unavailable to commenters. The D.C. Circuit has repeatedly held that an agency's failure to show its work warrants vacatur of a rule; this case should be no different.

CMS also never justifies the back-of-the-hand treatment it gave comments challenging its methodology. Confronted with independent models that could not replicate CMS's actuarial conclusions, CMS was obligated to explain why it found those independent models unpersuasive. But all CMS did was say it "disagreed" with those models and repeated, with minimal elaboration, its actuaries' own (unexplained) analysis. That is not the sort of reasoned

engagement with comments that the D.C. Circuit's caselaw demands.

If that were not enough, the 0.2 percent cut is substantively flawed. There are at least two obvious logical defects that CMS does not explain. First, CMS's actuaries inexplicably excluded medical-stay cases (the "medical MS-DRGs" discussed in our summary judgment motion) from their analysis. Rather than try to defend that choice, CMS attempts to mask it by invoking its rationale for including *surgical*-stay cases ("surgical MS-DRGs"). That misses the point: Plaintiffs do not dispute the inclusion of surgical MS-DRG cases in the estimate; they challenge the exclusion of all of the other inpatient stays involving medical MS-DRGs. Second, CMS still has not explained how a new rule that makes it more difficult to qualify for inpatient admission will result in an *increase* in the number of inpatient stays.

CMS urges this Court to ignore those glaring defects, arguing that the agency is entitled to "particular deference" for its actuaries' estimates. But even "particular deference" cannot save estimates that are so wholly unexplained that the public cannot follow the logic.

Finally, CMS failed to comply with the procedures required by the APA and the Medicare Act, finalizing the payment cut without promulgating it "by regulation." For this reason, too, the 0.2 percent cut is fatally flawed. Plaintiffs' motion for summary judgment should be granted and CMS's cross motion should be denied.

ARGUMENT

I. CMS Did Not Offer Interested Parties Adequate Notice Of The Data Underlying Its Proposed Rule Or A Meaningful Opportunity To Comment On It.

CMS concedes that the APA's notice requirement means it must explain the technical basis underlying the 0.2 percent cut "in time to allow for meaningful commentary" and that an agency that fails to do so "commits serious procedural error." Opp. 28 (quoting *Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530-31 (D.C. Cir. 1982)).

However, CMS still has not—and cannot—point to anywhere in the proposed rule, or the administrative record, where it offered such an explanation. Instead, it cobbles together requests for public comments, and reports related to the Medicare criteria for inpatient admissions generally, to assert that " 'appropriate determination of a beneficiary's patient status [wa]s a systemic and widespread issue.' " Opp. 31 (quoting R.R. 728).

That is true. It is also irrelevant. Not one of the reports CMS cites addresses what matters here: the logical gap between CMS's decision to adopt a more stringent test for inpatient admissions and an *increase* in the number of inpatient admissions. Nor does any report explain how CMS's actuaries arrived at their estimated net shift of 40,000 cases.

That is the key point. Plaintiffs do not claim that CMS's adoption of the *two midnights* rule was unexplained. Rather, Plaintiffs' claim is that CMS's *estimate that there will be a net increase of 40,000 inpatient cases* was unexplained. Summ. J. Mot. 13-14. Nothing in the proposed rule, or anything that preceded it, explains how CMS's actuaries reached that counter-intuitive conclusion. And where, as here, an agency "rest[s] a rule on data that, [in] critical degree, is known only to the agency," the rule cannot stand. *Time Warner Entertainment Co. v. FCC*, 240 F.3d 1126, 1140 (D.C. Cir. 2001) (citation and internal quotation marks omitted); *see also* Summ. J. Mot. 13-16.

Connecticut Light & Power Co., on which CMS exclusively relies, is inapposite. In that case, the fire safety standards included in the Nuclear Regulatory Commission's proposed rule were developed "against a background of five years during which the Commission explored safety proposals in a public form *and exposed the important technical studies to adversarial comment*." 673 F. 2d at 532 (emphasis added). Even though the relevant technical studies were not mentioned or discussed in the notice of proposed rulemaking, "[t]here was in fact a common

store of experience on which the NRC drew, that had been developed and accumulated in interaction with the utilities during the five-year period that followed the Browns Ferry fire." *Id.* And that "common store of experience" directly informed the proposed rule at issue; the very fire safety requirements that had been the subject of five years' worth of debate were included in the proposed rule. *See id.* at 528–30. Even then, the D.C. Circuit concluded that "[t]he Commission complied but barely with the procedures mandated by the Administrative Procedure Act for notice and comment rule-making" and "came perilously close to foreclosing any useful participation whatsoever during the rule-making process itself." *Id.* at 528.

There is no similar "common store of experience" here, and CMS did not "expose[] the important technical studies to adversarial comment." *Id.* at 532. At most, interested parties were aware that CMS was considering doing *something* about the criteria for inpatient admission and that whatever it was might influence admission decisions. For instance, the CMS requests for comments demonstrated that the agency might modify the benchmark period for inpatient status. *See* R.R. 95. The Medicare contractor report, likewise, suggested that the benchmark period might increase from the current one day to something longer than that. *See* R.R. 728. And the Office of the Inspector General report hinted that the then-pending two midnights rule might have some unspecified influence on hospitals' admissions practices. *See* R.R. 1974.

None of these reports touches on the (supposedly) data-driven conclusion at the core of this proceeding: that increasing the benchmark period would increase the net number of inpatients, thus increasing costs. Thus none of the reports satisfies CMS's obligation to " 'make available technical studies and data that it has employed in reaching the decisions to propose particular rules.' " *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (citation omitted).

Nor do publicly available Medicare claims data amount to adequate notice of the technical basis for the 0.2 percent cut. CMS says certain commenters' attempts to duplicate its actuaries' estimates using public data demonstrate that the technical basis it provided for the 0.2 percent was sufficient to allow meaningful comment. Opp. 34-35. But as those same commenters pointed out, they *could not*, despite their best efforts, duplicate CMS's analysis. R.R. 4654-55, 5010. That only underscores that CMS's explanation of its methodology and identification of the data it used were insufficient. Far from bolstering CMS's case, commenters' unsuccessful attempts at replication prove only how deficient CMS's notice was.

CMS protests that it is "difficult to predict the behavioral consequences of hospitals confronted with new or clarified rules" because "there are multiple variables." Opp. 33. That is exactly right. As CMS itself notes, cost projections are not "an accounting exercise." *Id.* But that is precisely *why* CMS must make available its actuaries' methodology and underlying assumptions in enough detail for hospitals and other stakeholders to evaluate them. Without adequate information about the assumptions underlying CMS's actuaries' 40,000 net-inpatient estimate, the Medicare claims data are meaningless standing alone. Making different particular assumptions yields widely divergent—and even opposite—results. *See* R.R. 4654-55, 5010.

Unable to seriously contest the sufficiency of the technical data provided, CMS retreats to the last refuge of the desperate administrative agency: harmless error. Opp. 36. The agency argues that no one was prejudiced by its failure to explain. The harmless-error rule, however, is very rarely used to save agency action in these circumstances, and the D.C. Circuit has emphasized that it is " 'not . . . a particularly onerous requirement' " for plaintiffs challenging flawed agency action. *Jicarilla Apache Nation* v. *U.S. Dep't of the Interior*, 613 F.3d 1112, 1121 (D.C. Cir. 2010) (citation omitted). Indeed, "[t]he court has not required a particularly

robust showing of prejudice in notice-and-comment cases, holding that 'an utter failure to comply with notice and comment cannot be considered harmless *if there is any uncertainty at all as to the effect of that failure*.' " *Chamber of Commerce of U.S. v. SEC*, 443 F.3d 890, 904 (D.C. Cir. 2006) (quoting *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 96 (D.C. Cir. 2002)) (emphasis added). To vacate a rule for failing to disclose the underlying methodology or model during the notice-and-comment period, the D.C. Circuit requires only that that plaintiffs show with "reasonable specificity" they could mount a "credible challenge" to the 0.2 percent cut had they been afforded an opportunity to do so. *Owner-Operator Indep. Drivers Ass'n v. Federal Motor Carrier Safety Admin.*, 494 F.3d 188, 202–03 (D.C. Cir. 2007).

Plaintiffs clear that low bar with room to spare. For one thing, had CMS provided in the proposed rule even the severely limited information it finally revealed in the IPPS Final Rule, Plaintiffs would have been able to raise the objection regarding medical MS-DRGs, discussed below. They also would have voiced more detailed concerns about the agency's still-undisclosed methodology. And they would have been able to show that alternative models, using more realistic assumptions, reached the opposite result: Medicare Part A payments to hospitals would decrease under the two midnights rule, rather than increase. *See* R.R. 4654. There is no question Plaintiffs were prejudiced by CMS's failure to provide adequate information about the methodology and assumptions its actuaries used.

The cases demonstrate that Plaintiffs were required to show no more prejudice than this. For example, in *Owner-Operator Independent Drivers Association*, the petitioner argued that the Federal Motor Carrier Safety Administration had failed to provide an adequate explanation for its crash-risk model and the hours-of-service safety rules adopted based on that model because the underlying data showed a much higher level of risk than that included in the model's

assumptions. The agency's decision to use a particular data point generated by the model, like here, was "entirely unexplained"; the agency likewise "offered no explanation" for its methodology for calculating the estimated risk relative to average driving hours. *Id.* at 203-05. The D.C. Circuit found that it had "no difficulty in concluding that the agency's failure to disclose the methodology of the operator-fatigue model in time for comment was prejudicial. The arguments that the petitioner has raised before this court [critiquing the model] amply demonstrate that it would have mounted a 'credible challenge' had it been afforded an opportunity to do so." *Id.* at 202-03 (citation omitted). Just so here.

Even CMS's favorite case, *United States v. Johnson*, "support[s] the limited role of the harmless error doctrine in administrative law." 632 F.3d 912, 931-32 (5th Cir. 2011). The Fifth Circuit explained that in "the vast majority of agency rulemaking, which produces nuanced and detailed regulations that greatly benefit from expert and regulated entity participation[,] . . . . a finding of harmless error for inadequate notice-and-comment procedures" is "rare[.]" *Id.* This is not one of those rare cases.

II. CMS Did Not Sufficiently Explain Its Methodology Or Adequately Respond To Comments In The IPPS Final Rule.

The IPPS Final Rule is as flawed as the IPPS Proposed Rule. Confronted with widespread outcry that its analysis was not adequately explained, CMS doubled down, providing a few additional details, but hardly enough to "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) (citation omitted). And faced with competing models that differed from its actuaries' analysis, CMS dismissed them with a conclusory statement that it "disagreed" with the models' findings. The APA demands much more from CMS than that *ipse dixit*.

A. CMS Did Not Sufficiently Explain Its Methodology In The IPPS Final Rule.

Plaintiffs explained in the opening brief (Summ. J. Mot. 17) that when an agency bases its rules on models or other data-driven analysis, the agency must " 'explain the assumptions and methodology used in preparing the model[.]' " *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1035 (D.C. Cir. 2001) (citation omitted). In response, all CMS has to offer is the soothing assurance that it "clearly articulated the underlying actuarial assumptions regarding the shifts between inpatient and outpatient hospital settings." Opp. 34.

Not a single citation to the administrative record follows that sentence, however. For good reason: Far from "clearly articulating" the assumptions underlying its actuarial model, CMS remained impermissibly cryptic. To be sure, CMS explained that it had included certain diagnostic codes and had excluded others on the ground that they were not expected to shift the outcome. R.R. 728. But CMS never explained *why* it thought those codes would not change the results; it only "assumed" as much. R.R. 2047. CMS had to do more than that; it had to "reasonably explain[] why it chose to rely on" those assumptions. *West Virginia v. EPA*, 362 F.3d 861, 870 (D.C. Cir. 2004). It did not.

But even if CMS could justify its decision to include and exclude certain diagnostic codes in its actuarial modeling, "important aspect[s]" of the methodology underlying the IPPS Final Rule were still "wholly unexplained." *Owner-Operator*, 494 F.3d at 205. CMS never explained how its actuaries decided what cases would shift from inpatient to outpatient and vice versa and in what quantities. As CMS itself emphasizes in its brief, actuarial science depends on "'concepts and observations distilled from the experience of practitioners.'" Opp. 33 n.11 (citation omitted). CMS was constrained to reveal these subjective inputs in order to explain what in its actuaries' "experience" justified their use. But CMS never did so, and its failure to

"advert to the data and methods of calculation it used in such a way as to allow . . . opponents and reviewing courts to understand how [CMS] reached its conclusions" renders the IPPS Final Rule arbitrary and capricious. *Advanced Micro Devices v. CAB*, 742 F.2d 1520, 1523 (D.C. Cir. 1984).

B. CMS Did Not Adequately Respond To Commenters' Challenges.

Not only was the model underlying CMS's IPPS Final Rule unexplained, but CMS also essentially ignored commenters that pointed out that flaw. An agency has a "duty to respond to significant comments…, for 'the opportunity to comment is meaningless unless the agency responds to significant points raised by the public.' " *Alabama Power Co. v. Costle*, 636 F.2d 323, 384-85 (D.C. Cir. 1979) (citation omitted). And "[a]n agency's failure to respond to relevant and significant public comments 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) (citation omitted).

CMS's response to commenters in the IPPS Final Rule fell well short of those marks. CMS says it responded to major criticisms raised during the comment period by " 'disagree[ing] with commenters who indicated that [its] actuaries' estimated increase in IPPS expenditures of $220 million was unsupported and insufficiently explained to allow for meaningful comment.' " Opp. 37-38 (quoting R.R. 1361). But a bare statement of disagreement with commenters is not enough. CMS had to respond in a "*reasoned manner* to those [comments] that raise significant problems." *Reyblatt v. U.S. Nuclear Regulatory Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997) (emphasis added). And requiring a reasoned response is no empty formalism; it ensures that the agency "demonstrate[s] the rationality of its decision-making process" by forcing it to confront and give reasons for rejecting commenters' proposed alternatives. *Grand Canyon Air Tour Coal.*

v. FAA, 154 F.3d 455, 468 (D.C. Cir. 1998).

CMS claims its conclusory disagreement was sufficient because the "majority" of comments "merely expressed general disagreement with the actuaries' estimates and did not offer any counter-analysis specifying what the 'correct' estimate should be." Opp. 35. That argument comes dangerously close to violating the D.C. Circuit's "developing 'chutzpah' doctrine." *Marks* v. *CIR*, 947 F.2d 983, 986 (D.C. Cir. 1991). The *reason* commenters could not provide a more detailed rebuttal to CMS's analysis is that the analysis was so vague as to *defy* detailed rebuttal—exactly what commenters told CMS. *See, e.g.*, R.R. 4954-55. The generality of the comments is a symptom of CMS's inadequate explanation, not a flaw with the comments.

In any event, many commenters *did* offer a specific rebuttal to CMS's actuarial analysis, explaining that CMS's result both could not be replicated and was contrary to their models using the same CMS data. *See, e.g.*, R.R. 4653-54. Yet faced with these specific challenges, CMS said they were unavailing because its actuaries "continue to estimate" that there would be a net shift of 40,000 patients from outpatient to inpatient settings. R.R. 1362.

That bare conclusion is not the reasoned response the APA requires. CMS "must provide more than its own *ipse dixit* for its decision; there must be a rational connection between the factors considered and the decision made." *Texas Bankers Ass'n v. National Credit Union Admin.*, 888 F. Supp. 184, 190 (D.D.C. 1995). Indeed, CMS's "*ipse dixit* conclusion, coupled with its failure to respond to contrary arguments resting on solid data, epitomizes arbitrary and capricious decisionmaking." *Illinois Pub. Telecomm. Ass'n v. FCC*, 117 F.3d 555, 564 (D.C. Cir. 1997). CMS had to do more to defend its actuaries' estimates. It never did, and that renders the IPPS Final Rule arbitrary and capricious.

City of Waukesha v. EPA, 320 F.3d 228 (D.C. Cir. 2003), on which CMS relies, provides a useful comparison. There, "EPA summarized its reasons for choosing [one] model and stated that it had 'reviewed the documents submitted by the commenter that purport to provide new scientific evidence to counter the [a]gency's position . . .' . . . and that 'the submissions cite anecdotal or case report data, provide comment on other documents or positions or policy decisions or selected observations' and 'do not provide the kind of data that EPA discusses in the remainder of this response.' " *Id.* at 258. By contrast, CMS here did not explain what methodology or model its actuaries used at all. *See* R.R. 1361. And when commenters attempted to perform their own analyses and reached the opposite result, CMS did not explain why its methods were superior. *City of Waukesha* is of no help to the agency.

In the end, CMS tries to paint this case as one where Plaintiffs merely "take issue with [CMS's] decision to implement [its] proposal over their objections." Opp. 39. Hardly. Plaintiffs' objections are far more fundamental. The "process of notice-and-comment rule-making is not to be an empty charade"; instead, "[i]t is to be a process of reasoned decision-making." *Connecticut Light & Power*, 673 F.3d at 528. CMS's failure to meaningfully engage with commenters is not the "reasoned decision-making" the APA requires. *Id.*

III. CMS Did Not Provide a Reasoned Basis For The 0.2 Percent Payment Cut.

CMS's IPPS Final Rule is also substantively flawed. CMS is never quite able to explain why the two midnights rule—which is supposed to make it *harder* to classify a patient as an inpatient—would make the number of inpatients stays *increase*. CMS's brief instead focuses on irrelevant aspects of the rule and makes a broad appeal to the "deference" owed expert agency judgments. But this Court cannot defer to the illogical and unexplained, and the IPPS Final Rule cannot be upheld.

A. CMS Does Not Explain Its Exclusion Of Medical MS-DRGs Or Why A Narrower Definition Of "Inpatient" Will Mean More Inpatient Stays.

As Plaintiffs explained in their motion, the fundamental substantive flaws with the IPPS Final Rule—at least so far as its shadowy methodology can be discerned—are that it excluded medical MS-DRGs when calculating the encounters that will shift from inpatient from outpatient, and that it did not impose a similar limitation in judging the encounters that will shift the other way. Mot. for Summ. J. 22-23. That made a muddle of its model. *See id.*

CMS understands the challenge. It acknowledges that Plaintiffs question the consideration of surgical MS-DRGs "to the exclusion of medical MS-DRGs" in estimating the shift from inpatient to outpatient. Opp. 40. But rather than address the problem head-on, CMS offers a *non sequitur*. It argues "there was a reasoned basis for [its] actuaries' consideration of surgical MS-DRGs in estimating the movement from inpatient to outpatient and long observation cases in estimating the movement from outpatient to inpatient." *Id.* at 42.

That misses the point. Plaintiffs do not dispute the *inclusion* of surgical MS-DRGs in CMS's estimates; they dispute the *exclusion* of the short inpatient stays involving medical MS-DRGs. CMS never even offers an explanation (much less a reasoned explanation) for *excluding* hundreds of thousands of medical cases that do not involve a surgery. "No matter how rudimentary a claim, an agency is not entitled under the APA to respond with a non sequitur." *City of Vernon, Cal.* v. *FERC*, 845 F.2d 1042, 1048 (D.C. Cir. 1988).

CMS cites one case: *Universal Health Services of McAllen*. Opp. 40. As CMS apparently sees it, because any line-drawing necessarily includes some categories and excludes others, it need not explain why it chose to ignore medical MS-DRGs in its actuarial calculations. *See id.* But that is not the law. The APA requires agencies to provide full explanations for all of its meaningful choices, including why certain variables are in and out of the agency's calculus.

See, e.g., *Am. Tel. & Tel. Co. v. FCC*, 974 F.2d 1351, 1355 (D.C. Cir. 1992) ("If, on remand, the FCC again decides to exclude promotional rates from average price calculations, it will have to provide an adequate explanation for doing so."). CMS did not do that here.

In any event, *Universal Health Services of McAllen* does not support CMS. In that case, plaintiffs challenged CMS's criteria for hospitals seeking reclassification to another geographic area for purposes of using that area's Medicare reimbursement rates. *Universal Health Servs. of McAllen, Inc. v. Sullivan*, 770 F. Supp. 704, 708 (D.D.C. 1991) *aff'd*, 978 F.2d 745 (D.C. Cir. 1992). In other words, CMS was literally engaged in an act of line-drawing—*i.e.*, determining which hospitals would fall within which geographic area based on the proximity criteria specified by CMS—the result of which necessarily was that certain hospitals would fall within one geographic area and certain hospitals would fall within another. *See id.* at 718. The court's statement regarding "line-drawing exercise[s]" arose in that limited context. *See id.* It in no way justifies CMS's failure to explain how it could accurately estimate the number of encounters that would shift from outpatient to inpatient without accounting for medical MS-DRGs.

Furthermore, CMS also still has not explained how a new rule that narrows the definition of "inpatient" for purposes of a hospital stay—namely, by requiring a physician to expect a beneficiary to need hospital care for a period spanning *two* midnights and establishing a presumption that a hospital stay lasting less than two midnights should generally be an outpatient stay—will result in an *increase* in the number of inpatient stays. It defies common sense. And a conclusion that "defies . . . commonsense" means that it cannot " 'be ascribed to a difference in view or the product of agency expertise.' " *American Federation of Government Employees, Local 2924 v. FLRA*, 470 F.3d 375, 383 (D.C. Cir. 2006) (citation omitted).

CMS argues that although Plaintiffs believe the two midnights rule makes it more difficult to claim a hospital stay on an inpatient basis, it "reasonably could have concluded otherwise," because "the decision to admit becomes easier as the time approaches the second midnight," Opp. 41 (quoting R.R. 1354), and "some commenters representing the hospital community believed that patients who have been actively monitored for more than 24 to 48 hours as outpatients under observation and cannot be safely discharged are likely sufficiently complex cases." *Id.* (quoting R.R. 395). But CMS never linked those statements to an expected increase in inpatient stays during the rulemaking process, much less gave any indication that those statements affected its actuarial analysis. To the extent the Department of Justice attempts to articulate that explanation now, "[i]t is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *State Farm*, 463 U.S. at 50. "[C]ounsel's explanation to this court cannot substitute for 'reasoned decisionmaking at the agency level.' " *Williams Gas Processing-Gulf Coast Co. v. FERC*, 475 F.3d 319, 329 (D.C. Cir. 2006) (citation and emphasis omitted).

In any event, even assuming that "the decision to admit *becomes easier* as the time approaches the second midnight," as CMS claims, Opp. 41, that would affect only the subset of the observation or outpatient stays that have already lasted more than one night—*i.e.*, stays in which a beneficiary has been an outpatient receiving observation services for one day, overnight, and into a second day, and the physician expects that the beneficiary will continue to need care into a third day. It has no bearing on the hundreds of thousands of outpatient stays that last for less than one night. Nor does it account for the hundreds of thousands of short inpatient stays that, under the two midnights rule, generally will be treated as outpatient. Even CMS's litigation counsel cannot rationally explain its model.

Out of explanations, the agency simply string-cites cases in which courts gave deference to agency decisions based on predictive judgments. These cases—which CMS never bothers to apply to the facts here—are not analogous.

In some, the agencies engaged in reasoned, thorough analysis, and specifically articulated their reasoning in the rulemaking docket. In *National Wildlife Federation*, for example, the court explained that the EPA met its "heaviest of obligations to explain and expose every step of its reasoning." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 563 (D.C. Cir. 2002) (quoting *American Lung Ass'n v. EPA*, 134 F.3d 388, 392 (D.C. Cir. 1998)), *supplemented sub nom.*, *In re Kagan*, 351 F.3d 1157 (D.C. Cir. 2003). In *St. John's United Church of Christ v. FAA*, 550 F.3d 1168, 1173-74 (D.C. Cir. 2008), FAA did enough "though barely so" where it relied on the benefit-cost ratios for the overall O'Hare program or Phase 1 Airfield and described the intended land use in project justification documents. And in *BNSF Ry. Co. v. Surface Transp. Bd.*, 526 F.3d 770, 781 (D.C. Cir. 2008), the Board's "reasoned predictions" were not arbitrary and capricious where "[t]he agency has adopted a straight-line, phase-in approach that is routinely used to estimate the depreciation of assets." But those cases are useful only as contrast, because in them the agencies showed their work and used variables that made sense. Here CMS adopted an unexplained, illogical model that was against all notions of how real-world patient populations behave. Summ. J. Mot. 22-23.

CMS also relies on cases where the plaintiffs did not challenge any specific numerical prediction. The hospitals in *Methodist Hospital*, for example, challenged a policy that denied retroactive effect to a revised wage index used in determining Medicare reimbursement rates under the PPS. *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1226 (D.C. Cir. 1994). The dispute centered on the agency's interpretation of a provision of the Medicare statute; there

was no unexplained predictive judgment at issue. *Id.* *Rural Cellular* is similarly off-base. The question in that case was whether an undisputed, dramatic increase in the universal support subsidy between 2001 and 2007 indicated a possible future crisis, such that an interim fix would be needed. *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1098 (D.C. Cir. 2009). It was not, as it is here, a challenge to a specific calculation to offset a projected increase. And, in any event, in *Rural Cellular*, there was a logical connection between the specific facts found and the choice made; the court found that "the dramatic increase in . . . high-cost support, on its own, was enough to justify the Commission's prediction about the effect on consumers." *Id.* at 1108.

CMS has not established any similar logical connection here. For that reason, no degree of deference can save the IPPS Final Rule.

IV. CMS Did Not Promulgate The IPPS Final Rule "By Regulation" As The Medicare Act Demands.

Last, but certainly not least, the IPPS Final Rule is procedurally unsound because CMS did not promulgate it "by regulation" as the Medicare Act requires. Summ. J. Mot. 24-26.

CMS does not dispute the well-established principle that preambles to regulations are not, themselves, regulations. *Utah Power & Light Co. v. Sec'y of Labor*, 897 F.2d 447, 450 (10th Cir. 1990). CMS instead argues that regulations need not be codified in the Code of Federal Regulations. Opp. 44. But "[a]gency statements 'having general applicability and legal effect' are to be published in the Code of Federal Regulations." *Nat'l Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009). The 0.2 percent cut was not published in the Code of Federal Regulations. It thus cannot have "general applicability and legal effect." It is that simple.

CMS has no real answer. Rather, it simply alleges—in conclusory fashion—that "Plaintiffs cobble together out-of-context statements from inapposite cases[.]" Opp. 43. It never explains *why* these cases are "inapposite." In fact, it is CMS's cases that are not on point.

For instance, CMS points to a three-factor test in *The Wilderness Society v. Norton* that, it suggests, defines whether the 0.2 percent payment cut is a "regulation" as required by the Medicare Act. *Id.* at 42. Not quite. The three-prong analysis simply guides courts "[i]n determining whether an agency has issued a binding norm or merely a statement of policy[.]" *The Wilderness Soc. v. Norton*, 434 F.3d 584, 595 (D.C. Cir. 2006).

That is a key difference. Plaintiffs do not allege that the 0.2 percent payment cut was intended to be a mere statement of policy. CMS might very well have *intended* the cut to have the force of law—but the agency still failed to promulgate it "by regulation." *See* 42 U.S.C. § 1395ww(d)(5)(I)(i); 42 U.S.C. § 1395hh(a)(1). The D.C. Circuit's three-part test for separating binding rules from non-binding policy statements is irrelevant.

In any event, even *The Wilderness Society* emphasizes the significance of publication in the CFR. As the D.C. Circuit explained, "[a]lthough the agency twice gave notice in the Federal Register of proposed policies," the policies were not a binding regulation because the agency "never published a final version of the [policy] in either the Federal Register or, *more significantly*, in the Code of Federal Regulations." *Id.* at 595-96 (emphasis added). That is because "[t]he real dividing point between regulations and general statements of policy is publication in the Code of Federal Regulations,' " not merely publication in the Federal Register. *Id.* at 596 (quoting *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538-39 (D.C. Cir. 1986)) (internal quotation marks omitted). CMS's own case refutes its argument.

In the end, as the government elsewhere has explained, "[t]he purpose of the CFR is to present the official *and complete* text of agency regulations in one organized publication[.]"[1] Not every CMS policy must be codified as a regulation. But where the agency wishes to make

[1] NATIONAL ARCHIVES, Federal Register: About the CFR, *available at* http://www.archives.gov/federal-register/cfr/about.html (last visited Oct. 17, 2014) (emphasis added).

an adjustment to prospective payment amounts—thereby establishing a change to a substantive legal standard governing the payment of services—this is what the Medicare Act requires. *See* 42 U.S.C. §§ 1395ww(d)(5)(I)(i), 1395hh(a)(1). CMS's failure to obey that command provides yet another reason why the IPPS Final Rule must be vacated. *See Vencor Nursing Centers, L.P. v. Shalala*, 63 F. Supp. 2d 1, 11 (D.D.C. 1999).

CONCLUSION

For the foregoing reasons and those in Plaintiffs' motion for summary judgment, the Court should grant Plaintiffs' motion for summary judgment and deny CMS's cross-motion.

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Respectfully Submitted,

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