IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SHANDS JACKSONVILLE MEDICAL CENTER, INC., *et al.*

Plaintiffs,

v.

SYLVIA M. BURWELL,

Defendant.

Civil Action No. CIV-14-263-RDM

DEFENDANT'S SUPPLEMENTAL MEMORANDUM REGARDING VACATUR

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

PRELIMINARY STATEMENT

There is a kind of flow to Medicare. Claims never stop coming, and it falls to Medicare's administrative contractors to process them and continuously pay out tax dollars pursuant to the Secretary's instructions. The Secretary makes major updates to those instructions annually, pursuant to Congress's direction and delegation, in regular payment rulemakings that build upon each previous year's effort. The result is a massive stream of dollars from taxpayers to healthcare providers, the course of which the Secretary and Congress alter somewhat from year to year.

Here, the Secretary predicted that a change she was making to hospital payment rules for FY 2014 would artificially increase hospital payments by $220 million beginning the same year, so she simultaneously imposed a 0.2% downward adjustment to hospital payment rates in order to offset the increase. 78 Fed. Reg. 50,496, 50,953 (Aug. 19, 2013). Plaintiffs say that the rulemaking by which the Secretary imposed this predictive course correction failed to comply with the procedural requirements of the Administrative Procedure Act, 5 U.S.C. § 553, in various ways. If the Court agrees with Plaintiffs, it must decide whether equity would have it leave the adjustment in place back in FY 2014 while the Secretary reconsiders it in a corrective proceeding on remand, or instead vacate the adjustment and force the Secretary to consider whether to re-insert it somewhere downstream. *See Fertilizer Institute v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) (remand without vacatur appropriate "when equity demands").

Outright vacatur would be inequitable in light of the "serious possibility" that the Secretary will re-affirm the adjustment after curing any defects in her rulemaking on remand. *See Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993) ("serious possibility" agency would come to same fee allocation after correcting procedural deficiencies on remand counseled against vacatur). The Secretary has only six weeks ago (in her

latest proposed payment rule for calendar year 2016) offered a fuller explanation and defense of the assumptions behind her actuaries' estimate that the two-midnight rule would cause a $220 million annual increase in payments to hospitals (including the assumption that short stay medical-DRGs would continue to be billed as inpatient), and re-evaluated that estimate in light of now-historical data on payment trends for FY 2014. Medicare Program: Short Inpatient Hospital Stays, 80 Fed. Reg. 39,200, 39,369 (July 8, 2015). She not only found her actuaries' assumptions to be "reasonable" despite recent criticisms, *id.*, but also found them to be "consistent with" the observed behavior of hospitals in FY 2014, *id.* at 39,370. In light of this latest regulatory development revisiting and confirming the challenged assumptions from the FY 2014 rule, and other reasons discussed below, it would be straightforward for the Secretary to cure any procedural deficiencies in her rulemaking on remand, and it is, at a minimum, seriously possible that she would re-affirm the adjustment having done so. This likelihood that the adjustment will ultimately stand is itself a reason to remand without vacatur. *See U.S. Telecom. Ass'n v. FBI*, 276 F.3d 620, 627 (D.C. Cir. 2002) (remanding without vacating solely in light of likelihood agency would cure procedural defect on remand).

Vacatur would also be inequitable because of the disruption that it would cause, both permanently and in the interim. Vacatur would alter the flow of Medicare payments going back to FY 2014, entitling Plaintiffs (and other hospitals that timely sought review or still could) to a refund of up to $220 million per year, even while the two-midnight rule (and the increase in hospital payments that the Secretary predicted it would cause) remains in place. Doing so would not only impose a substantial burden on the Medicare trust fund (and give hospitals the windfall from this payment-rule change that the Secretary had sought to avoid), it would impose a needless administrative burden on the agency, which would be tasked both with refunding the

FY 2014 adjustment and mitigating the effect of the vacatur on down-stream payment years, themselves based on the FY 2014 rule, through additional administrative measures. The D.C. Circuit has found both sorts of disruption—loss of taxpayer funds and administrative burden—to be reasons to remand without vacatur. *Compare Allied-Signal*, 988 F.2d at 151 ("vacating may be quite disruptive . . . the Commission would need to refund" fees that had already been collected) *with Black Oak Energy, LLC v. FERC*, 725 F.3d 230, 244 (D.C. Cir. 2013) (avoidance of needless administrative "transaction cost" counseled against vacatur).

In short and as elaborated upon below, there is a serious possibility that the Secretary would re-affirm the 0.2% downward adjustment even after correcting any deficiencies in her FY 2014 rulemaking that the Court might identify, and vacatur of the adjustment would significantly disrupt Medicare payments. Accordingly, the Government respectfully requests that, should the Court find the Secretary's FY 2014 rulemaking deficient in any respect on procedural grounds, it remand to the agency for additional proceedings in light of its opinion without vacating the adjustment.

STANDARD OF REVIEW

"[W]hen equity demands, an unlawfully promulgated regulation can be left in place while the agency provides the proper procedural remedy." *Fertilizer Inst. v. U.S. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991). So it is that the D.C. Circuit "and other federal circuit courts have repeatedly found it appropriate to remand an agency action without vacating it." *ICORE, Inc. v. FCC*, 985 F.2d 1075, 1081–82 (D.C. Cir. 1993); *see also In re Core Communications, Inc.*, 531 F.3d 849, 863 (D.C. Cir. 2008) ("Remand without vacatur is common in this circuit[.]").

The decision whether to remand without vacatur is governed in this Circuit by a two-factor inquiry known as the "*Allied-Signal* test," e.g. *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1048 (D.C. Cir. 2002). A court applying this test evaluates "[1] the seriousness of the

order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and [2] the disruptive consequences of an interim change that may itself be changed." *Allied-Signal*, 988 F.2d at 150–51. Either factor can support remand without vacatur independently. *Compare Fox Television Stations*, 280 F.3d at 1049 ("though the disruptive consequences of vacatur might not be great, the probability that the [agency] will be able to justify retaining the [] Rule is sufficiently high that vacatur of the Rule is not appropriate") *with North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008) (remanding without vacatur in light of disruptive consequences, despite determination in *North Carolina v. E.P.A.*, 531 F.3d 896 at 929 (D.C. Cir. 2008) that "very little will survive remand in anything approaching recognizable form")).

ARGUMENT

I. First Factor: There is a Serious Possibility that the Secretary Would Re-Affirm the Adjustment After Correcting any Deficiencies on Remand

The Court's inquiry under the first *Allied-Signal* factor is a probabilistic one; the Court evaluates "the likelihood that 'deficiencies' in an order can be redressed on remand, even if the agency reaches the same result." *Black Oak Energy, LLC v. FERC*, 725 F.3d 230, 244 (D.C. Cir. 2013) (quoting *Allied-Signal*, 988 F.2d at 150). Courts have found this factor to favor remand where redress was a "serious possibility," *Allied-Signal*, 988 F.2d at 151, merely "plausible," *Black Oak Energy*, 725 F.3d at 244, or "not unlikely," *Fox Television Stations*, 280 F.3d at 1049.

Here, Plaintiffs primarily take issue with the rulemaking's handling of the actuaries' estimate that the rule change would increase hospital payments by $220 million annually. *E.g.* Bakersfield MSJ at 9–12; AHA MSJ at 13–16; Shands MSJ at 24–27; Athens MSJ at 15–17. But some Plaintiffs also take issue with another discrete aspect of the rulemaking imposing the adjustment: they argue that the Secretary did not sufficiently explain her judgment that it would

be appropriate to offset any estimated increase (rather than let the hospitals keep it). *See* Shands MSJ at 23–24.

The rulemaking was in no way defective, as explained in the Secretary's merits briefs, so no remand is warranted. But even if there were shortcomings in the rulemaking, it is not unlikely (indeed, there is a serious possibility) that the agency would impose the -0.2% adjustment even after correcting any such shortcomings on remand, as explained below.

A. Estimated Increase in Hospital Payments

Plaintiffs' main focus is the Secretary's estimate that adoption of the two-midnight rule would lead to a $220 million increase in hospital payments. Specifically, they break their attack on the estimate into three procedural challenges: that they were denied a meaningful opportunity to comment on the methodology by which the Secretary's actuaries came to that estimate, *e.g.* Bakersfield MSJ at 9–12; that the Secretary's final rule did not sufficiently respond to such comments regarding that methodology as commenters did offer, *e.g.* Athens MSJ at 21–25; and that the Secretary in any event did not sufficiently explain the methodology in her final rule, *e.g.* AHA MSJ at 16–18, 20–24.

It would be straightforward for the Secretary to address any of these alleged defects on remand and there is a serious possibility that she would re-affirm the adjustment having done so, so the first *Allied-Signal* factor counsels against vacatur should the Court find a defect in this aspect of the rule, as explained in point 1, below. To avoid this conclusion, which flows from straightforward application of the first *Allied-Signal* factor to the facts of this case, Plaintiffs may urge the Court to create a *per se* rule that the first *Allied-Signal* factor counsels against vacatur whenever a "notice" violation is found, no matter how likely it is that the error would be corrected. No such *per se* rule exists, as explained in point 2.

1. Likelihood of redress

It would not be difficult for the Secretary to correct any alleged defects in her explanation of her actuaries' methodology. The Secretary has offered a fuller explanation of that methodology as recently as the Calendar Year 2016 OPPS Proposed Rule, which explains in detail both the assumptions made by the actuaries and the reasoning behind those assumptions. *See* Medicare Program: Short Inpatient Hospital Stays, 80 Fed. Reg. 39,200, 39,369 (July 8, 2015). To cure any alleged opportunity to comment violation, the Secretary would publish that explanation (further supplemented, if need be, in light of the Court's opinion) in a Federal Register notice seeking additional comment on her actuaries' estimate. Then, after expiration of this additional comment period, the Secretary would either issue a Federal Register notice explaining her decision to continue to rely on her actuaries' original estimate in light of any comments she might receive, or take any necessary administrative actions effectuating her decision not to do so. This would not only cure any alleged "opportunity to comment" defect, but also the Secretary's alleged failure in the Final Rule to respond to comments or sufficiently explain her actuaries' methodology.[1] The Government expects that, if the Secretary were to re-

[1] As discussed above, if the Court were to find that the Secretary denied Plaintiffs an opportunity to comment on her actuaries' methodology, the "cure" would entail a process whereby, after a renewed comment period, the Secretary would offer a renewed explanation and response to comments. Accordingly, if the Court agrees with Plaintiffs on the merits point that the Secretary denied them a meaningful opportunity to comment on the actuaries' methodology, it need not reach the merits of their arguments that the Secretary also failed to respond to comments about or explain that methodology in her final rule. A remand without vacatur remedy as to the "comment" violation would also cure any such downstream violations (and vacatur because of any alleged "comment" violation would make the proper remedy for any downstream procedural defects a moot point). *Cf.* Transcript of Motions Hearing Before the Honorable Randolph D. Moss at 20:1-10 (Aug. 3, 2015) ("If the Court were to conclude that the opportunity for comment was deficient . . . would the Court need to reach [other merits questions]?"). On the other hand, if the Court found no "comment" defect but did find insufficient explanation or response to comments in the final rule, corrective action on remand would begin (and end) with the second step of the process described above.

affirm the adjustment on remand, this process would take four to six months.[2] If the Secretary were to decide to abandon or alter the adjustment on remand the process might take longer, despite the agency's commitment to expeditious resolution of any remand, because the Secretary would also have to consider how to implement that decision (just as she would need to do in response to a vacatur, *see infra* Part II). During the remand, the Government could file periodic status reports to keep the Court apprised of the agency's progress.

This is essentially the process followed on remand in *Gerber v. Norton*, 294 F.3d 173 (D.C. Cir. 2002), another remand-without-vacatur case involving an alleged failure to provide a meaningful opportunity to comment. First the agency issued a notice requesting additional comments. Notice of Availability and Public Comment Period for Documents Associated with the Incidental Take Permit, 68 Fed. Reg. 25,058 (May 9, 2003) (on remand from *Gerber*) ("In response to a ruling by the Court of Appeals, the U.S. Fish and Wildlife Service [] announces the availability of two documents . . . and the opening of a 60-day comment period"). That would cure any "opportunity to comment" defect. After reviewing those comments, and responding as appropriate, the agency explained its reasons for reaffirming its initial decision. Documents Associated with Proceedings Pursuant to Remand, 68 Fed. Reg. 52,609 (September 4, 2003) ("The [U.S. Fish and Wildlife] Service has reviewed and considered [supplemental] comments and has prepared a final decision . . .").

There is also a serious possibility that, having sought renewed comment and offered additional explanation of her actuaries' methodology, the Secretary would again rely on their

[2] The Government's expectation that a corrective remand re-affirming the adjustment would take four to six months is premised on neither party appealing the remand order. *Cf. In re St. Charles Preservation Investors, Ltd.*, 916 F.2d 727, 729 (D.C. Cir. 1990) (per curiam) ("It is well settled that, as a general rule, a district court order remanding a case to an agency for significant further proceedings is not final."). Were Plaintiffs to appeal, the duration of proceedings on remand might be affected.

estimate that the two-midnight rule would cause an artificial $220 million increase in hospital payments. Additional comments on the actuaries' methodology would lead to a change in their estimate only if (1) some commenter called to the agency's attention some methodological point the agency did not consider or failed properly to evaluate and (2) the agency determines to alter its methodology in light of that point. But, after discussing the actuaries' assumptions in a statement after the Final Rule, A.R. 2046–48, the Secretary has in the recent CY 2016 OPPS Proposed Rule revisited and further explained the bases for those assumptions and nonetheless announced her intent to continue to follow her actuaries' estimate as "reasonable." *See* Medicare Program: Short Inpatient Hospital Stays, 80 Fed. Reg. 39,200, 39,369 (July 8, 2015) ("Our actuaries have determined that the methodology, data, and assumptions used here are reasonable for the purpose of estimating the overall impact of the proposed policy.").

The discussion in the CY 2016 OPPS Proposed Rule specifically addresses various aspects of the actuaries' methodology and assumptions that have been called into question here. This includes both the reasoning behind the actuaries' assumptions and the decision to rely on an estimate that incorporates such assumptions. *See* 80 Fed. Reg. at 39,369 (explaining why actuaries excluded medical DRGs in estimating number of cases formerly billed as inpatient that would be billed as outpatient after two-midnight rule); *id.* (explaining why actuaries excluded outpatient stays shorter than two midnights or not for observation care or a major procedure in estimating number of cases formerly billed as outpatient that would be billed as inpatient after two-midnight rule); *id.* (estimated "30 percent" payment differential between outpatient and inpatient systems includes consideration of beneficiary's copay in outpatient cases); *id.* at 39,370 (explaining actuaries' determination that despite possibility of variation from assumptions, "a

model [making such assumptions] . . . yielded a reasonable estimate of the net effect of the 2-midnight policy" (emphasis in original)).

Additionally, as reflected in that proposed rule, the actuaries have also now reviewed actual hospital billing data for FY 2014, and plan to continue to do so for purposes of future annual rulemakings. *Id.* at 39,370. "The data thus far," the actuaries found, "is consistent with the assumptions used . . . to develop the original – 0.2 percent adjustment estimate." *Id*.

It is far from certain that commenters will offer (and the agency will credit) still other as-yet-unexplored arguments, let alone arguments that the agency will find compelling enough to warrant a methodological shift from an estimate that has been borne out by actual experience. So there is a serious possibility that the Secretary would, after receiving additional comments on her actuaries' methodology, nonetheless rely upon their estimate that adoption of the two-midnight rule would lead to an artificial $220 million increase in payments to hospitals. In light of this likelihood that the Secretary would come out the same way after curing any defect relating to her actuaries' methodology on remand, the first *Allied-Signal* factor counsels in favor of remand without vacatur as to this alleged defect.

2. **No *per se* rule governs the Court's inquiry under the first *Allied-Signal* factor here.**

Counsel for Plaintiffs suggested at argument that the alleged denial of a meaningful opportunity to comment is in a class of "notice" violations that receive special treatment in the *Allied-Signal* analysis. Specifically, counsel for Plaintiffs argued that the first *Allied-Signal* factor counsels in favor of vacatur *per se* as to "notice" violations—whatever the actual likelihood of redress in any particular "notice" case—and assumed that the Secretary's alleged failure to offer a meaningful opportunity to comment on the actuaries' methodology is such a "notice" violation. Transcript of Motions Hearing Before the Honorable Randolph D. Moss at

4:15-18 (statement of Ms. Stetson) (Aug. 3, 2015). Plaintiffs are wrong on both counts: first, there is no such *per se* rule for "notice" violations, and, second, in any event, the alleged violations at issue here are not the sort of violations that would warrant putting a thumb on Plaintiffs' side of the *Allied-Signal* scale. So the analysis just set forth—and not any *per se* rule—governs application of the first *Allied-Signal* factor here.

First, there is no rule that "notice" violations receive special negative (or positive) consideration in applying the *Allied-Signal* test. The D.C. Circuit has consistently held that the *Allied-Signal* test governs the decision whether to remand without vacatur and that the first factor depends on "the likelihood that 'deficiencies' in an order can be redressed on remand, even if the agency reaches the same result[,]" *Black Oak Energy, LLC v. FERC*, 725 F.3d 230 at 244. That's it.

Plaintiffs' misunderstanding presumably arises from the D.C. Circuit's statements that "deficient notice" of a proposed rule "is a fundamental flaw that normally," (in *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009)), or even "almost always," (in *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2011) (quoting *Heartland*)), leads to vacatur. *Cf. Daimler Trucks North America LLC v. EPA*, 737 F.3d 95, 103 (D.C. Cir. 2013) ("the court typically vacates when an agency *entirely fails* to provide notice and comment" (emphasis added)). But the *Heartland* and *Allina* opinions did not themselves purport to overrule *Allied-Signal* or to create a categorical rule that the first *Allied-Signal* factor weighs in favor of vacatur in all "notice" cases, even where (as here) the context of a particular case indicates the agency could well come to the same result after redressing the underlying defect. Instead, they merely described what "normally," *Heartland*, 566 F.3d at 199, or perhaps "almost always" happens, *Allina*, 746 F.3d at 1110. Nor could they have created such a rule, as that rule

would conflict with the Circuit's consistent practice of evaluating the first *Allied-Signal* factor by looking to the likelihood of redress in a particular case. *E.g. Allied-Signal*, 988 F.2d at 151 ("serious possibility"); *Louisiana Federal Land Bank Ass'n, FLCA v. Farm Credit Admin.*, 336 F.3d 1075 (D.C. Cir. 2007) ("not unlikely"); *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1049 (D.C. Cir. 2002) ("not unlikely"); *U.S. Telecom. Ass'n v. FBI*, 276 F.3d 620 (D.C. Cir. 2002) ("not so clear"); *Sugar Cane Growers Coop. of Florida v. Veneman*, 289 F.3d 89 (D.C. Cir. 2002) ("at least possible").

Furthermore, Plaintiffs' attempt to create a *per se* rule cannot be reconciled with the numerous cases in which the Court of Appeals has found remand without vacatur appropriate, even in cases where (unlike here) the agency utterly failed to engage in notice-and-comment rulemaking, *see Sugar Cane Growers Coop. of Florida v. Veneman*, 289 F.3d 89, 98 (D.C. Cir. 2002) ("We have previously remanded without vacating when the agency failed to follow notice-and-comment procedures.") (collecting cases)). Nor can such a categorical rule be reconciled with the point that the *Allied-Signal* test is a guide to the Court in wielding its equitable and therefore essentially case-specific remedial power—a principle inconsistent with "per se" rules. *See Fertilizer Institute v. U.S. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) (power to remand without vacatur based in equity); *Holland v. Florida*, 560 U.S. 631, 649–50 (2010) ("exercise of a court's equity powers . . . must be made on a case-by-case basis" (quoting *Baggett v. Bullitt*, 377 U.S. 360, 375 (1964)).

Second, the alleged defect at issue here is not even the same kind as the defects that *Heartland* and *Allina* noted often flunk *Allied-Signal*'s first factor. At issue in *Heartland* was an utter failure to engage in notice and comment. *See Heartland*, 566 F3d at 199 ("the agency had not gone through the notice and comment procedure required by the *APA*" in *Bowen v.*

Georgetown Univ. Hosp., 488 U.S. 204 (1988)). And *Allina* dealt with the functionally identical situation (from the commenter's perspective) in which an agency's ultimate rule was not a "logical outgrowth" of the agency's proposed rule. *Allina*, 746 F.3d at 1108 (actual notice of final rule "would doubtless have triggered an avalanche of comments, in contrast to the mere 26 pages that were actually submitted").

Plaintiffs' argument here, in contrast, is not that the agency did not put them on notice of the final rule (the proposed rule, after all, is identical to the final one). Rather, Plaintiffs' argument is that they were denied a meaningful opportunity to *comment* on the wisdom of that rule because the agency did not adequately explain the underlying rationale in its proposal, *e.g.* Bakersfield MSJ Mem. at 6 (agency denied "opportunity to meaningfully comment"); an argument that actually sounds in 5 U.S.C. § 553(c) (requiring an opportunity to comment) rather than in 5 U.S.C. § 553(b) (requiring notice of proposed rule). *See Chamber of Commerce v. SEC*, 443 F.3d 890, 901–902, 908 (D.C. Cir. 2006) (treating this sort of procedural defect as a violation of 5 U.S.C. § 553(c)).

Thus, even if *Allina* and *Heartland* recognized a *per se* rule in favor of vacatur for certain "notice" deficiencies (but they did not), that rule would not apply to the alleged failure to provide a meaningful opportunity for comment here. This is not hair splitting; the fact that "meaningful opportunity" cases are different from "utter failure" and "logical outgrowth" cases has been recognized both by the D.C. Circuit (in the *Allina* opinion itself) and by Congress (in the Medicare statute). *See Allina*, 746 F.3d at 1110 (prejudicial error rule for denial of opportunity to comment due to absence of "critical materials" from notice may be less stringent than for "utter failure" and "logical outgrowth" cases "because of the possible tension" of the "critical materials doctrine" with *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council,*

Inc., 435 U.S. 519 (1978)); 42 U.S.C. § 1395hh ("If . . . a final regulation . . . is not a logical outgrowth of . . . a . . . notice . . . [it] shall not take effect.").

This distinction is an important one: unlike "utter failure" and "logical outgrowth" cases, where courts have vacated rules with some regularity,[3] the D.C. Circuit has held outright vacatur to be *inappropriate* in every "meaningful opportunity" case where it has considered the issue. *See Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 242 (D.C. Cir. 2008) ("On remand, the Commission shall afford a reasonable opportunity for public comment on the unredacted studies . . . make the studies part of the rulemaking record, and provide a reasoned explanation of its choice of an extrapolation factor[.]") (citing *Allied-Signal*); *Chamber of Commerce*, 443 F.3d at 908 (vacating rule, but withholding issuance of the mandate for at least 90 days to allow agency time to cure defect through new comment period); *Gerber v. Norton*, 294 F.3d 173, 184 (D.C. Cir. 2002) ("We . . . remand to the district court with instructions to remand to the agency for further proceedings" in light of failure of agency to make relevant underlying data available during comment period) (citing *Sugar Cane Growers*, 289 F.3d at 98); *Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1135 & n.4 (D.C. Cir. 1995) ("the rule should be remanded for further proceedings without being vacated"; "we assume that the agency will act with due haste to provide the requisite opportunity for meaningful comment and explanation").

[3] Courts in this Circuit have tended to vacate in cases of "utter failure" to engage in notice-and-comment rulemaking, *e.g. Sprint Corp. v. FCC*, 315 F.3d 369 (D.C. Cir. 2003); *Utility Solid Waste Activities Group v. EPA*¸ 236 F.3d 749 (D.C. Cir. 2001); *Mendoza v. Perez*, 72 F. Supp. 3d 168 (D.D.C. 2014); *In re Long Distance Telephone Service Federal Excise Tax Refund Litigation*, 853 F. Supp. 2d 138 (D.D.C. 2012). But they have not always done so. *See Sugar Cane Growers Coop. of Florida v. Veneman*, 289 F.3d 89 (D.C. Cir. 2002 (remanding without vacatur in such a case). Similarly, courts in this Circuit have tended to vacate in "logical outgrowth" cases, *e.g. Environmental Integrity Project v. EPA*, 425 F.3d 992 (D.C. Cir. 2005); *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2011); *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250 (D.C. Cir. 2005); *AFL-CIO v. Chao*, 496 F. Supp. 2d 76 (D.D.C. 2007). But, again, they have not always done so. *E.g. Fertilizer Institute v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) (remanding without vacatur in such a case).

That "utter failure" and "logical outgrowth" cases have ended in vacatur more often than "opportunity to comment" cases makes sense: in "utter failure" and "logical outgrowth" cases, prior to the final rule the agency did not formally alert interested parties about a proposed course of action, and did not take any comment whatsoever on any aspect of the ultimate rule—its legal basis, factual support, policy judgments, or execution. In "meaningful opportunity" cases (like this one), on the other hand, the *dramatis personae* are already present and accounted for, and the matter to be revisited on remand is generally a much narrower slice of the agency's decision (here, certain aspects of the methodology underlying the actuaries' estimate). *Cf. Heartland*, 566 F.3d at 199 (contrasting utter failure to engage in notice and comment with "agency's failure . . . to explain why it chose one approach rather than another for one aspect of an otherwise permissible rule"; holding remand without vacatur appropriate in latter case). That makes it much more straightforward to show, as the Government did above, that confirmation of the original rule is a serious possibility even after the rulemaking deficiency is corrected.

B. Decision to Offset Overpayment

Apart from their challenge to the Secretary's estimate that her payment rule change would increase hospital payments by $220 million, the *Shands* Plaintiffs also argue that the Secretary did not sufficiently explain her decision to offset an increase of any amount. *See* Shands MSJ at 23–24. Were the Court to agree (but it should not), the first *Allied-Signal* factor again counsels against vacating on this basis because any such deficient explanation could easily be redressed on remand, and very likely would be.

The Secretary has in other cases found it desirable (or in the language of 42 U.S.C. § 1395ww(d)(5)(I)(i), "appropriate") to ensure that a change in payment rules not artificially increase Medicare payments, *i.e.*, that a changed rule not cause an increase in payments to

hospitals for the same basket of services. *E.g. Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 700 (D.C. Cir. 2014) ("The Secretary determined there was an artificial increase unrelated to any actual change in the severity of illness treated. She therefore made a downward adjustment . . . [.]"). Indeed, the Secretary's reason for ensuring that the two-midnight rule not give hospitals a windfall at the expense of the taxpayers is reflected in the Medicare statute itself. Congress has again and again indicated that it is appropriate (and sometimes mandatory) for the Secretary to ensure that rule changes be made budget neutral. *E.g.* 42 U.S.C. § 1395ww(d)(8)(D) (mandating that geographic reclassification be budget neutral); Balanced Budget Act of 1997, Pub. L. No. 105-33 § 4410(a) (codified at 42 U.S.C. § 1395ww note) (mandating that "rural floor" for urban wage index be implemented in a budget neutral way); 42 U.S.C. § 1395l(t)(2)(E) (outlier adjustments shall be implemented "in a budget neutral manner"). In any such case hospitals could argue that they deserve to keep whatever increased payments for the same services would result from un-adjusted application of the new rule, but Congress and the Secretary have taken the opposite view.

Thus, if the Court were to find the Secretary's explanation of her judgment to offset the estimated increase resulting from the payment rule change in this case somehow deficient, there is no reason to doubt that the Secretary could articulate a fuller explanation of the desirability of budget neutrality in a supplemental Federal Register notice. And it is very likely that she would adhere to that well-established policy after giving the matter further consideration.

II. Second Factor: Vacatur Would Cause Significant Disruption

Where, as here, it is not "unlikely that the agency will be able to justify a future decision to retain the Rule," the second *Allied-Signal* factor "is only barely relevant." *Fox Television Stations, Inc.*, 280 F.3d at 1049; *see also U.S. Telecom. Ass'n v. FBI*, 276 F.3d 620, 627 (D.C.

Cir. 2002) (basing decision to remand without vacatur solely on conclusion that first *Allied-Signal* factor counseled remand). That said, vacatur would cause significant disruption, so the second *Allied-Signal* factor also supports leaving the adjustment in place while the Secretary cures any rulemaking deficiencies on remand.

Vacatur would cause two sorts of disruption. First is the loss of Medicare trust fund dollars. The D.C. Circuit has found precisely this sort of disruption to favor remand without vacatur under the second *Allied-Signal* factor. *See Heartland Regional Medical Center v. Sebelius*, 566 F.3d 193, 197–98 (D.C. Cir. 2009) (disruption of lost Medicare funds favored remand without vacatur); *see also Allied-Signal*, 988 F.2d at 151 (finding vacatur "quite disruptive" because agency would have to "refund" fees).

Vacatur would cost the taxpayers hundreds of millions of dollars by giving the hospitals the benefit of the artificial increase in payments that the -0.2% downward adjustment seeks to avoid. Hospitals could be expected not only to seek a refund of the -0.2% million adjustment to their payments for FY 2014 (a net of $220 million), but also for downstream payment years, which build in the FY 2014 payment rates. *Cf. Heartland*, 566 F.3d at 198 ("vacating the Medicare [payment rule] likely would have required HHS to make payments . . . for any subsequent years until the agency repromulgated the same rule[.]"). Indeed, a number of hospitals have already brought suit challenging the adjustment as it has been applied to their payments so far in FY 2015. *See Am. Hospital Ass'n v. Burwell* (D.D.C. No. 15-cv-0747 (RPM)); *Shands Jacksonville Med. Ctr. v. Burwell*, (D.D.C. No. 15-cv-01150 (RPM)) (challenging application of -.2% downward adjustment to FY 2015 hospital payments). Even assuming that the Secretary were able to issue a reconsidered adjustment following a vacatur by August of 2016—halfway through FY 2016—the interim disruption to the Medicare trust fund

(at potentially $220 million a year times two and a half fiscal years) could exceed half a billion dollars. Remand without vacatur would avoid that blow to the Medicare trust fund.

The fact that there is statutory authority for the Secretary to act retroactively when she deems it in the "public interest," 42 U.S.C. § 1395hh(e)(1)(A), does not alter this conclusion, because there is substantial doubt that the Secretary would exercise that authority to re-institute the adjustment at issue here retroactively following vacatur. *See Heartland*, 566 F.3d at 197–98 ("[W]e think it sufficient for the purpose of the second *Allied-Signal* factor that vacatur of the [procedurally defective Medicare rule at issue] would have raised substantial doubt about HHS's ability to recoup payments it made for years prior[.]"). It would certainly be in the "public interest" for artificially-increased payments not to be made to hospitals in the first place (the Secretary concluded as much by deeming it "appropriate" to impose the offsetting adjustment challenged in this case). But it is open to challenge whether or not it would be in the public interest to demand hospitals repay such funds. Among other considerations the Secretary might deem relevant to the decision whether to act retroactively are potential hospital reliance on payments received, *cf. Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 215 (1988) ("reliance interests" among bases for presumption against retroactivity), and the administrative burden of initiating and then effectuating a retroactive rulemaking to re-institute the adjustment following vacatur.

It is one thing to keep Medicare payments from flowing out in the first place, it is another thing to reverse the current. Indeed, counsel for Plaintiffs stated Plaintiffs' belief that retroactive application of any adjustment would not just be doubtful, but impossible. *See* Transcript of Motions Hearing Before the Honorable Randolph D. Moss at 11:4-16 (statement of Ms. Stetson)

(Aug. 3, 2015) (arguing that retroactive application here would not come within "very limited circumstances where HHS can retroactively implement a rule").

In fact, in *Adirondack*, the Secretary did *not* recoup hundreds of millions that were paid out over several years due to an artificial increase in hospital payments caused by a change in payment rules, instead opting only to remove the downstream effect of the increase on payment rules for subsequent years. *See Adirondack Med. Ctr. v. Sebelius*, 891 F. Supp. 2d 36, 42 (D.D.C. 2012) (Secretary did not begin to impose adjustment to offset artificial increase in rural and sole-community hospital payments caused by adoption of MS-DRG system in FY 2008 until FY 2011). The hospitals there received a sizable windfall, at the taxpayers' expense, due to the lag between implementation of the rule change in one year and the Secretary's ultimate implementation of an adjustment to offset it several years later. *See id.* at 41 ("sole community and rural hospitals (like Plaintiffs) generally obtained higher payments in FY 2008 and FY 2009). The Secretary here sought to avoid such a costly result by basing her section (d)(5)(I)(i) adjustment in this case on an *estimate* of the artificial increase, rather than take a wait-and-see approach. If the Court vacates, however, the damage will be done—despite emerging data that bears out the underlying estimate. *See* Medicare Program: Short Inpatient Hospital Stays, 80 Fed. Reg. 39,200 at 39,369 (July 8, 2015). So the second *Allied-Signal* factor also counsels against vacatur.

Even if a retroactive rulemaking were certain (rather than doubtful), the second *Allied-Signal* factor would nonetheless counsel against vacatur because vacatur would unsettle hospital payments systemwide—in FY 2014 and in subsequent payment years. This would create challenges for the past, present, and future of Medicare payments, forcing the agency to consider and as necessary implement corrective administrative measures. Remand without vacatur is

appropriate because it would avoid this waste of scarce administrative resources. *See Black Oak Energy, LLC v. FERC*, 725 F.3d 230, 244 (D.C. Cir. 2013) ("transaction cost[]" counseled against vacatur).

First, vacatur would create the challenge of effectuating a refund; the Secretary would need to develop and implement an administrative measure for paying hospitals the appropriate fraction of their FY 2014 payments. Second, vacatur would create a challenge for subsequent payment years—which are based on FY 2014 rates—forcing the Secretary to determine whether and how to adjust ongoing and future hospital payments (for 2015, 2016, and so on) until any re-promulgated adjustment is imposed. And third, if the Secretary were ultimately to re-instate the adjustment retroactively at some future date, effectuating that decision would create its own administrative challenge. That burden underscores the doubt, discussed above, that the taxpayers could get back the half-billion or more in Medicare trust fund dollars at stake were the Court to vacate.

CONCLUSION

Accordingly, should the Court conclude that the rulemaking by which the Secretary imposed the challenged adjustment was defective in one or more respects, Defendant respectfully requests that it remand for further action by the agency in light of its ruling without vacating the adjustment.

Dated: August 24, 2015

Respectfully submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General

JOEL McELVAIN
Assistant Branch Director
Federal Programs Branch

DANIEL BENSING
Senior Trial Counsel

Federal Programs Branch

/s/ Matthew J.B. Lawrence
MATTHEW J.B. LAWRENCE
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue NW
Washington, DC 20530
Tel: (202) 616-8105
Fax: (202) 616-8470
Email: Matthew.Lawrence@usdoj.gov

Attorneys for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of August 2015, I caused the foregoing document to be served on Plaintiff's counsel of record electronically by means of the Court's CM/ECF system.

/s/ Matthew J.B. Lawrence
MATTHEW J.B. LAWRENCE