UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, Defendant.	)	Case No. 1:18-cv-02841-RMC
UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, *et al.*, Plaintiffs, v. ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, Defendant.	)	Case No. 1:19-cv-00132-RMC

MEMORANDUM OF THE *UNIVERSITY OF KANSAS HOSPITAL AUTHORITY* PLAINTIFFS IN OPPOSITION TO MOTION TO MODIFY

The Secretary's motion for reconsideration is a strange document. Unable to locate any defect in the order that this Court has entered, the Secretary decries the chaos that might have ensued if an entirely different ruling, one purely of his own imagining, had been issued instead. *If* the Court had declared the entire Medicare Outpatient Prospective Payment System (OPPS) unlawful, and *if* the Court had proceeded to vacate the entire rule governing payments under that system, the Secretary warns, the disruptive consequences of such a ruling would be so severe that the Court would be justified in staying its hand. If one were to proceed from the same premises as does the Secretary, he might very well be correct.

But this Court's actual order bears no resemblance to the one that the Secretary has invented. This Court did not strike down the entire system of OPPS payments. Only one discrete portion of the Secretary's 2019 OPPS rule was at issue in this litigation, and this Court appropriately limited its review to that portion of the rule. In Section X.B of the 2019 OPPS rule, 83 Fed. Reg. 58,818, 59,004-59,015 (Nov. 21, 2018), the Secretary sought a 30 percent cut in OPPS payment rates for one particular type of outpatient service, evaluation and management (E/M) services performed at excepted off-campus provider-based departments. The Secretary attempted to justify this payment cut as an exercise of his "methods" authority under 42 U.S.C. § 1395*l*(t)(2)(F). This Court vacated Section X.B, correctly holding that "a 'method' … is not a price-setting tool, and the government's effort to wield it in such a manner is manifestly inconsistent with the statutory scheme." Memorandum Opinion, ECF No. 31, at 19 (Sept. 17, 2019). Since the Secretary had not attempted to apply a budget-neutrality offset for payment rates for any other form of outpatient service when he imposed his payment cut, implementation of this Court's ruling is now straight-forward. The Secretary need only now follow the statute and pay the Plaintiff Hospitals the rate that applies under the remainder of the OPPS rule for E/M services, absent his unlawful payment reduction.

It was entirely appropriate, then, for this Court to vacate the portion of the rule that declared the payment reduction, and to leave the remainder of the OPPS rule untouched. The Secretary's challenge to the vacatur order (which in any event is waived) fails to show any error in this Court's vacatur of Section X.B, let alone the sort of clear error of law that could warrant reconsideration. First, there is no need for a remand without vacatur, since the Secretary cannot fix his statutory violation on remand, and no disruption results from an order that results simply in the payment to the Plaintiff Hospitals of the ordinary OPPS rate for their outpatient services. Second, this Court

correctly limited its review to Section X.B of the 2019 OPPS rule, as the rest of the rule functions entirely sensibly in the absence of the Secretary's unlawful payment cut. Third, the Secretary cannot now use a remand to search for some other theory to cut payment rates for E/M services in his 2019 OPPS rule; any such effort would suffer from a host of procedural and substantive defects, not the least of which is that it would run afoul of Congress's protection of OPPS payment rates for excepted off-campus departments in Section 603 of the Bipartisan Budget Act of 2015. Finally, the Secretary's alternative request for a stay of vacatur rests on the same incorrect premises as his reconsideration motion does, and it should be rejected for the same reasons.

ARGUMENT

I. The Secretary Has Waived His Request for Remand Without Vacatur

The Plaintiff Hospitals sought vacatur of the Secretary's rate cut for E/M services at excepted off-campus PBDs, and explained in briefing their entitlement to an order of vacatur. *See* Second Am. Compl., ECF No. 15, at 27 (Mar. 14, 2019); Pls.' Reply Mem. in Supp. of Their M.S.J. and Mem. in Opp'n to Def.'s Mot. to Dismiss, ECF No. 18, at 20 (Apr. 5, 2019).[1] The Secretary also briefed the question of remedies, but never disputed that vacatur would be required if the Plaintiff Hospitals were to prevail on the merits. *See* Reply in Supp. of Def.'s Mot. to Dismiss, ECF No. 21, at 16 (Apr. 19, 2019). Having failed to dispute the need for vacatur during the merits briefing, the Secretary should not be heard now to raise the issue on reconsideration. *See Carter v. Washington Metro. Area Transit Auth.*, 503 F.3d 143, 145 n.2 (D.C. Cir. 2007) (issue is "improperly raised" if argued for first time on reconsideration).

[1] All references to pleadings in this action entered before this Court's consolidation order are to docket entries in *University of Kansas Hospital Authority, et al. v. Azar*, No. 19-132.

In any event, even if the Secretary had properly preserved the issue, he could not meet his heavy burden to justify reconsideration of this Court's vacatur order. Such relief is not available "in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice." *Estate of Klieman v. Palestinian Auth.*, 923 F.3d 1115, 1122 (D.C. Cir. 2019) (internal quotation omitted). A showing of extraordinary circumstances would require proof, for example, of "a clear error of law in the first order." *Id.* In vacating the unlawful payment cut for E/M services, this Court did not commit any error of law, let alone a "clear" one or a "manifest[ly]" unjust one. To the contrary, as explained below, this Court faithfully followed circuit precedent that sharply limits the circumstances in which an agency could ask for a remand without vacatur of an unlawful rule.

II. This Court Correctly Vacated the Challenged Portion of the OPPS Rule

When a court holds that an agency rule is contrary to law, the "ordinary practice is to vacate" it. *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 673 (D.C. Cir. 2019). In "rare cases," however, the court may elect to remand the matter to the agency without vacating the rule, to give the agency the opportunity to correct its errors. *Id.* at 674. In addressing this possible remedy, the court balances "(1) the seriousness of the deficiencies of the action, that is, how likely it is the agency will be able to justify its decision on remand; and (2) the disruptive consequences of vacatur." *Id.*; *see also Allied-Signal, Inc. v. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993)).

This is not one of the rare cases where remand without vacatur might be justified. Both of the *Allied-Signal* factors weigh strongly in favor of vacatur of the Secretary's unlawful cut in payment rates for E/M services. First, the Secretary's payment cut was seriously—indeed fatally—flawed. As the Court explained in its Memorandum Opinion, the Secretary flatly

exceeded his statutory authority in pursuing his payment cut. This is not an error that could be cured on remand. Second, this Court's vacatur order will not be the least bit disruptive. Vacatur simply restores the normal OPPS rate that otherwise applies for the E/M services that the Plaintiff Hospitals perform, in the absence of the Secretary's unlawful payment reduction.

A. The Secretary's Payment Cut Is Fatally Flawed

It is not "likely" that the Secretary will be able to justify his decision on remand, *Am. Bankers Ass'n*, 934 F.3d at 674; it is not possible for him to do so at all. This Court did not find that the Secretary had committed a procedural violation, such as a failure to respond to comments or a failure to explain his reasoning, that conceivably could be cured on remand. *Cf. Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 268 (D.D.C. 2015) (remanding without vacatur to allow renewed opportunity for public comment on rule). Instead, this Court held that the Secretary had exceeded his statutory authority by attempting to impose a payment cut on one particular form of outpatient services under his paragraph (t)(2)(F) "methods" authority. No proceedings on remand could cure the Secretary's overreach in this regard.

The Secretary does not attempt to argue otherwise, but instead reasons that "there remains considerable doubt over the correct legal outcome," Mot. to Modify Order, ECF No. 33, at 2, because he might prevail on appeal. This confuses the issue. The "seriousness" prong of the *Allied-Signal* test measures, not the agency's likelihood of success on appeal, but instead "how likely it is the agency will be able to *justify its decision on remand*." *Am. Bankers Ass'n*, 934 F.3d at 674 (emphasis added); *see also Air Transp. Ass'n of Am. v. U.S. Dep't of Agric.*, 317 F. Supp. 3d 385, 391 (D.D.C. 2018). Any residual doubt as to whether the district court's ruling will be sustained on appeal is not a part of this analysis. *See Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1, 13 (D.D.C. 2019), *appeal pending*, No. 19-5198 (D.C. Cir. docketed July 15, 2019). In any event,

this Court's ruling on the merits was entirely correct, and is highly likely to be affirmed on appeal, for the reasons that the Plaintiff Hospitals have explained in their briefing on summary judgment.

B. No Disruptive Consequences Will Arise from the Vacatur

The second *Allied-Signal* factor also weighs heavily in favor of vacatur. This Court's order imposes no risk of disruption on the Secretary, or on providers, at all. It simply calls for the Secretary to apply the normal OPPS payment rate for the E/M services that had been the subject of his now-vacated payment cut. Those rates have already been calculated; all that remains is for payment to be made, to a finite number of Plaintiff Hospitals, at the proper statutory rate.[2]

The 2019 OPPS rule, like each year's rule implementing the outpatient prospective payment system, described the methodology that the Secretary used to calculate, among other things, the "OPD fee schedule increase factor," and thus the overall increase in the total budget for outpatient payments, 83 Fed. Reg. at 58,822, as well as "relative payment weights" for particular outpatient services, resulting in the calculation of the proportion of the overall budget that is payable for each form of outpatient service, *id.* at 58,827. The result was a table setting forth the

[2] This Court's vacatur order entitles each of the Plaintiff Hospitals, by virtue of their status as named plaintiffs in *University of Kansas Hospital Authority v. Azar*, to payment at the full OPPS rate for each of their claims for E/M services that they furnished from January 1, 2019, going forward. Each of the Plaintiff Hospitals presented administrative appeals challenging the Secretary's initial payment determination for claims for E/M services. The Court granted judicial review of the Secretary's payment determination by waiving further exhaustion of the administrative appeals process. *See* 42 U.S.C. § 1395ff(b)(1)(A) (establishing right to judicial review of final determination of Secretary). Having received a ruling in their favor, each of the Plaintiff Hospitals is now entitled to a revised payment determination--in this case, payment at the OPPS rate—for all of their 2019 claims for payment for E/M services, just as they would have if they had been forced to pursue the administrative appeals process under 42 U.S.C. § 1395ff to its conclusion. *See United States v. Mendoza*, 464 U.S. 154, 163-64 (1984) ("where the parties are the same, estopping the government spares a party that has already prevailed once from having to relitigate").

OPPS payment rate for each such service, including services that fall under the agency's HCPCS code G0463 for evaluation and management services. *See* Centers for Medicare & Medicaid Services, *Addendum B: Final OPPS Payment by HCPCS Code for CY 2019*, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html; 83 Fed. Reg. at 58,819 (incorporating Addendum B into final rule). That payment rate applies for all services that fall under code G0463, including E/M services performed at *on*-campus provider-based departments that were not subject to the Secretary's payment cut. Section X.B of the rule—the portion of the rule that this Court has vacated—did nothing to alter the payment rate that applies as a default rule for services falling under code G0463. All that Section X.B did was to take the payment rate that already applies for these services, and to cut that rate by 30 percent for services billed with the code G0463 and the payment modifier "PO," which reflects services performed at excepted off-campus provider-based departments. *See* 83 Fed. Reg. at 59,013-59,014. The vacatur of Section X.B, then, simply restores the normal OPPS payment rate for the Plaintiff Hospitals for these services.

The Secretary, then, is flatly wrong when he asserts that, as a result of vacatur, "there would be no payment rule in effect and no methodology by which [he] could make payments for affected outpatient hospital claims." Mot. to Modify Order at 2. There is a payment rule in effect, and the methodology for him to make payment to the Plaintiff Hospitals is laid out explicitly in the rule that he published and in the tables that he incorporated into his rule. As a result, the Secretary need only instruct his contractors to pay the claims of the several dozen Plaintiff Hospitals at the normal OPPS rate for their E/M services. The Secretary's warnings of potential disruption to OPPS payments, then, are entirely illusory.

The Secretary also asserts that remand without vacatur is warranted because, as a practical matter, it would be difficult for him to recoup excess payments from the Plaintiff Hospitals if he were later to prevail on appeal. Again, it is quite unlikely that the Secretary will succeed on appeal; as this Court has explained, his overbroad reading of his "methods" authority under paragraph (t)(2)(F) cannot be squared with the statute that Congress actually enacted. But in the unlikely event that the Plaintiff Hospitals would owe overpayments back to the Secretary as the result of a reversal on appeal, this would not pose the administrative obstacle that the Secretary claims. The recoupment of overpayments is a regular feature of Medicare's claims processing system. *See Popkin v. Burwell*, 172 F. Supp. 3d 161, 166 (D.D.C. 2016); 42 C.F.R. § 405.371(a). Moreover, all providers are obliged to assist the Secretary by acting in the first instance to return overpayments that they have identified as being owed. *See* 42 U.S.C. § 1320a-7k(d).[3] The possibility of reversal on appeal, then, does not weigh against vacatur under either prong of the *Allied-Signal* test.

III. Only the Challenged Portion of the OPPS Rule Is Properly at Issue in this Case

Unable to find any untoward consequences from an order that simply restores the normal operation of the OPPS payment system, the Secretary tries a bit of legal jujitsu. Although the Court's order on its face applies only to Section X.B of the 2019 OPPS rule, that section is inseparable from the remainder of the rule (the Secretary argues), so the order inadvertently must have brought down the entire system of OPPS payments. This line of argument defies both the law and common sense. The Secretary's attempt to modify the payment rate for one particular

[3] The Plaintiff Hospitals are long-standing and well-respected participants in the Medicare program, and there is no reason to doubt their willingness to cooperate with the Secretary, in the unlikely event that they are found to have received overpayments as a result of a reversal of this Court's order on appeal.

outpatient service was an entirely separate decision from his initial setting of payment rates for all OPPS services, and there is no reason to believe that the two decisions must stand or fall together.

A. This Court Lacks Jurisdiction to Hear the Secretary's Attempt to Invalidate the Remainder of His Rule

The Medicare Act shields many aspects of the Secretary's OPPS calculations from review. The statute declares that "[t]here shall be no administrative or judicial review" of, for example, "the establishment of groups and relative payment weights for covered OPS services," "the calculation of base amounts," and the "periodic adjustments" that the Secretary performs in setting payment rates for outpatient services in each year's OPPS rule. 42 U.S.C. § 1395*l*(t)(12). In asking this Court to expand its review from the particular payment cut for E/M services in Section X.B of the 2019 OPPS rule to the entirety of the OPPS system, the Secretary is asking the Court to engage in judicial review of, among other things, his establishment of groups, his calculation of relative payment weights, his calculations of base amounts, and his periodic adjustments. The judicial review bar in paragraph (t)(12) prevents such an inquiry.

Of course, the statute also bars review of the Secretary's use of "methods" under paragraph (t)(2)(F). 42 U.S.C. § 1395*l*(t)(12)(A). This Court held, correctly, that "CMS cannot shield any action from judicial review merely by calling it a 'method,' even if it is not that." Memorandum Opinion at 14. Because a raw payment cut for one particular form of service is not a "method" within the meaning of paragraph (t)(2)(F), this Court correctly reasoned, the Secretary's invocation of that provision was *ultra vires*, and the statute did not preclude its review of the payment cut. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004). But no party in this litigation has contended that the Secretary's initial calculations of payment rates for OPPS services was in any way *ultra vires*. The Secretary acted within his authority by following the statutory formulas for the calculation of the overall budget for OPPS payments for 2019 and the allocation of that budget

to payments for the various forms of OPPS services. It was only when he attempted to depart from those formulas to impose a payment cut for E/M services that he violated the statute. Accordingly, the statute forbids the Court from engaging in judicial review of any other aspect of the OPPS rule, apart from the particular provision that was *ultra vires*.

B. This Court Properly Severed the Remainder of the OPPS Rule from the Challenged Portion

Even if this Court did have jurisdiction to hear the Secretary's attempt to impeach his own rule, his effort would still fail. The APA defines "agency action" to include "the whole or a part of an agency rule [or] order." 5 U.S.C. § 551(13). Thus, the APA's cause of action for review of the lawfulness of "agency action," 5 U.S.C. § 706(2), permits a court to review and set aside only the particular portion of a rule that exceeds an agency's authority. "Two conditions limit the exercise of this power. First, the court must find that the agency would have adopted the same disposition regarding the unchallenged portion of the regulation if the challenged portion were subtracted. Second, the parts of the regulation that remain must be able to function sensibly without the stricken provision." *Carlson v. Postal Regulatory Comm'n*, --- F.3d ---, 2019 WL 4383260, at *10 (D.C. Cir. Sept. 13, 2019) (internal quotations and alterations omitted). Both elements of this test are satisfied here, and this Court correctly limited its review of Section X.B of the OPPS rule. At a minimum, this Court did not commit any clear error of law, or work any manifest injustice, in so limiting its review.

1. The Remainder of the Rule Functions Sensibly

Absent Section X.B, the remainder of the 2019 OPPS rule not only functions sensibly, it functions in accordance with Congress's instructions. As noted above, the statute sets forth a series of formulas for the Secretary to follow, first, in calculating the total pool of funds to be paid for outpatient services in a given year, and second, in allocating those funds among the various forms

of outpatient services that are paid under OPPS. *See* pp. 6-7, *supra*. The 2019 OPPS rule followed the statutory formulas to arrive at the calculation of payment rates for the full range of outpatient services, including E/M services payable under code G0463. It was only when the Secretary next proceeded to declare a 30 percent payment cut for E/M services performed at off-campus provider-based departments that he exceeded his statutory authority. This Court's order remedied that statutory violation by vacating Section X.B. The remaining portion of the rule simply describes the payment rates for outpatient services under the normal operation of the statute, in the same manner that each year's OPPS rule up until the 2019 rule has done.

2. The Secretary Would Have Adopted the Remaining Portions of the Rule in the Absence of the Payment Cut

There should be no reasonable question that the Secretary would have adopted the remainder of the OPPS rule, in the absence of Section X.B. He is required by law to publish an OPPS rule that calculates payment rates for outpatient services, and to do so annually. His performance of this mandatory duty is almost entirely a ministerial task, as the formula for the calculation of these rates is set forth in the statute itself. The Secretary could not seriously now contend that he intended his performance of his statutory duties to be contingent on the validity of his unlawful payment cut in Section X.B of the rule.

As the Secretary explained in the rule itself, he published his 2019 rule because he was statutorily obligated to do so. *See* 83 Fed. Reg. 58,818, 58,820 (Nov. 21, 2018); *see also id.* at 59,159. The OPPS statutes impose a mandatory duty on the Secretary to calculate the total budget for OPPS payments and the allocation of those payments, and to perform that calculation on an annual basis. *See* 42 U.S.C. § 1395*l*(t)(9)(A) ("The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) …"); *see also, e.g.*, *id.* § 1395*l*(t)(3)(C)(iv) ("OPD fee schedule increase

factor" is to be determined annually); (t)(5)(C)(i) (outlier adjustments are to be determined annually).

The statute sets forth in precise detail the specific calculations that the Secretary must perform in his annual rulemaking:

> Almost every provision in § 1395*l*(t)(2) governing OPPS payments requires that the Secretary "shall" compute payment amounts in a certain manner: the Secretary "shall" develop a classification system for covered services, § (t)(2)(A); "shall" use median or mean cost data to establish payment weights for those services, § (t)(2)(C); "shall" determine wage adjustment factors, § (t)(2)(D). Other than the Secretary's authority to group clinically similar services together for payment purposes pursuant to § (t)(2)(B), OPPS payments are calculated almost entirely based on steps the Secretary "shall" take.

Amgen, Inc., 357 F.3d at 115. For example, 42 U.S.C. § 1395*l*(t)(3)(C)(iv) describes the mathematical formula for calculating a given year's OPD fee schedule increase factor, which in turn determines the total amount of funds to be allocated for OPPS in that year. The statute does not leave that calculation to the Secretary's discretion; instead, he followed the statutory formulas in determining the total amount of funds available for OPPS payments for 2019. *See* 83 Fed. Reg. at 59,162 (describing calculations).

The Secretary is flatly wrong, then, when he suggests that he "may have reduced rates overall" in the absence of the payment cut for E/M services, Mot. to Modify Order at 6; the statute did not leave him with the power to do anything other than to perform the calculations specified in paragraph (t)(3)(C). The Secretary further misdescribes his own rule when he asserts that, in setting the 2019 payment schedule, he "took into account the approximately $300 million [in] reduced expenditure that would result from CMS's [purported] exercise of its Subsection (t)(2)(F) authority." *Id.* This is not so. First, his rule performed the calculations required by statute to arrive at a total budget for OPPS expenditures for 2019. *See* 83 Fed. Reg. at 59,160. Second, only

after those initial calculations were completed, his rule separately calculated the total amount of OPPS expenditures that would result from the inclusion of Section X.B in the rule. *See id.*

Given that "the initial setting of OPPS rates and later adjustments are *different decisions*." *Amgen, Inc.*, 357 F.3d at 116 (emphasis added), then, it is unsurprising that the Secretary, first, performed his statutory duty to initially set OPPS rates in accordance with the formula set by statute, and then, second, proceeded to consider "additional policy changes" that in his view would justify modifying those initial rates. 83 Fed. Reg. at 58,820. The "design of the regulation" in this manner, *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988), is a powerful indication that Section X.B is severable from the remainder of the rule. *See also Carlson*, --- F.3d ---, 2019 WL 4383260, at *11 ("These rates are not interconnected by statute and the [agency] analyzed them independently in separate ordering paragraphs."); *Davis Cty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997).

There is no meaningful doubt, then, that the Secretary made separate decisions, first, to publish the initial setting of OPPS payment rates for outpatient services as required by statute, and second, to seek to modify those initial rates for one particular form of outpatient service through an unlawful invocation of his "methods" authority. And there is no reason to believe that the first decision turned in any way on the second, or that the Secretary intended the entire 2019 OPPS rule to stand or fall together. The Secretary, after all, should be presumed to follow Congress's instruction in implementing the Medicare Act, and Congress has directed that "any application" of the Medicare Act that is held to be invalid (such as the payment cut for E/M services) shall not affect the validity of other applications of the statute (such as the remainder of the 2019 OPPS rule). *See* 42 U.S.C. § 1303 ("If any provision of this chapter, or the application thereof to any person or circumstance, is held invalid, the remainder of the chapter, and the application of such

provision to other persons or circumstances shall not be affected thereby."). This severability clause "confirm[s] that the Court need go no further" than to invalidate the unlawful payment cut for the Plaintiff Hospitals, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 586 (2012) (plurality opinion), as the Secretary should be presumed to have followed "Congress's explicit textual instruction to leave unaffected" the unchallenged portions of the rule, *id.* (plurality opinion); *accord, id.* at 645 (Ginsburg, J., concurring in relevant part).

IV. The Secretary Is Now Foreclosed from Pursuing Further Modifications to 2019 OPPS Rates

The Secretary confuses the severability issue when he suggests, Mot. to Modify Order at 6, that he might use a remand to replace Section X.B with some other, unnamed policy that would cut payment rates for E/M services in a different way. The severability question does not turn on whether the Secretary might now wish another try at his unlawful payment cut. The relevant question instead is whether the Secretary "would have adopted the same disposition *regarding the unchallenged portion* if the challenged portion were subtracted." *Epsilon Elecs., Inc. v. U.S. Dep't of Treasury*, 857 F.3d 913, 929 (D.C. Cir. 2017) (emphasis added); *see also Davis Cty. Solid Waste Mgmt.*, 108 F.3d at 1459. The unchallenged portion—that is, the initial setting of OPPS rates—of the 2019 rule did not depend on Section X.B, or on any replacement for Section X.B that the Secretary might now offer, for its validity. In any event, any renewed effort by the Secretary to cut 2019 rates for E/M services would be both procedurally and substantively invalid.

A. Any New Effort to Modify OPPS Payment Rates Would Not Be a Logical Outgrowth of the Secretary's Proposed Rule

The Secretary's proposed rule for 2019 OPPS payment rates described his methodology for the initial setting of rates for outpatient services and his proposal to invoke his "methods" authority to cut payment rates for E/M services for excepted off-campus provider-based

departments. *See* 83 Fed. Reg. 37,046 (July 31, 2018). The Secretary did not describe any other theory in which he might pursue a payment cut for those services, other than to note that he had considered pursuing a budget-neutral approach to the issue and had concluded that such an approach would serve no useful purpose. *Id.* at 37,143. The Secretary adhered to the same reasoning in his final rule:

> We stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37143) that we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the movement of the volume within the OPPS system in the aggregate …. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply reallocate expenditures that are unnecessary within the OPPS, we believe that this method must be adopted in a nonbudget neutral manner.

83 Fed. Reg. at 59,009.

After concluding that a budget-neutral approach would not be "effective[]" in his proposed rule and in his final rule, the Secretary could not now use a remand to contradict himself. Providers certainly could not have "anticipate[d] that such a volte-face with enormous financial implications would follow the Secretary's proposed rule." *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1109 (D.C. Cir. 2014). For this reason, the Medicare Act would forbid the Secretary from giving effect to a new form of a payment cut that he had specifically rejected in his proposed rule. *See* 42 U.S.C. § 1395hh(a)(4).

B. Any New Effort to Modify OPPS Payment Rates Would Be Unlawfully Retroactive

What is more, the 2019 calendar year is nearly complete. Any renewed effort by the Secretary at a payment cut for E/M services for the current year would reach services that the Plaintiff Hospitals have already performed, and thus would be unlawfully retroactive. The Medicare Act sharply limits the circumstances in which the Secretary may act retroactively:

> A substantive change in regulations … shall not be applied … retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest.

42 U.S.C. § 1395hh(e)(1)(A). A new payment cut for E/M services could not be justified under this provision. Such a new rate would not be "necessary to comply with statutory requirements"; the remaining portion of the 2019 OPPS rule already comports with the statute. Nor would such a payment cut serve the "public interest." *See United States v. Ross*, 848 F.3d 1129, 1132 (D.C. Cir. 2017) (parallel language in APA, allowing immediate publication of rule where notice and comment would be "contrary to the public interest," states an exception that "is to be narrowly construed and only reluctantly countenanced"). Whatever economic goals the Secretary might have had in mind in pursuing his payment cut in the first instance, no purpose would be served now by denying payment to the Plaintiff Hospitals at the statutorily-dictated rate for services that they have already performed.

C. Any New Effort to Modify OPPS Payment Rates Would Violate Section 603 of the Bipartisan Budget Act

Finally, any new attempt at a payment cut for E/M services would not cure Section X.B's legal defects. Congress acted in 2015 to preserve OPPS payment rates for services performed by excepted off-campus provider-based departments. *See* Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 598 (2015). As Congress explained when it passed clarifying legislation the following year, Section 603 "effectively grandfathered any off-campus PBD [hospital outpatient department] that was billing outpatient services before [the] date of [its] enactment." H.R. Rep. No. 114-604, at 10 (2016), and its legislation guaranteed that existing "[o]ff-campus facilities … continue to receive the higher payment rates that apply to an outpatient department on the campus of a hospital," *id.* at 20. By enacting Section 603, then, Congress

"demonstrated that it retains for itself the authority to make … selective funding decisions in this highly complicated intersection of patient needs, medical care, and government funding through the relative payment weight system." Memorandum Opinion at 26.

The Plaintiff Hospitals explained in their summary judgment briefing that the Secretary's payment cut for E/M services was *ultra vires*, not only because he incorrectly invoked his "methods" authority to attempt to justify it, but also because the Secretary's actions flouted Congress's instructions in Section 603. The Secretary's suggestion that he intends to use a remand to continue to violate Section 603 should not be countenanced, then. Whether he chooses to describe his effort as an exercise of his "methods" authority under paragraph (t)(2)(F), or as an exercise of any other authority in the OPPS statute, the Secretary does not have the authority to ignore Congress's instructions that excepted off-campus departments must be paid at OPPS rates.

IV. The Secretary's Alternative Request for a Stay Rests on His Incorrect Belief that No Payment Rule Is Currently in Effect

The Secretary also asks the Court to stay its vacatur order pending the government's decision whether to authorize an appeal. He fails entirely, however, to discuss the standards for a stay pending appeal, let alone attempt to explain how his request could meet the standards for such "extraordinary relief." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 904 F.3d 1014, 1017 (D.C. Cir. 2018). The only justification he offers for this request is his statement that, absent a stay, "there would be no payment rule in effect and no methodology by which [he] could make payments for affected outpatient hospital claims." Mot. to Modify Order at 2. But, as explained above, this is a patently incorrect reading of the 2019 OPPS rule and of this Court's vacatur order. The vacatur of Section X.B of the rule leaves the separately-calculated payment rates in effect for all services, including E/M services furnished at excepted off-campus provider-based departments.

The "methodology" for payment is the one already laid out in the remainder of the 2019 rule, which describes the "payment rule [that is] in effect."

CONCLUSION

For the foregoing reasons, the Plaintiff Hospitals respectfully request that the Court deny the Secretary's motion for reconsideration.

Dated: October 1, 2019

Respectfully submitted,

/s/ Mark D. Polston
Mark D. Polston (Bar No. 431233)
Christopher P. Kenny (Bar No. 991303)
Nikesh Jindal (Bar No. 492008)
Joel McElvain (Bar No. 448431)
KING & SPALDING LLP
1700 Pennsylvania Av., N.W.
Suite 200
Washington, D.C. 20006
202.626.5540 (phone)
202.626.3737 (fax)
MPolston@kslaw.com

Counsel for the Plaintiffs in Case No. 19-132