IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

BRIEF ON REMEDY

INTRODUCTION

The Court concluded that the defendants – the U.S. Department of Health and Human Services and its Secretary (referred to collectively throughout as "the Agency") – acted in an *ultra vires* fashion by reducing the payment rate for drugs purchased through the 340B Program in the 2018 Outpatient Prospective Payment System ("OPPS") Rule, 82 Fed. Reg. at 52, 362. Memorandum Opinion ("Op."), Dec. 27, 2018, ECF No. 25. Accordingly, the Court instructed the parties to file "supplemental briefing on the appropriate remedy." Order, Dec. 27, 2018, ECF No. 24.

The proper remedy, assuming plaintiffs are entitled to one, is for the Court to remand the matter to the Agency.[1] When a district court reviewing agency action identifies a non-harmless flaw in an agency rule, the standard remedy is to remand the matter to the agency because, in this

[1] Defendants' position on this suit remains unchanged: Plaintiffs are not entitled to relief, and the case should be dismissed. But to address the Court's Order, the arguments made in this brief are based on the premise that plaintiffs are entitled to some relief.

situation, the district court is acting as an appellate tribunal. *Northern Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012). That is precisely the situation here.

The decision to remand a matter to an agency raises a related question, however: Should the Court vacate the rule, or remand without vacatur? The D.C. Circuit has established a two-part test to guide that inquiry, which looks to the seriousness of the alleged flaw in the rule and the potentially disruptive consequence of vacatur. *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993). Application of that test here demonstrates that vacatur is not warranted. Among other things, vacatur would cause great disruption to Medicare's payment system for outpatient claims. It would either result in application of an old rule, designed to last only a year, or a need for the Agency to promulgate a new rule to fill a regulatory vacuum. Vacatur would also introduce problems with the statutory budget neutrality requirement that would necessitate the entire OPPS to be recalculated for 2018: When the Agency decreased the payment rate for drugs purchased through the 340B Program, it correspondingly increased the payment for other items and services covered under the OPPS. Increasing payments for drugs purchased through the 340B Program in calendar year 2018 would upend this budget-neutral balance, affecting the more than *110 million* OPPS claims the Agency expect to process for 2018. *See* Declaration of Elizabeth Richter, Jan. 31, 2019, ¶¶ 3, 7. And attempts to remedy the violations of the budget neutrality obligation would be expensive (both in time and resources) and upset the expectations of those who received payments on millions of claims for items and services other than 340B Program drugs. *See Id.* ¶¶ 7, 9. They could also negatively affect Medicare beneficiaries. *Id.* ¶ 8. Plaintiffs' apparent desire to receive windfall payments on 340B Program drugs does not justify wreaking such "havoc" on the

Medicare system. *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Circ. 2004) (describing the effect of piecemeal review of elements of the OPPS).

Remand without vacatur is the better option. It affords the Agency an opportunity to craft a remedy in the first instance, which is consistent with the "substantial deference that Courts owe to the Secretary [of Health and Human Services] in the administration of such a 'complex statutory and regulatory regime.'" *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 2018 WL 6831167, at *13 (D.D.C. Dec. 28, 2018) (quoting *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993)). Perhaps the Agency would choose to prospectively increase the payment for 340B Program drugs as a remedy for the previous decrease. *See id*. at 12-13. Perhaps, instead, the Agency would choose to tackle a retroactive change, notwithstanding the challenges described above. Perhaps there is another option. Whatever the case, the choice should rest with the Agency in the first instance, given the potential for disruption in the immense and complex system that has been entrusted to the Agency to operate.

In short, the proper remedy is a remand of this matter to the Agency without vacatur of the 2018 OPPS Rule, and a denial of the remainder of the relief sought by plaintiffs.

ARGUMENT[2]

Plaintiffs seek three remedies, namely, they request that the Court: (1) vacate the 2018 OPPS rule, (2) order the Agency to apply the 2017 OPPS reimbursement rate to remaining claims for drugs purchased through the 340B Program, and (3) order the Agency to pay the hospital plaintiffs and the 340B Program participants who are members of the association plaintiffs the difference between the 2017 OPPS reimbursement rate and the 2018 OPPS reimbursement rate for all drug purchases made through the 340B Program.[3] Compl. at pp. 23-24; Op. at 33-34. The Court should remand without vacatur and reject the remainder of plaintiffs' requests.

The Court should not vacate the 2018 OPPS rule. When a court concludes that a rule violates the law, the court must determine whether to vacate the rule and remand to the agency or

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[2] The Court concluded that the Agency acted in an *ultra vires* fashion. But it is unclear whether the Court concluded that the preclusion provisions did not apply and, therefore, determined, under the APA, that the Agency's action was *ultra vires*, or in the alternative, whether the Court relied on its non-statutory review authority to invalidate *ultra vires* agency actions. *See* Op. at 21-23. Ultimately, however, it does not matter because the application of proper remedial principles dictate the same result: A remand to the Agency to permit it to provide appropriate relief through rulemaking.

Whether under the APA or nonstatutory review, courts consider equity when crafting remedies. Take first APA review. While 5 U.S.C. § 706(2)(A) provides that "the reviewing court shall ... hold unlawful and set aside agency action ... found to be ... not in accordance with law," section 702 states that "[n]othing herein ... affects ... the power or duty of the court to ... deny relief on any other appropriate ... equitable ground ...." *See Oglala Sioux Tribe v. U.S. Nuclear Regulatory Comm'n*, 896 F.3d 520, 536 (D.C. Cir. 2018). And as nonstatutory review is an exercise of a court's equitable authority, equity necessarily guides the court's remedial choices. *See Jaffee v. United States*, 592 F.2d 712, 718 (3d Cir. 1979) (referring to a claim seeking nonstatutory review as an equitable action). Thus, the analysis is essentially the same, and it will be treated as such here.

[3] Plaintiffs also sought an injunction regarding the 2019 OPPS Rule, but the Court has already rejected that request for relief because the Complaint does not explicitly challenge the 2019 OPPS Rule, and Plaintiffs failed to demonstrate that they satisfied the presentment requirement with respect to that rule. Op. at 34 n. 25.

whether to remand the matter to the agency without vacating the rule. "The decision whether to vacate depends on the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993) (quotation marks omitted). "There is no rule requiring either the proponent or opponent of vacatur to prevail on both factors . . . Rather, resolution of the question turns on the Court's assessment of the overall equities and practicality of the alternatives." *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 270 (D.D.C. 2015).

Neither *Allied-Signal* factor favors vacatur. First, there remains some "doubt about whether the agency chose correctly," *Allied Signal*, 988 F.2d at 150, notwithstanding the Court's decision that the Agency exceeded its "adjustment" authority and therefore acted in an *ultra vires* fashion. That decision rests on two conclusions: 1) the Agency cannot consider cost of acquisition unless it is has the data specified in 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("Section I"), and 2) the term "adjustment" does not countenance a reduction in the reimbursement rate as large as 30%. Op. at 27-30. But the statute does not explicitly preclude the consideration of the cost of acquisition in 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("Section II"), and it is reasonable to read the statute to mean that the cost of acquisition *must* be considered, under Section I, if the Agency possesses the data specified in the statute, but *may* be considered, under Section II, even if it does not. Moreover, as the Agency pointed out in its reply brief, it is common in the law to use the term "adjustment" to refer to changes as large as 30%. *See, e.g., Asbun v. Resende*, 2017 WL 24781, at *1 (S.D. Fla. Jan. 3, 2017) (referring to a report and recommendations "30% downward adjustment to the lodestar calculation" of attorney's fees); *Davis v. Comm'r IRS*, 109

T.C.M. (CCH) 1450 (T.C. 2015) (discussing "30% adjustment[s]" to property appraisals); *ASARCO LLC v. Americas Mining Corp*., 396 B.R. 278, 352 (S.D. Tex. 2008) (discussing a "30% downward adjustment" made to a corporate valuation "to account for size and foreign risk"). Thus, there is "doubt about whether the agency chose correctly," and, given the potential for appellate review, some possibility that the Agency would be permitted to make that choice again.

The second *Allied-Signal* factor weighs heavily against vacating the rule, because doing so would wreak havoc on the Medicare reimbursement system for outpatient services. *Cf.* Op. at 35. The portion of the rule addressing payment for drugs purchased under the 340B Program cannot be severed from the rest of the OPPS rates set forth in the 2018 OPPS rule. "Severance and affirmance of a portion of an administrative regulation is improper if there is 'substantial doubt' that the agency would have adopted the severed portion on its own." *Davis County Solid Waste Mgmt. & Energy Recovery Special Serv. Dist. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir.1997). Here, the impropriety of severance is clear. The law requires this type of payment adjustment to the OPPS system to be made in a budget neutral manner. 42 U.S.C. § 1395*l*(t)(14)(H). Accordingly, when the Agency reduced the payment rate for drugs purchased through the 340B Program, it increased the payment rate for other items and services covered by the 2018 OPPS Rule by 3.2%. 82 Fed. Reg. at 52,623. In other words, the various payment rates addressed in the OPPS are necessarily connected. The Agency plainly would not have enacted these OPPS rates without addressing the payment rate for 340B Drugs. And, as a result, if the Court were to vacate the portion of the rule dealing with the payment rate for drugs purchased through the 340B Program, it would have to vacate other rates set by 2018 OPPS Rule in their entirety.

Vacating the 2018 OPPS Rule would likely leave the Agency in an untenable position. After vacating a rule, courts sometimes reinstate the rule previously in effect. *See Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 757 (D.C.Cir.1987). Other times, they "leave[ ] it to the agency to craft the best replacement for its own rule." *Small Refiner Lead Phase–Down Task Force v. EPA*, 705 F.2d 506 (D.C. Cir. 1983). One judge in this district has said the choice depends on the facts of the case. *Oceana, Inc. v. Evans*, 389 F. Supp. 2d 4, 6 (D.D.C. 2005) (discussing the two approaches). Based on the facts of this case, there is no good choice. The rule previously in effect, before the 2018 OPPS Rule, was the 2017 OPPS Rule. But that rule was designed to last for only a year, given the regulatory requirement for the Agency to annually update the OPPS payment rates. 42 U.S.C. § 1395*l*(t)(9). Thus, it would be contrary to the design of the 2017 OPPS Rule to hold that it could spring back into existence and be used for the payment of 2018 OPPS claims.

Even if the 2017 OPPS Rule were an option, however, applying it to 2018 OPPS claims would produce operational problems. The 2017 OPPS Rule provided a higher payment rate for drugs purchased through the 340B Program – and, thus, would likely be welcomed by Plaintiffs. But it also generally provided a lower payment rate for other items and services. *See* 82 Fed. Reg. at 52,623. Thus, paying Plaintiffs for their drug purchases under the 340B Program using the payment rate in the 2017 OPPS rule would violate the statutory budget neutrality requirement, given that other items and services were paid for under the higher rates provided for under the 2018 OPPS (which, in this scenario, are no longer offset by the lower rate for 340B Program drugs). 42 U.S.C. § 1395*l*(t)(9)(B).[4]

[4] A retroactive change in Medicare Part B payment policy could have implications for other types of insurance as well, including the Medicare Advantage program. Generally speaking,

And there would be difficulties in trying to remedy this budget-neutrality issue by recouping money for all of the non-340B-Program-related claims. To cure the budget neutrality defect, the Agency would have to apply the 2017 OPPS Rule to items and services originally provided while the 2018 OPPS Rule was in place, and, on the basis of the newly applicable 2017 OPPS Rule, seek to recoup funds paid out by Medicare.

Although there is generally a presumption against the retroactive application of agency rules, *see Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 207, 215, (1988), 42 U.S.C. § 1395hh(e)(1)(A), authorizes it if "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). Accordingly, if the Secretary were to apply the reborn 2017 OPPS rule retroactively to meet the budget neutrality requirement, he could. But doing so would necessitate recoupments of approximately $1.6 billion in payments made on millions of non-340B Program claims for calendar year 2018 as a result of the rate adjustments. (Recall, the Agency expects to process over 110 million OPPS claims related to 2018. Richter Decl. ¶ 3.) CMS would face huge logistical hurdles in making such recoupments: the process would require tens of thousands of hours of work, take at least a year, and add between $25-30 million in administrative costs. *See Id.* ¶ 7. The recoupment

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Medicare Advantage plans are coordinated care plans and pay providers based on the plan's contract with the provider. Some plans, however, such as preferred provider organization plans, pay for covered services which are received out-of-network. In such cases, the plan pays the provider the original Medicare rate. When a Medicare Advantage organization's coverage responsibilities include payment for original Medicare services furnished to an enrollee by a non-contract provider, the Medicare Advantage plan's payment to the provider must be equal to the total dollar amount that would have been authorized for such services under Medicare Parts A and B, less any cost sharing provided for under the plan. *See* 42 U.S.C. § 1395w-22(a)(2); 42 C.F.R. § 422.100(b)(2). So, if CMS revisits the payment amounts due under Medicare Part B OPPS, Medicare managed care plans may likewise have to revisit the payment amounts that they previously provided to their out-of-network providers as well.

effort could also affect the timely processing of claims and, thereby, potentially affect the ability of Medicare beneficiaries to get needed services. *Id.* at 9. In addition, the attempts at recoupment likely would result in numerous legal challenges to the Agency's work from those who disagreed with the Agency's retroactivity analysis or other aspects of the recoupment. And even if turned aside, these suits would impose significant costs on the government.

The retroactive application of the 2017 OPPS Rule could also significantly affect Medicare beneficiaries. A Medicare beneficiary's "cost-sharing amount . . . is generally 20% of the allowed Medicare payment rate." Richter Decl. ¶ 8. Thus, "[f]or example, if Medicare previously paid $3,300 for a drug in 2018, but as a result of a judicial decision it was determined that the correct Medicare-allowable amount should have been $5,300 for that drug, the cost-sharing amount borne by the Medicare beneficiary would increase by $400." *Id.* Accordingly, "CMS is very concerned about the potential for confusion and anxiety among Medicare beneficiaries if CMS were to recalculate Medicare payments and change beneficiary financial obligations for calendar year 2018. . . ." *Id.*

In short, the retroactive application of the 2017 OPPS Rule would significantly disrupt the administration of the processing and payment of Medicare claims, and would impose potential delays in payments for OPPS services and providers.

The alternative to the reinstitution of the 2017 OPPS Rule following vacatur would be to leave it to the Agency to fill in the post-vacatur gap. This option is no more tenable. There would inevitably be a regulatory vacuum before the Agency could promulgate a new rule to replace the 2018 OPPS. The result of this vacuum would be uncertainty and delay with respect to processing the remaining 2018 claims.

Once the Agency moved past this difficult transition period by promulgating a new rule, the Agency would face problems substantially similar to those it would face if it were to apply the 2017 OPPS Rule. To account for an increased payment rate for drugs purchased through the 340B Program, the new rule would have to reduce the payment rate for other items and services covered by the OPPS, lest it run afoul of the statutory budget neutrality requirement. But accounting for this budget neutrality requirement would set the Agency on a course to recoup funds paid under a previous rule, and therefore unsettle the expectations of beneficiaries and those who had been paid, and raise the serious logistical problems of recoupment.

Because of these kinds of problems, courts in this district have declined to vacate payment rules in similar circumstances. In *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 270 (D.D.C. 2015), the court declined to vacate Medicare's 2014 hospital in-patient prospective payment system ("IPPS") rule, notwithstanding serious doubts about whether the IPPS improperly reduced payments to hospitals for almost all in-patient services by 0.2%. *Id.* at 268. The court based its decision on the "disruptive consequences" that would be caused by vacatur, including the difficulty of recouping already paid funds and limits on the retroactive application of rules. *Id.* at 269-271. And in *Am. Great Lakes Ports Ass'n v. Zukunft*, 301 F. Supp. 3d 99, 100-101, 104 (D.D.C. 2018), this Court declined to vacate a rule issued by the Coast Guard regarding the "rates that international shippers must pay to maritime pilots on the waters of the Great Lakes." This Court reasoned that the disruptive consequences of vacatur are "clear" to the extent that "pilotage associations might be required to issue refunds" as a result of the rule change wrought by vacatur. *Id.* at 104.

The same conclusion is warranted here under the *Allied-Signal* analysis, *i.e.*, the Court should not vacate the 2018 OPPS Rule and, thereby, throw the status of millions of already paid

Medicare claims into doubt. Instead, the Court should remand this matter to the Agency for it to take appropriate remedial action. *Shands Jacksonville Medical Center* is again instructive. As noted, in that case, the court declined to vacate the 2014 IPPS and remanded the matter to the Agency. On remand, the Agency reconsidered the 0.2% reduction to the IPPS – which it had applied in 2015 and 2016, as well as 2014 – and, after taking comments on the issue, made a remedial upward adjustment of .6% to the 2017 IPPS. *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 2018 WL 6831167, at *7 (D.D.C. Dec. 28, 2018). The Court rejected challenges to the Agency's approach of using a prospective payment adjustment as a proxy for the past payment reduction, holding (1) that "reasonableness is the touchstone for determining whether the Secretary's response to a past deficiency is appropriate under the Medicare Act" and (2) that the Secretary's response was reasonable. *Shands Jacksonville Med. Ctr., Inc*., 2018 WL 6831167, at *12-13. The Secretary could determine that a similar prospective remedial adjustment is appropriate here. Or some other remedy may be warranted. Indeed, the Agency could ultimately decide to institute retroactive changes to the 2018 OPPS, and tackle the difficulties (and disruption) inherent in doing so. But it should not be forced by the Court to do so. To the contrary, the selection of a remedy should be entrusted to the Agency in the first instance given the "substantial deference that Courts owe to the Secretary [of Health and Human Services] in the administration of such a 'complex statutory and regulatory regime.'" *Id.* at 13 (quoting *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993)).

The above discussion demonstrates the flaws not only in plaintiffs' request that the Court vacate the 2018 OPPS rule, but also the flaws in its requests that the Court order the Agency to (1) pay remaining claims for drugs purchased through the 340B Program at the 2017 OPPS rate and (2) pay the hospital plaintiffs and the 340B Program participants who are members of the

association plaintiffs the difference between the 2017 OPPS payment rate and the 2018 OPPS payment rate for all drug purchases made through the 340B Program. These requests would run aground on the statutory budget neutrality requirement, absent a herculean recoupment effort that would unsettle the expectations of Medicare payment recipients and impose a very significant burden on the Medicare system.

There are a few other flaws with plaintiffs' requests worth mentioning. First, the Court did not decide that the 2017 OPPS payment rate was the only rate that the Agency could have lawfully applied in 2018. To the contrary, while the Court rejected the adjustment made by the Agency, it recognized that the Agency had the ability to make some adjustments under the statute. Op. at 28 (noting that the "Secretary is permitted to make 'adjust[ments]' to those rates for whatever reasons he deems 'necessary'"). Thus, on remand, the Agency need not assume that the 2017 OPPS payment rate is the baseline from which any remedy must be judged. Second, an injunction requiring the Agency to pay a specified amount is not an appropriate remedy. As the D.C. Circuit noted in *Northern Air Cargo v. U.S. Postal Serv*., 674 F.3d 852, 861 (D.C. Cir. 2012), a case in which the APA did not apply (because Congress has exempted the Postal Service from it), "[w]hen a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal."

CONCLUSION

The Court should remand this matter to the Agency without vacatur, and permit the Agency to determine what remedial measures are appropriate and at what pace. The Court should deny plaintiffs' other remedial requests. If the Court vacates 2018 OPPS Rule, or grants

any of plaintiffs' other remedial requests, then defendants request that the Court stay the order to afford the Solicitor General sufficient time to decide whether to pursue appeal. 28 C.F.R. § 0.20(b); 28 U.S.C. § 2107(b).[5]

Date: January 31, 2019

Respectfully submitted,

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Counsel for Defendants

[5] If an appeal is authorized, defendants may seek a stay of this Court's judgement pending resolution of the appeal.

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FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

DECLARATION OF ELIZABETH RICHTER

I, Elizabeth Richter, declare as follows:

1. I am the Deputy Center Director of the Center for Medicare within the Centers for Medicare & Medicaid Services ("CMS"). CMS is the federal agency within the United States Department of Health and Human Services ("HHS") responsible for administering the Medicare and Medicaid programs. The Center for Medicare is responsible for, among other things, developing the policies for, and managing the operations of, the fee-for-service portion of the Medicare program, including Medicare Part B payments. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me by CMS staff and contractors in the course of my official duties.

2. I am familiar with the subject matter of the above-captioned lawsuit. More specifically, I am aware that the district court in this case has concluded that the defendants – the U.S. Department of Health and Human Services and its Secretary – acted in an *ultra vires* manner by reducing the payment rate for drugs purchased through the 340B Program in the 2018

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Outpatient Prospective Payment System ("OPPS") Final Rule. I further understand that the court instructed the parties to file "supplemental briefing on the appropriate remedy."

3. The Medicare OPPS typically processes more than 100 million outpatient hospital claims every calendar year. For the 2018 OPPS calendar year, the agency expects to process more than 110 million such claims.

4. These OPPS claims relate to items and services provided by approximately 3,900 facilities for outpatient items and services covered under the OPPS. These items and services are provided to millions of different Medicare beneficiaries, who, by statute, are required to pay cost-sharing for such items and services, which is usually 20% of the total Medicare payment rate.

5. To provide some additional context for this payment system, in the 2018 OPPS calendar year Final Rule CMS estimated that OPPS expenditures would exceed $55 billion in Medicare Part B payments by the federal government and almost $14 billion in Medicare beneficiary cost-sharing payments, for a total of more than $69 billion in Medicare payments for the more-than 100 million claims submitted.

6. Medicare OPPS claims are paid every year according to OPPS payment rates that are established in advance of the upcoming calendar year. Developing this payment system, which is done on an annual basis, is a complicated process that begins several months before the release of the proposed rule, which typically occurs around July of each year. The process culminates in a final rule, usually released on or around November 1 to allow for the 60-day period required under the Congressional Review Act before the new payment rates take effect on January 1. The complex and interconnected nature of the many calculations necessary to develop the OPPS payment rates are described in greater detail on the CMS website. This 40-page "claims

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accounting" document sets forth an accounting of the claims CMS used to calculate average costs for OPPS services, which were ultimately used to establish final payment rates for the 2018 OPPS. *See* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPPS-FR-Claims-Accounting.pdf

7. In the calendar year 2018 OPPS Rule, CMS provided that as a result of the policy change with respect to drugs acquired under the 340B program, the agency estimated a payment reduction of $1.6 billion in separately paid OPPS drug payments. As required by statute, this reduction was offset in a budget neutral manner, and, as a result, CMS adjusted payments for *all non-drug* OPPS services by an equal amount (that is, CMS raised rates for non-drug items and services by $1.6 billion). A potential remedy that would address reversing this policy would be to reprocess *all* claims for items and services furnished by all providers paid under the OPPS (including those that are not party to this case), but that potential remedy requires an arduous, disruptive and time-consuming process of recalculating all OPPS rates for 2018 (because of the budget neutral aspect of the policy change), as well as a significant update of the claims processing system that would then apply newly calculated OPPS payment rates to all previously submitted 2018 claims. We estimate that it would cost between $25 million and $30 million in additional administrative expenses.

8. Moreover, this potential remedy could have a significant impact on the cost-sharing obligations of Medicare beneficiaries. If CMS is required to undertake the process of recalculating and reapplying new 2018 OPPS payment rates, that retroactive change in payment amount could significantly alter a Medicare beneficiary's cost-sharing amount, which is generally 20% of the allowed Medicare payment rate. For example, if Medicare previously paid

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$3,300 for a drug in 2018, but as a result of a judicial decision it is determined that the Medicare-allowable payment amount should have been $5,300 for that drug, the cost-sharing amount borne by the Medicare beneficiary would increase by $400. Notably, this problem arises is in the context of a system that processes more than 100 million claims each calendar year. CMS is very concerned about the potential for confusion and anxiety among Medicare beneficiaries if CMS were to recalculate Medicare payments and change beneficiary financial obligations for calendar year 2018 because beneficiaries could be responsible for different cost-sharing amounts, which could be higher or lower than their original cost-sharing obligations, depending on the mix of items and services they received – i.e., if a beneficiary only received a 340B-acquired drug his cost-sharing would increase, and if he only received a non-drug OPPS service his cost sharing would decrease. The total amount of beneficiary cost-sharing impacted by reprocessing all such claims was estimated at $320 million in the 2018 OPPS final rule.

9. In addition, CMS utilizes Medicare contractors to process OPPS claims, and to reprocess all 2018 OPPS claims would take a substantial amount of time to effectuate. Based on the number of providers and claims involved for the 2018 OPPS calendar year, and the statutory requirement to continue to timely process real-time claims for the current period, among other things, we estimate this process would take at least a year. To date, CMS does not yet have all final-action claims submitted by providers for calendar year 2018, but based on claims received so far, we estimate if this potential remedy is mandated, that over 110 million claims would have to be reprocessed for 2018 OPPS claims, and that this would result in an additional administrative cost of paying Medicare contractors an additional $25-$30 million as referenced above. Moreover, based on current workload and agency estimates, for the vast majority of Medicare contractors (who process Medicare claims on behalf of CMS), it will take at least one

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year to complete all the adjustments for all the claims once new OPPS payment rates are calculated, developed, and loaded into Medicare claims-processing software. Medicare contractors have existing workloads to process claims, and they still are responsible for processing newly submitted claims for services furnished in 2019 in a timely manner. The timely processing of 2019 claims as they are submitted is important to ensure that providers receive payment from Medicare and can continue to provide services to beneficiaries, but it is also important because, by statute, the government would owe an additional amount of interest on such claims unless it continues to process them. Put simply, there is a limit to the number a claims a particular Medicare contractor can process in a day, and the year-long time estimate above is based on current workload and the additional claims that contractors might be able to process in addition to their normal workload.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: January 31, 2019

Baltimore, Maryland

Elizabeth Richter