IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 14-CV-851-JEB
ALEX M. AZAR, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Defendant.	)	

PLAINTIFFS' RESPONSE REGARDING NON-DEADLINE REMEDIES

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INTRODUCTION

The Court following the March 22, 2018 hearing asked Plaintiffs to "submit specific proposals (and reasons therefor) that they wish the Court to impose via mandamus and explain why current procedures are insufficient." This brief responds to that order.[1]

Below and in the attached proposed order, Plaintiffs set forth tailored, specific proposals that address the Court's related goals of (1) preventing additional cases from entering the backlog; (2) resolving cases currently in the backlog; and (3) creating incentives for providers and the Department of Health and Human Services (HHS) to settle pending appeals on terms fair to both sides. Each proposal is both legally permissible and practically feasible. And together, they will make a non-trivial dent in the backlog, even if they do not completely eliminate it.

Plaintiffs' proposals fall into four broad categories: (1) Recovery Audit Contractor (RAC) prevention, (2) settlement, (3) relief from the negative impacts of the backlog, and (4) maintenance of efforts and status reports. For each remedy, Plaintiffs set out the ordering paragraph that the Court should enter and then explain why the remedy is both legally permissible and not futile.

To be clear: Although Plaintiffs have worked hard to come up with new proposals, the ball is in HHS's court. The D.C. Circuit remanded to this Court for the Court to decide what is *possible* to solve the backlog, not a freewheeling inquiry as to what steps HHS would *prefer* to take to solve the backlog. *See American Hosp. Ass'n v. Price*, 867 F.3d 160, 162, 166 (D.C. Cir. 2017) (*AHA II*). Each remedy Plaintiffs propose is legal and not futile, and that is all the Court must find to order HHS to carry those steps out.

[1] Plaintiffs argued in their motion for summary judgment that the Court should re-impose its deadline-based remedy (Dkt. No. 47) because HHS had not shown that meeting that deadline would be impossible. *See* Dkt. No. 72-1 at 16-18. Plaintiffs stand by that argument. This brief addresses the Court's alternative request for a list of the *non*-deadline remedies it can impose. *See* Dkt. No. 81 at 3.

If the Court elects not to enter a deadline remedy, it should enter Plaintiffs' proposed order.

ARGUMENT

I. THE COURT SHOULD ORDER HHS TO PREVENT A NEW WAVE OF RAC DENIALS AND APPEALS.

A. HHS Should Impose A Financial Penalty On RACs With High Overturn Rates At the ALJ Level.

> *HHS must allow the current RAC contracts to expire at the end of the current contract year and any new RAC contract must include a term that a RAC that has an overturn rate at the ALJ level greater than 40% in a given quarter will receive a 25% reduction in the applicable contingency fee for all claims for which a contingency fee is earned during that quarter.*

To ensure that the RAC program cannot retake its place as the leading contributor to the appeals backlog, the Court should require HHS to impose a 25% financial penalty on RACs with a greater-than-40-percent overturn rate at the ALJ level in a given quarter. *See* Dkt. No. 72-1 at 7 (proposing financial penalties on RACs with high ALJ overturn rates). A financial penalty on RACs with high ALJ overturn rates counteracts RACs' incentive to deny debatable claims. *See* Dkt. No. 81 at 10 (the Court noting its desire to "chang[e] some incentives"). RACs, after all, are paid on a contingency basis. *See* 42 U.S.C. § 1395ddd(h)(1)(B)(i). A RAC that is confronted with a debatable claim will therefore have a natural (and rational) tendency to deny it; it gets a fee for denying the claim, and gets nothing for approving it. *See* Dkt. No. 77 at 5.

The threat of being overturned at the ALJ level is not enough to neutralize the financial incentives that catapulted the appeals backlog to hundreds of thousands of cases; stronger medicine is required. A RAC that is overturned will not receive its contingency fee, true, but that puts it in the same position it would have been in had it approved the claim initially. And there is a significant likelihood that a provider whose claim is wrongly denied will not go to the

trouble of appealing all the way to the ALJ level given the years-long backlog. *See* Dkt. No. 72-1 at 8.

HHS has argued that further action to prevent RACs from reemerging as the leading contributor to the already staggering backlog is unnecessary because RAC appeals are currently low. *See* Dkt. No. 75 at 19-20. Plaintiffs' measures, however, are designed to ensure that new RAC appeals *remain* low and that HHS and RACs are not tempted in the future once again to use questionable tactics targeting high-dollar hospital claims to increase RAC receipts. That concern is more than speculative. Just last week, the RAC trade-industry association publicly complained that "[t]he significant scale back of the RAC program over the past few years has caused [RACs] to lose the ground we had previously gained." Kristin Walter, Council for Medicare Integrity, *Congress Needs To Do Something About Improper Medicare Billing Practices*, The Hill (June 12, 2018), https://tinyurl.com/ycbm2wdn; *see also* Letter from Kristin Walter, Council for Medicare Integrity, to Alex Azar, Sec'y, Dep't of Health and Human Servs., at 2 (Mar. 6, 2018), https://tinyurl.com/yatvhljk (urging HHS to increase both "the volume and type of claims reviewed" by RACs) (capitalization altered). Further measures are essential to maintain and continue the decline in RAC-related appeals.

HHS has also contended that it is barred from applying penalties to RACs with high overturn rates. *See* Dkt. No. 66-1 at 27. Plaintiffs have explained why that is wrong as a matter of law. *See* Dkt. No. 72-1 at 7-8; Dkt. No. 43 at 10. Even HHS publicly agrees. The November 30, 2016 Statement of Work available on its website provides that "[f]ailure to enter [certain] necessary information timely will result in a 25% reduction in the applicable contingency fee for the affected claims." Statement of Work for the Part A/B Medicare Fee-for-Service Recovery Audit Program — Regions 1-4, at 37 (Nov. 30, 2016), *available at* https://tinyurl.com/jztek8r. If

HHS can penalize RACs that fail to enter information in a timely fashion, then it can penalize RACs with high ALJ overturn rates.

In any event, HHS's purported legal concerns can be addressed by turning Plaintiffs' proposed penalty into an incentive payment for RACs with low ALJ overturn rates.[2] The Court can direct HHS to reduce the base contingency fee given to RACs by 25% and then restore the 25% reduction for RACs that have a greater-than-60-percent affirm rate at the ALJ level in a quarter. And *that* cannot be unlawful because HHS already provides incentive payments to RACs with low overturn rates, albeit not at the ALJ level. Dkt. No. 66-1 at 24. The Court can reach the same penalty result through an incentive payment.

B. HHS Should Shift Hospital-Related Claims To Quality Improvement Organizations.

Within 60 days of this order, HHS must require that any new reviews of hospital claims that would be performed by RACs are instead performed by quality improvement organizations.

The Court should further prevent RAC program increases by requiring HHS to transition hospital claims that would be performed by RACs to quality improvement organizations (QIOs). QIOs, established under 42 U.S.C. § 1320c-3, are groups "of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare." Centers for Medicare & Medicaid Servs., *Quality Improvement Organizations* (Apr. 19, 2018), https://tinyurl.com/h6tquz7. QIOs can conduct payment reviews "for the purposes of determining whether providers and practitioners are delivering services that are reasonable and

[2] HHS's contingency-fee bonus for RACs with high accuracy rates for claims reviewed at the initial contractor level (Dkt. No. 66-1 at 24) is the wrong incentive in the wrong place. Contractors below the ALJ level largely rubber-stamp RAC decisions. *See* Dkt. No. 77 at 6 n.1. Providing a "bonus" for success at that lower-tier level of review thus will do nothing to prevent RACs from reflexively denying debatable claims. As the D.C. Circuit recognized, the ALJ level is where a provider receives an independent, de novo review. *American Hosp. Ass'n v. Burwell*, 812 F.3d 183, 185 (D.C. Cir. 2016) (*AHA I*).

medically necessary, whether the quality of services meets professionally recognized standards of care, and, for inpatient services, whether the services could be effectively furnished on an outpatient basis or in a different type of inpatient facility." Medicare Program: Short Inpatient Hospital Stays, 80 Fed. Reg. 70,298, 70,545 (Nov. 13, 2015). That description makes QIOs tailor-made for reviewing hospital claims.

HHS's previous action of moving inpatient-status claims from RACs to QIOs has succeeded in reducing the number of RAC appeals. *See* Dkt. No. 66-1 at 24-25. No surprise there. QIOs are paid on a flat-fee, rather than contingent-fee, basis, removing RACs' incentive to deny debatable claims. *See id.* In addition, QIO first-level reviewers are physicians, who are more likely to understand the complex clinical judgments that underlie hospital claims. *See* Centers for Medicare & Medicaid Servs., *Quality Improvement Organization Manual* § 4310 (July 11, 2003), *available at* https://tinyurl.com/y9a5oxnc (detailing "first level physician review"). If the first-level physician review identifies a potential concern, the hospital is entitled to an opportunity to discuss the case with the reviewer. *Id.* § 4530. That consultation allows reviewers to better-understand hospitals' decisionmaking processes and allows hospitals to better understand the reviewers' concerns.

Shifting hospital claims to QIOs will not leave RACs with nothing to do. RACs can continue to review claims that do not present the same sort of intensive judgment calls that hospital claims do, like claims from other providers or suppliers such as durable equipment manufacturers. RACs thus can still fulfill their statutory purpose of "identifying underpayments and overpayments and recouping overpayments" without reviewing hospital claims. 42 U.S.C. § 1395ddd(h)(1).

II. THE COURT SHOULD REQUIRE HHS TO REDOUBLE ITS SETTLEMENT EFFORTS.

A. HHS Should Bring Inpatient Rehabilitation Facility Claims To A Prompt, Fair Settlement.

> *Within 90 days of this order and every 90 days thereafter, HHS must either settle outstanding inpatient rehabilitation facility claims or file a notice with the Court (under seal, if necessary) detailing (1) the steps HHS has taken towards settlement, (2) the most-recent demands and offers from each side, and (3) HHS's reasons for not accepting the hospitals' most-recent settlement demand.*

From the beginning of these remand proceedings, Plaintiffs have emphasized that HHS has a class of claimants clamoring to settle: inpatient rehabilitation facilities. *See* Dkt. No. 72-1 at 11. Despite that, HHS has still failed to settle with the inpatient rehabilitation facilities. *Id.* If HHS is serious about eliminating the backlog through settlements, it should demonstrate to the Court (under seal, if necessary) that it is making a good-faith attempt to resolve these claims. And if HHS is correct that inpatient rehabilitation facilities are making unreasonable settlement demands, the information required by Plaintiffs' proposal would reveal that.

B. HHS Should Make Good-Faith Settlement Offers To Participants In Its Settlement Conference Facilitation Program.

> *HHS must, at each settlement conference convened as part of its expanded Settlement Conference Facilitation program, make a good-faith settlement offer that is based on the claimant's historical success rate at the ALJ level or the historical success rate at the ALJ level for claims of a similar kind. For each settlement conference that does not result in a settlement agreement, HHS must file with the Court every 90 days (under seal, if necessary) a notice (1) detailing the settlement offer made to the provider or supplier, including the evidence supporting the settlement offer, (2) the provider's or supplier's last, best, and final counteroffer, if any, and (3) HHS's reasons for not accepting the provider's or supplier's final counteroffer.*

HHS should also demonstrate its commitment to settlement by making an evidence-based settlement offer to every provider and supplier that participates in its Settlement Conference

Facilitation program. As it stands, HHS does not promise that it will make a settlement offer or that the settlement offer will bear any relation at all to the strengths and weaknesses of its position. All HHS will tell providers is that "[t]he settlement agreement percentage is negotiated between both parties and based on the unique circumstances of each appellant's appeals." U.S. Dep't of Health & Human Servs., *Settlement Conference Facilitation (SCF): Frequently Asked Questions*, https://tinyurl.com/y9wehkh6 (June 15, 2018) ("Should I expect to receive at least 62% of the approved amount of the appealed claims on my SCF Request Spreadsheet?"). That increases the risk that HHS will present providers with take-it-or-leave-it offers that undervalue the providers' claims, forcing them to walk away or accept far less than their claims are rationally worth, even after discounting for the time-value of money and the uncertainty of ALJ litigation.

HHS has contended that requiring it to make settlement offers would essentially require it to offer settlements to fraudsters, because many claims in the backlog are supposedly tainted by program-integrity concerns. *See* Dkt. No. 75 at 8-11. Plaintiffs have explained why HHS's program-integrity objections are likely overstated. *See* Dkt. No. 66-1 at 12; Dkt. No. 77 at 11. But Plaintiffs' proposal effectively removes program-integrity claims HHS is unwilling to settle from the mandatory-settlement-offer process; the Settlement Conference Facilitation program permits HHS to exclude claims from providers with program-integrity issues. *See* U.S. Dep't of Health & Human Servs., *Settlement Conference Facilitation* (June 15, 2018), https://tinyurl.com/y85d237y (explaining that "[t]he appellant may be excluded from participation if he or she has or has had False Claims Act litigation or investigations pending against them, or other program integrity concerns, including pending civil, criminal, or

administrative investigations"). HHS's program-integrity concerns are thus addressed by Plaintiffs' proposal.

HHS has also argued that forcing it to settle claims would lead providers to appeal every denial in hopes of cashing in on an HHS settlement offer, with HHS having no realistic opportunity to say "no." *See* Dkt. No. 66-1 at 17-18. But Plaintiffs' current proposal does not require HHS to settle any particular claims. It requires only that HHS make a good-faith, evidence-based settlement offer to each provider with which it negotiates. If providers are being intransigent, the information called for by Plaintiffs' proposal (which HHS can submit under seal, if necessary) will lay that bare. And if HHS is refusing to negotiate in good faith, the information called for by Plaintiffs' proposal will reveal that, too. Plaintiffs' proposal is therefore a targeted remedy ensuring that HHS engages in good-faith, verifiable settlement discussions and that providers do not hold out for 99 cents on the dollar.

III. THE COURT SHOULD ORDER HHS TO AMELIORATE THE BACKLOG'S HARMFUL EFFECT ON PROVIDERS.

A. HHS Should Reduce The Interest Charged On Funds Not Recouped From Providers While Their Appeals Are Part Of The Backlog.

Within 90 days of this order, HHS must undertake a demonstration project that reduces to the London Interbank Offered Rate the interest on balances retained by providers while their appeals remain in the backlog.

Once HHS determines an overpayment has been made, providers are required to repay it within 30 days of the determination date or else "interest shall accrue on the balance . . . at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payment." 42 U.S.C. § 1395g(d). At current rates, those regulations call for interest on unrefunded alleged overpayments to run at a whopping 10.25%. Centers for Medicare & Medicaid Servs., *Notice of New Interest Rate for Medicare Overpayments and*

Underpayments — 3d Quarter Notification for FY 2018, at 5 (Apr. 17, 2018), *available at* https://tinyurl.com/yabw587a.

That leaves providers in a bind. On the one hand, a provider can give the purported overpayment to HHS and get repaid if it prevails before an ALJ. But that can leave providers without needed funds for years as its appeal lingers in the backlog. *See AHA II*, 867 F.3d at 172 (Henderson, J., dissenting) (detailing the "real-world" problems that recoupment and the backlog are imposing on Plaintiffs). On the other hand, a provider can decline to repay the purported overpayment and take its chances with an ALJ hearing. When ALJ appeals were being decided in 90 days, providers gambled with little interest. But with ALJ appeals taking as many as *three years* to decide, *id.* at 171, a hospital runs the risk of repaying the entire claim plus an additional third in interest if it does not prevail. That is no real choice at all; any rational hospital—even one confident in its chances—will repay pending appeal. And that creates an incentive for HHS to offer low-ball settlements or resist potential backlog-reduction efforts. If HHS has all the claimed overpayments pending appeal, it is not harmed by the backlog.

Plaintiffs have previously proposed tolling the interest due on purported overpayments once the 90 days allowed for an ALJ decision has passed. Dkt. No. 72-1 at 19. But the Court raised the concern that tolling interest altogether would create an incentive for providers to appeal all denials and use the ALJ backlog to retain overpayments—and benefit from the time-value of that money—for even meritless appeals. *See* Dkt. No. 81 at 11. Plaintiffs' current proposal addresses that concern by keeping some provider skin in the game; if their appeal fails, they will have to pay some interest, which will deter them from filing indiscriminate appeals. But Plaintiffs' proposal removes the current punitive interest rate that makes recoupment during the appeal period the only viable option for providers. Plaintiffs' proposal, in the Court's words,

"align[s] everyone's interest." *Id.* at 13. And because most all providers repay a claimed overpayment in 30 days to avoid the current punitive interest rates, this proposal will effectively apply to only new appeals, reducing the amount of interest that HHS might lose.

HHS has argued that it cannot use its demonstration-authority power to toll interest or suspend recoupment. *See* Dkt. No. 75 at 22. But as Plaintiffs have explained, the demonstration-authority power is sufficiently capacious to allow the reduction in interest that Plaintiffs propose. *See* Dkt. No. 77 at 10. Allowing hospitals to retain capital needed for purchasing equipment and offering services would "improve the coordination, quality, and efficiency of health care services." 42 U.S.C. § 1315a(a)(1). And HHS could rationally conclude that a demonstration reducing interest obligations on providers enhances the "efficiency and economy of health services," *id.* § 1395b-1(a)(1)(A), by correcting the skewed incentives created by the current punitive interest rates. It is not impossible for HHS to invoke its statutory demonstration power to reduce the interest rates on backlogged appeals.

B. HHS Should Allow Providers And Suppliers To "Rebill" Claims For Up To Six Months.

For six months after this order, HHS must allow providers and suppliers to rebill denied claims in return for dismissing any pending appeal related to that claim.

A claim for reimbursement of Medicare services must be submitted within one year of the services being provided. *See* 42 U.S.C. §§ 1395f(a)(1), 1395n(a)(1), 1395u(b)(3)(B)(ii). In some instances, a claim is denied because a RAC or other reviewer believes that a provider should have used a billing code different than the one submitted. Under the normal, timely appeal process, a provider whose argument for a different code is rejected on appeal can frequently "rebill" the claim under the reviewer-preferred code and receive some repayment—the statutory one-year time period to submit a claim had not yet run.

With the backlog, however, providers have been deprived of the ability to rebill following an adverse ALJ decision because the provider's claim will always be adjudicated one year after services were rendered. Given that unfairness, Plaintiffs considered proposing that providers be given six months to rebill after they (finally) receive an ALJ decision. That would put providers in the same position they would have been without the backlog. But Plaintiffs understand that allowing rebilling after ALJ appeals are concluded could ultimately *add* to the backlog by creating an incentive for providers to appeal every coding denial, knowing that they can rebill after an appeal.

Plaintiffs' proposal instead uses rebilling as a settlement tool, requiring HHS to allow providers to rebill if they are willing to withdraw appeals associated with their rebilled claims. That step will allow rebilling to act as a form of settlement, with the provider forgoing the full billed amount in return for a lower, rebilled amount. Although Plaintiffs do not know how many appeals in the backlog arise from disputes susceptible to rebilling, allowing rebilling in return for appeal dismissals has the potential to remove some appeals from the backlog.

HHS has ample authority to implement Plaintiffs' proposal. The Medicare Act allows HHS to "specify exceptions to the [one] calendar year period" and thereby extend the permissible period to rebill. 42 U.S.C. § 1395f(a) (Medicare Part A claims); *id.* §1395u(b)(3) (Medicare Part B claims). HHS can exercise that authority and allow rebilling to serve as a way to settle cases in the backlog.

C. HHS Should Toll The Time To File Section 340B Appeals.

HHS must toll the time for hospitals to file appeals arising out of the Section 340B component of the hospital outpatient prospective payment program regulation published at 82 Fed. Reg. 52,356 (Nov. 13, 2017) to and including 90 days after a final, non-appealable decision in American Hospital Association v. Azar*, No. 18-5004 (D.C. Cir.).*

Plaintiffs have previously pointed out (Dkt. No. 78) that HHS is needlessly causing hospitals to file thousands of protective appeals by refusing to toll the time for hospitals to file appeals arising out of the reduction in reimbursement that certain providers, known as 340B hospitals, receive under the Medicare hospital outpatient prospective payment system for drugs purchased under Section 340B of the Public Health Act, 42 U.S.C. § 256b(a)(1). *See* Medicare Program: Hospital Outpatient Prospective Payment & Ambulatory Surgical Center Payment Systems & Quality Reporting Programs, 82 Fed. Reg. 52,356 (Nov. 13, 2017). AHA contends that the reimbursement reduction was illegal and sued late last year to challenge it. HHS moved to dismiss the complaint on several grounds, including that the 340B hospitals had not presented their reimbursement claims for payment to HHS within the meaning of the Social Security Act. The district court granted the motion to dismiss. *See American Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45 (D.D.C. 2017).

AHA has appealed the district court's decision to the D.C. Circuit and the case was argued and submitted on May 4, 2018. *American Hosp. Ass'n v. Azar*, No. 18-5004 (D.C. Cir.). In order to avoid potential arguments from the government that 340B hospitals that do not administratively appeal the legality of a reduced rate will be time barred from seeking recovery if the court holds that the reduction in payments is unlawful, AHA proposed that the Secretary agree to toll the deadline for such appeals until resolution of the 340B litigation—an arrangement that would preserve the 340B hospitals' right to full reimbursement in the event the 340B

litigation is successful. HHS has refused to toll the time, meaning that Section 340B hospitals will have to protect their interests in the interim by filing thousands upon thousands of additional claim appeals, which will add to the current ALJ-level backlog.

HHS has contended that the 340B hospitals' claims are statutorily unreviewable and that their appeals will not add to the backlog because they will be promptly dismissed. *See* Dkt. No. 79. But that assumes the answer to the statutory reviewability question currently being litigated. Because Section 340B hospitals will not know until the case concludes whether their claims *can* be reviewed, they will out of an abundance of caution file protective appeals to preserve their rights unless HHS tolls the deadline for such appeals. And that shows the pointlessness of HHS refusing to toll the time to file appeals.

HHS may extend the time to file an administrative appeal. 42 U.S.C. § 1395ff(b)(1)(D)(i). The Court should require HHS to do so for Section 340B hospital claims arising out of the pending litigation and avoid the needless addition of thousands of protective appeals to the backlog.

IV. THE COURT SHOULD ORDER HHS TO MAINTAIN ITS CURRENT EFFORTS TO FIGHT THE BACKLOG AND DIRECT STATUS REPORTS EVERY 90 DAYS.

A. HHS Should Maintain Its Current Efforts To Fight The Backlog.

HHS must maintain its current efforts to combat the backlog, including all of the measures outlined in its motion for summary judgment. Dkt. No. 66-1. HHS may reduce or alter its existing programs to fight the backlog upon application to the Court and for good cause shown.

In its motion for summary judgment, HHS debuted several new efforts to combat the backlog, including the Low Volume Appeals program, the expanded Settlement Conference Facilitation program, and others. *See* Dkt. No. 66-1. Although Plaintiffs disagree those steps are all that can be done, they certainly agree that they are steps that should be attempted. Without a

mandamus order, however, HHS could abolish any of these programs at any time. The Court should therefore ensure that HHS remains committed to its current efforts by requiring leave of court to alter the programs set forth in HHS's motion for summary judgment. Plaintiffs anticipate readily consenting to alterations genuinely designed to address the backlog, which should result in few contested modification applications.

B. HHS Should Continue To Submit Status Reports Every 90 Days.

HHS must submit reports every 90 days regarding the status of the backlog and including the information required by the other portions of this order.

Finally, the Court should require HHS to submit status reports every 90 days regarding the status of the backlog and including the information required by the other parts of the proposed order. Those continued status reports will allow Plaintiffs to seek additional remedies if it appears that HHS is not carrying out in good faith the steps called for by Plaintiffs' proposed order. HHS does not object to continued status reports if the Court imposes a mandamus remedy. *See* Dkt. No. 75 at 30.

CONCLUSION

For the foregoing reasons and those in Plaintiffs' prior briefs, if the Court does not elect to enter a deadline-based remedy, it should enter Plaintiffs' attached proposed order.

Respectfully submitted,

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Dated: June 22, 2018.

CERTIFICATE OF SERVICE

I certify that on June 22, 2018, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all counsel, who are registered users.

/s/ Catherine E. Stetson