IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Rule 7(h) of the Rules of the United States District Court for the District of Columbia, Plaintiffs the American Hospital Association, Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center (collectively, "Plaintiffs," and Baxter, Covenant, and Rutland collectively, the "Plaintiff hospitals") respectfully submit this motion for summary judgment on their mandamus claim against Defendant Sylvia Mathews Burwell, Secretary of Health and Human Services ("HHS").

As explained more fully in the accompanying Memorandum of Points and Authorities, which is incorporated by reference herein, Plaintiffs bring this action to remedy unlawful delays in HHS's adjudication of Medicare claim appeals. Systemic delays within the four-step administrative appeals process are postponing by years the adjudications to which providers like Plaintiff hospitals are entitled by statute. Most significantly, although the Medicare Act provides for hearing and adjudication by an Administrative Law Judge ("ALJ") at the third level of appeal within ninety days, it currently is taking well over a year for such adjudications to occur. The length of delay will further increase because on December 24, 2013, HHS announced that it had

become so backlogged at the ALJ level that, effective July 15, 2013, it had imposed a moratorium on the assignment of new claim appeals to ALJs for hearing that is expected to last a minimum of two years.

HHS's delays violate the clear timetables set forth by Congress in the Medicare Act, 42 U.S.C. §§1395-1396v, are egregious and unreasonable, and should be remedied. The delays are causing severe harm to providers of Medicare services, like the Plaintiff hospitals, which cannot recover the Medicare reimbursement to which they are entitled for claims that were improperly denied.

Plaintiffs' claims are appropriate for summary judgment because they are grounded in statutory mandates and facts publicly conceded by HHS. As a matter of law and undisputed fact, the Court should grant mandamus relief and require the Secretary of HHS to comply with the statutory deadlines for the Medicare claim appeals process.

Dated: July 11, 2014

Respectfully Submitted,

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PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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Plaintiffs the American Hospital Association ("AHA"), Baxter Regional Medical Center ("Baxter"), Covenant Health ("Covenant"), and Rutland Regional Medical Center ("Rutland") (collectively, "Plaintiffs," and Baxter, Covenant, and Rutland collectively, the "Plaintiff hospitals") respectfully submit this memorandum in support of their motion for summary judgment on their mandamus claim against the Secretary of Health and Human Services ("HHS").

INTRODUCTION

Plaintiffs bring this action to remedy unlawful and egregious delays in HHS's adjudication of Medicare claim appeals. Systemic delays within the four-step administrative appeals process are postponing by *years* the adjudications to which providers like Plaintiff hospitals are entitled by statute. Without those adjudications, the hospitals cannot recover the Medicare reimbursement to which they are entitled for claims that were improperly denied. Rather than resolving these delays, however, HHS has formalized them. In December 2013, HHS's Office of Medicare Hearings and Appeals ("OMHA") declared a moratorium on the assignment of new claim appeals to an Administrative Law Judge ("ALJ") for hearing. That is the stage of the Medicare administrative appeals process at which hospitals are entitled to independent review of their claims and historically have had the greatest rate of success. The suspension of appeals assignments is expected to last for at least two years and likely longer, a timeframe that does not even include the actual hearing or rendering of a decision once the suspension is lifted.

This delay of several years stands in stark contrast to the statutory requirement in the Medicare Act that ALJ appeals be *decided within ninety days*. 42 U.S.C. § 1395ff(d)(1)(A). As a result, approximately 800,000 appeals currently languish at the ALJ level, representing over a

billion dollars in denied Medicare reimbursement. These are funds that are withheld from hospitals for services already rendered – an economic deprivation that is threatening the very ability of America's hospitals to provide high-quality patient care and services to their communities. Plaintiff Baxter, for example, has so much tied up in the appeals process that it cannot afford to replace a failing roof over its surgery department, purchase new beds for its intensive care unit, engage in basic upkeep of its facilities, or purchase necessary capital items.

The facts of HHS's delays are undisputed; they are admitted by HHS itself. Court intervention is needed now to compel HHS to comply with its statutory obligations. No relief other than mandamus will suffice to address HHS's unlawful delays or to provide the Plaintiff hospitals their indisputable rights under the Medicare Act. As a matter of law and undisputed fact, the Court should grant mandamus relief and require the Secretary of HHS to comply with the statutory deadlines for the Medicare claim appeals process.

FACTUAL BACKGROUND

I. Medicare

The Medicare program was enacted in 1965 under Title XVIII of the Social Security Act to provide health insurance primarily to individuals sixty-five years of age and older. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395-1396v). The program's main objective is to ensure that its beneficiaries have access to health care services. *Id.* The Plaintiff hospitals qualify as providers of hospital services under Title XVIII, also known as the Medicare Act.

When hospitals furnish services to a Medicare beneficiary, they thereafter submit a claim for reimbursement to a Medicare Administrative Contractor ("MAC") that conducts the initial review of the claim. 42 U.S.C. § 1395ff(a)(2)(A). MACs are government contractors

responsible for processing Medicare claims and making payments to hospitals, doctors, and others that furnish medical care to Medicare beneficiaries. 42 U.S.C. § 1395kk-1(a)(3). MACs review a hospital's claim for reimbursement and either pay the claim or deny it.

Some claims initially paid by MACs are then subjected to an additional level of oversight. In a process known as "post-payment review," third-party contractors, including Medicare Recovery Audit Contractors ("RACs"), audit and frequently reverse MAC payment decisions. *See* 42 U.S.C. § 1395ddd(h)(1). RACs are paid based on the amount of Medicare reimbursement they recover from hospitals for purportedly "improper" payments, *id.*, and they can audit hospital claims paid by MACs dating back three years, *see* Statement of Work for the Medicare Fee-for-Service Recovery Audit Program, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111RACFinSOW.pdf, at 9. As Medicare's only contingency-fee-based contractors, RACs have engaged in wide-ranging audits of Medicare claims, frequently questioning the medical judgment of health care providers and denying claims for the types of services that qualify for the largest amount of reimbursement.

II. The Appeals Process

When a hospital's claim for reimbursement under Medicare is denied (by a MAC, RAC, or otherwise), the hospital has a right to file an administrative appeal under the Medicare Act. Appeals of both pre- and post-payment claim denials are subject to a four-step administrative process, as set forth by statute. *See* 42 U.S.C. § 1395ff. The first two steps of the process are overseen by the Centers for Medicare & Medicaid Services ("CMS") within HHS; the third (the ALJ level) is overseen by OMHA; and the fourth is overseen by the Departmental Appeals

Board ("DAB") within HHS.[1] A chart depicting the administrative appeals process is attached hereto as Exhibit 1. The four appeals steps are as follows:

Step 1. When a hospital's claim for reimbursement under Medicare is denied by a MAC, or in post-payment review by a RAC or other contractor, the first step in the administrative appeals process is for the hospital to present the denied claim to the MAC again for redetermination. *Id.* § 1395ff(a)(3)(A). The MAC must render a redetermination decision within sixty days. *Id.* § 1395ff(a)(3)(C)(ii).

Step 2. If unsatisfied with the MAC's redetermination, a hospital can appeal the MAC's decision to a Qualified Independent Contractor ("QIC") for reconsideration. *Id.* § 1395ff(c). QICs must render a decision within sixty days. *Id.* § 1395ff(c)(3)(C)(i).

Step 3. A hospital may next request a hearing before an ALJ. *Id.* §§ 1395ff(b)(1)(E)(i), 1395ff(d)(1)(A). Review by an ALJ is the first opportunity for an independent review of a claim. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 931(b)(2), 117 Stat. 2066, 2398 (2003) ("The Secretary shall assure the independence of administrative law judges . . . . In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from [CMS].") The ALJ is required both to hold a hearing and render a decision within ninety days. *Id.*; 42 C.F.R. § 405.1016(a). This is the level of the appeals process at which hospitals typically have been able to obtain relief from adverse RAC determinations. *See, e.g.*, Decl. of J. Geppi ("Geppi Decl.") ¶ 13.

[1] The DAB division that conducts the fourth level of administrative review is the Medicare Appeals Council and accordingly is referred to as "MAC" in the regulations. This memorandum uses the shorthand "DAB" instead of "MAC" to avoid possible confusion with the Medicare Administrative Contractors that conduct initial determinations and redeterminations.

Step 4. Finally, a hospital can appeal its claim to the DAB. *Id.* § 1395ff(d)(2); 42 C.F.R.§ 405.1108(a). In that event, the DAB conducts a *de novo* review of the ALJ decision and either renders its own decision or remands to the ALJ for further proceedings. *Id.* In either event, the DAB must act within ninety days. *Id.*

The Medicare Act also provides for a process by which the QIC, ALJ, and DAB levels of review may be bypassed, known in the regulations as "escalation."[2] Specifically, if the QIC is unable to complete its review within sixty days, it must notify all parties that it cannot complete the reconsideration within the statutory timeframe and offer the hospital the opportunity to "escalate" the appeal to an ALJ. 42 U.S.C. § 1395ff(c)(3)(C)(ii); 42 C.F.R. § 405.970. The QIC will continue the reconsideration process unless and until the hospital files a written escalation request. 42 C.F.R. § 405.970(c)(2).

Similarly, if an ALJ has not held a hearing and rendered a decision within ninety days, a hospital may bypass the ALJ level by escalating its claim to the DAB. 42 U.S.C. § 1395ff(d)(3)(A). In such situations, the QIC's decision becomes the decision subject to DAB review. 42 C.F.R. § 405.1104; 42 C.F.R. § 405.1108(d). This means that if the hospital has previously escalated from the QIC (and thus has bypassed both QIC and ALJ review), only the record from the MAC is available for consideration. The DAB may conduct additional proceedings, including a hearing, but (unlike at the ALJ level) is *not* required to do so. 42 C.F.R. § 405.1108. In fact, Judge Constance B. Tobias, Chair of the DAB, has explained that, in escalation situations, the DAB will "NOT hold a hearing or conduct oral argument unless there is

[2] The "escalation" provisions were added to the Medicare Act in 2000 as part of an overall reform to the appeals process that shortened decision deadlines and created the four-step administrative appeals process that exists today. Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Pub L. No. 106-554, 114 Stat. 2763.

an extraordinary question of law/policy/fact." Ex. 2 (OMHA "Medicare Appellant Forum" Presentation dated Feb. 12, 2014) ("OMHA Forum Presentation") at 117. The DAB has 180 days in which to act on an escalated request, rather than its usual ninety. 42 C.F.R. § 405.1100(c)-(d).

Likewise, if the DAB has not rendered a decision within ninety days on its review of an ALJ's decision, a hospital may bypass the DAB and seek judicial review in federal court. 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132. Under the regulations, a hospital may file an action in federal district court if the DAB notifies it that no decision will be issued and if the claim meets an amount-in-controversy requirement (currently $1,430). 42 C.F.R. § 405.1132(b); 42 C.F.R. § 405.1006(c); Notice of Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014, 78 Fed. Reg. 59702-03 (Sept. 27, 2013). Hospitals having claims that do not meet the amount-in-controversy requirement for escalation must simply wait out the delays.[3]

III. The Delays

The statutory time periods governing the appeals process provide for all levels of administrative review to be completed within a total of about one year. In practice, however, the time it takes to pursue a claim appeal through HHS far exceeds the timeframes established by the Medicare Act.

[3] In cases of an initial escalation past the ALJ level, a hospital may escalate the appeal to federal court if the DAB fails to render a decision within 180 days. 42 C.F.R. § 405.1132; 42 C.F.R. § 405.1100(d). In the event of this "double escalation," the only agency decision available to the federal court for review is the QIC's decision, made without a hearing. In the event of a "triple escalation" (from the QIC, from the ALJ, and from the DAB), only the MAC record is available for review.

Enormous increases in the rates of appeal, due in significant part to providers challenging inappropriate denials by overzealous RACs, have caused a massive backlog at the ALJ level of the appeals process. In just two years (2012 and 2013), the backlog of ALJ-level appeals *quintupled,* growing from 92,000 to 460,000 pending claims. Ex. 3 (Mem. from Nancy J. Griswold to OMHA Medicare Appellants dated Dec. 24, 2013) ("Griswold Memorandum"). The value of appealed, RAC-denied claims alone currently exceeds $1.8 billion. Ex. 5 ("Exploring the Impact of the RAC Program on Hospitals Nationwide: Results of AHA RAC*Trac* Survey, 1st Quarter 2014," dated May 28, 2014) ("RAC*Trac* Survey"), at 47.

The ALJs have not come close to keeping up with the growing volume of appeals. The workload of OMHA's sixty-five ALJs increased by almost 300% from fiscal year 2012 to fiscal year 2013. *See* Ex. 2 (OMHA Forum Presentation) at 16. In fiscal year 2013, of the 384,151 appeals that were filed, only 79,303 were decided – a meager twenty-one percent. *See id.* at 12 (reflecting decision figures); Ex. 4 (OMHA *Important Notice Regarding Adjudication Timeframes*) ("*Important Notice*") (reflecting adjusted appeals receipts figures). Indeed, as of December 2013, it was taking an average of sixteen months before an ALJ even *heard* a case – approximately thirteen months longer than the ninety-day statutory deadline for an ALJ *decision*. *See* Ex. 2 (OMHA Forum Presentation), at 11; Ex. 3 (Griswold Memorandum).

The backlog of appeals, and resulting delays in adjudication, have reached a crisis point. On December 24, 2013, OMHA's Chief ALJ, Nancy Griswold, announced that HHS, through OMHA, had suspended the assignment of all new appeals to ALJs (other than those by Medicare beneficiaries) as of July 15, 2013. Ex. 3 (Griswold Memorandum). The suspension is expected to last for a minimum of two years, with additional post-assignment hearing wait times expected to exceed six months when the suspension is eventually lifted. *Id*. As recently as February 14,

2014, Judge Griswold conceded that the wait times for a hearing before an ALJ are "unacceptable." Ex. 6, Michelle M. Stein, *ALJs Lay Out Path Forward For Stakeholders As Appeals Backlog Continues*, Inside Health Policy, Feb. 20, 2014 ("Path Forward").

The situation is getting only worse. In fiscal year 2014, OMHA has received between 10,000 to 16,000 appeals per week, Ex. 7 (Statement of N. Griswold before the U.S. House Committee on Oversight and Government Reform, Subcommittee on Energy Policy, Health Care & Entitlements on July 10, 2014) ("Griswold Statement"), at 4, and has stated that it projects a twenty to twenty-four week delay even in *docketing* new appeals. Ex. 4 (*Important Notice*). From there, the new appeals will await assignment indefinitely, while the moratorium persists. As of July 1, 2014, 800,000 appeals were pending at the ALJ level. Ex. 7 (Griswold Statement) at 4. And HHS's self-imposed suspension in assignment of appeals to ALJs does not alter the requirement that a hospital appeal an unfavorable QIC decision within sixty days, meaning that the backlog at the ALJ level will increase dramatically as appeals continue to roll in without being assigned or decided. *See* 42 U.S.C. § 1395ff(b)(1)(D)(ii); 42 C.F.R. § 405.1014(b)(1). The more than two-year moratorium on assignment of new appeals to an ALJ, taken together with an expected delay of at least six additional months to receive a hearing even after the moratorium is lifted, mean hospitals lodging new appeals from the QIC to the ALJ can realistically expect to wait close to *three years*, and probably longer, even to obtain an ALJ hearing – let alone to receive a decision. *See* Ex. 4 (*Important Notice*); Ex. 3 (Griswold Memorandum).

The DAB – the last level of administrative review – is similarly inundated. At the end of fiscal year 2013, the DAB had 4,888 pending appeals, 112% more than it had at the end of fiscal year 2012. Ex. 2 (OMHA Forum Presentation) at 106. HHS projects that 7,000 DAB appeals

will be received in fiscal year 2014. *Id.* at 107. That number is expected to rise to over 8,000 for fiscal year 2015. *Id.* As with the ALJs, the DAB is seeing an increased caseload due to the behavior of the RACs and other Medicare contractors. HHS itself recognizes that, like the ALJs, the DAB cannot keep up with the dramatic increase in appeals. HHS has conceded that the DAB is "unlikely to meet the 90-day deadline for issuing decisions in most appeals." *Id.* at 110.

Although HHS has recognized the severity of the problem, it has not resolved it. The moratorium already has been in place for a full year. The website HHS hosts to provide updated information about the scope of the delays serves as a regular reminder that the delays are only worsening with no action by HHS.[4] HHS has admitted that proposed reforms under consideration by HHS are "longer-term solution[s]" that will "take time." Ex. 6 ("Path Forward").

LEGAL STANDARD

Summary judgment must be granted when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Summary judgment is particularly appropriate when," as here, "the issues presented for the Court's resolution are primarily questions of law." *Appalachian Voices v. McCarthy*, ___ F. Supp. 2d ____, 2013 WL 5797633, at *4 (D.D.C. Oct. 29, 2013); *see In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10, 13 (D.C. Cir. 2005) (affirming grant of

[4] *See Important Notice Regarding Adjudication Timeframes*, Office of Medicare Hearings & Appeals, U.S. Dep't of Health & Human Servs., *available at* http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html (last visited July 11, 2014). HHS has recently announced two pilot programs designed to *avoid* the full adjudication of each of the hundreds of thousands of pending ALJ claims. *See Office of Medicare Hearings & Appeals*, Office of Medicare Hearings & Appeals, U.S. Dep't of Health & Human Servs., *available at* http://www.hhs.gov/omha/ (last visited July 11, 2014).

summary judgment to hospitals to compel the Secretary to reopen Notices of Program Reimbursement).

In this case, Plaintiffs move for summary judgment on their claims under the Mandamus Act, which provides that "[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. A plaintiff will prevail on a claim seeking relief in the nature of mandamus if (1) it has a clear and indisputable right to relief, (2) the agency has a clear duty to act, and (3) it has no other adequate remedy. *United States v. Monzel*, 641 F.3d 528, 534 (D.C. Cir. 2011) (citing *Power v. Barnhart*, 292 F.3d 781, 784 (D.C. Cir.)). Where, as here, a mandamus claim is based on agency delay, the court also must consider whether the agency's delay is "so egregious as to warrant mandamus." *Telecomms. Research & Action Center v. FCC*, 750 F.2d 70, 79 (D.C. Cir. 1984) ("*TRAC*"). Mandamus rests within the discretion of the court, *In re Cheney*, 406 F.3d 723, 729 (D. C. Cir. 2005) (en banc), and is warranted where "'compelling . . . equitable grounds'" exist, *In re Medicare Reimbursement Litig*., 414 F.3d at10 (citation omitted).

ARGUMENT

Although mandamus is "an extraordinary remedy reserved for extraordinary circumstances," an "administrative agency's unreasonable delay presents such a circumstance because it signals the 'breakdown of regulatory processes.'" *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004) (citation omitted). Unreasonable delay requires court intervention to correct "transparent violations of a clear duty to act," *In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000), because "[i]t is obvious that the benefits of

agency expertise and creation of a record will not be realized if the agency never takes action." *TRAC*, 750 F.2d at 79.

That is the situation here. HHS has a statutory duty to conduct and conclude an ALJ hearing in Medicare claim appeals within ninety days. It has conceded that it is failing to do so and further that its delays are "unacceptable." Ex. 6 ("Path Forward"). Hospitals cannot obtain hearing and review by an ALJ for years. The only available alternative – "escalation" to higher levels of review – is no alternative at all in this scenario, as it necessarily deprives hospitals of the unique and substantive benefits of the ALJ level of review, including the right to present testimony in support of their claims.

Absent mandamus, hospitals will be forced to wait out HHS's extraordinary delays, without Medicare payments for services that were already furnished to beneficiaries and to which they may have been entitled all along. These harms to hospitals provide the "compelling . . . equitable grounds" that support a district court's grant of mandamus. *In re Medicare Reimbursement Litig*., 414 F.3d at 10. Accordingly, the Court should grant Plaintiffs summary judgment on their mandamus claim because (I) Plaintiffs are entitled to mandamus relief and (II) the delays in the Medicare appeals process are sufficiently egregious to warrant this court's intervention. As shown more fully below, this is precisely the kind of case for which the remedy of mandamus exists.

I. PLAINTIFFS ARE ENTITLED TO MANDAMUS RELIEF.

Application of mandamus law to the undisputed facts of this case demonstrates that summary judgment is warranted under this Circuit's mandamus test, because (A) Plaintiffs have a clear and indisputable right to relief and HHS has a clear duty to act, and (B) Plaintiffs have no other adequate remedy. *Monzel*, 641 F.3d at 534.

A. Plaintiffs Have A Clear And Indisputable Right To Relief, And HHS Has A Clear Duty To Act.

Plaintiffs easily meet the first two mandamus factors, which are closely interrelated and frequently assessed together. They turn on the question whether the agency was clearly directed by law to perform a duty or, conversely, whether the agency could choose to act (or not act). Mandamus will issue "where the duty to be performed is ministerial and the obligation to act peremptory, and clearly defined." *13th Reg'l Corp. v. U.S. Dep't of Interior*, 654 F.2d 758, 760 (D.C. Cir. 1980). That is this case.

There can be no doubt that HHS was clearly directed by statute to adjudicate Medicare appeals within specific timelines, and that the Plaintiff hospitals are entitled to adjudications of their appeals within those timeframes. *See* 42 U.S.C. § 1395ff (requiring adjudication by the QIC within sixty days, by an ALJ within ninety days, and by the DAB within ninety days). In fact, the statute conveys both a clear duty (on HHS) and a clear right (on the Plaintiff hospitals). Unless waived by the party seeking review, an ALJ "*shall* conduct and conclude a hearing . . . and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed." 42 U.S.C. § 1395ff(d)(1)(A) (emphasis added). One "dissatisfied with any initial determination" likewise "*shall* be entitled to . . . a hearing thereon by the Secretary." 42 U.S.C. § 1395ff(b)(1)(A) (emphasis added). The language of the statute is mandatory, not permissive. *Compare Baptist Mem. Hosp. v. Sebelius*, 603 F.3d 57, 63 (D.C. Cir. 2010) (denying mandamus relief because there is no clear duty to act where the statutory language – "may" – is permissive and not mandatory).

Nor can there be any question that HHS is not performing its duty to adjudicate appeals at the ALJ level within ninety days: HHS has announced that it will not even assign appeals for consideration by an ALJ within that time period, let alone decide them. Ex. 3 (Griswold

Memorandum). The Plaintiff hospitals indisputably have a right to adjudication of their considerable numbers of ALJ claims that either (a) have been pending for longer than ninety days or (b) are subject to the HHS moratorium (or both). As to the former, HHS already has failed to perform its statutory duty. As to the latter, HHS has stated conclusively that it will fail to perform its statutory duty in the future. Accordingly, the first two factors for mandamus relief are met because Plaintiffs have a clear and indisputable right to relief and HHS has violated its clear duty to act. *Monzel*, 641 F.3d at 534.

B. Plaintiffs Have No Adequate Alternative Remedy.

Mandamus also should be granted because it serves as Plaintiffs' only meaningful means of relief from HHS's unlawful and indefinite delays in adjudicating ALJ appeals. The Supreme Court has explained that the requirement that a plaintiff have "no adequate remedy" as an alternative to mandamus is "'a condition designed to ensure that the writ will not be used as a substitute for the regular appeals process.'" *United States v. Jicarilla Apache Nation*, 131 S. Ct. 2313, 2342 n. 11 (2011) (Ginsburg, J., concurring) (quoting *Cheney v. United States Dist. Ct. for D.C.*, 542 U.S. 367, 380-81 (2004)). Here, Plaintiffs seek only to ensure that the existing appeals process functions as required by statute and to be heard within that process.

The permissive "escalation" process for appeals is not an adequate alternative remedy for the protracted and widespread unlawful delays at issue in this case. As discussed above, the Medicare Act allows providers to skip entire levels of review by escalating claim appeals that have not been decided within statutorily-specified time periods. 42 U.S.C. § 1395ff(c)(3)(C)(ii); 42 U.S.C. § 1395ff(d)(3)(A)-(B). Here, however, the overloaded docket and massive delays at each of the levels of review within HHS along with loss of the impartial evidentiary hearing at the ALJ level make escalation an inadequate remedy. In fact, escalation in these circumstances

would create the potential for even greater harm than that already being caused by the delays themselves – either by depriving hospitals of an ALJ hearing altogether, or by subjecting them to even longer delays than they would endure if they waited out the delays at the ALJ level.

1. Escalation From The ALJ To The DAB Is Inadequate Because It Would Deprive Hospitals Of Their Right To A Hearing And Force Them To Continue To Wait For Relief.

Escalation of claim appeals from the ALJ level to the DAB level is both substantively and procedurally inadequate.

Substantively, hospitals would forfeit the very hearing before an ALJ to which they are entitled by law and which, in the hospitals' experience, is the most valuable and effective level of administrative review. An ALJ is required to hold a hearing. 42 U.S.C. § 1395ff(d)(1)(A). Not so at the DAB: "the party requesting [DAB] review does not have a right to a hearing before the [DAB]." 42 C.F.R. §405.1108(a). Although the DAB "may" conduct a hearing in the event of an escalation from the ALJ, *id.*, HHS already has stated that the DAB will *not* do so "unless there is an extraordinary question of law/policy/fact." Ex. 2 (OMHA Forum Presentation) at 117. Further, publicly available information about the DAB's actions in past escalated cases reveals that it has not conducted a hearing in *any* of them. *See, e.g., In Re Pembroke Pines MRI, Inc.*, M-12-2514, 2013 WL 7395502 (DAB Feb. 19, 2013); *In Re W. Md. Health Sys.*, M-13-732, 2013 WL 7395525 (DAB Feb. 21, 2013). No adequate remedy exists, and no exhaustion is required, where, as here, an agency has expressly stated that it will not offer the relief sought. *In re Medicare Reimbursement Litig.*, 309 F. Supp. 2d 89, 98 (D.D.C. 2004), *aff'd*, 414 F.3d 7 (D.C. Cir. 2005) (holding that, where the Secretary had announced she would not reopen past Notices of Program Reimbursement on the basis of a changed statutory interpretation, plaintiffs had no duty to exhaust their claims by seeking that relief).

The Medicare Act, in fact, makes clear that a decision to escalate is a decision that may result in forfeiture of the right to a hearing: "In the case of a failure by an administrative law judge to render a decision" by the statutory deadline, "the party requesting the hearing *may* request a review" by the DAB "*notwithstanding* any requirements for a hearing for purposes of the party's *right* to such review." 42 U.S.C. §§ 1395ff(d)(3)(A) (emphasis added). Notably, the statute firmly places the decision whether to escalate an appeal in the hands of the requesting party. Escalation is permissive, not mandatory, and only the party appealing the Medicare denial can weigh whether escalation involving the forfeiture of the ALJ hearing is an adequate remedy in each unique circumstance.

It is not an adequate remedy here. The importance of the hearing available at the ALJ level cannot be overstated. The ALJ represents the first independent adjudicator in the appeals process. Decl. of I. Holleman ("Holleman Decl.") ¶ 11; Decl. of J. Wallace ("Wallace Decl.") ¶ 14. During the hearing, hospitals can present oral testimony, including testimony of clinicians, in support of their claims. Holleman Decl. ¶ 11; Wallace Decl. ¶ 14; Geppi Decl. ¶ 14. They have the opportunity to respond to the ALJ's questions in real-time through the hearing process, much as litigants do when they appear live before a judge or jury. Holleman Decl. ¶ 11; Wallace Decl. ¶ 14; Geppi Decl. ¶ 14. This is an opportunity they do not have at previous levels of "cold paper record" review before the MAC and the QIC. At the ALJ level, hospitals also are afforded the opportunity to provide written submissions detailing and supporting their arguments. Geppi Decl. ¶ 14. Hospitals find that they are most likely to succeed on their appeals at the ALJ level, when given the chance to present live testimony to an independent adjudicator. *Id.* ¶ 13. Given the value of the ALJ hearing, hospitals cannot afford to choose to forfeit them in the hundreds of thousands of claims pending at the ALJ level, particularly given HHS's indication that the DAB

will not hold hearings in escalated cases. *See* Holleman Decl. ¶ 12; Wallace Decl. ¶ 16; Geppi Decl. ¶ 15. In fact, HHS has acknowledged as much.[5]

Escalation of appeals from an ALJ to the DAB also cannot afford adequate procedural relief. Because the DAB is inundated in much the same way as ALJs are, escalating from the ALJ to the DAB level would be futile, leaving the hospitals waiting at the DAB level or causing their appeals to be remanded to the ALJ, still with no reasonable prospect of being heard and this time at the end of the line. Indeed, there are just *four* Appeals Officers responsible for DAB review of Medicare entitlement, managed care, and prescription drug claims, in addition to the claims from providers such as Plaintiff hospitals challenging fee-for-service payment denials. *See* Ex. 2 (OMHA Forum Presentation), at 103-104. At the end of fiscal year 2013, the DAB had 4,888 pending appeals. *Id.* at 106. HHS projects that seven thousand DAB appeals will be received in fiscal year 2014 alone. *Id.* at 107. HHS has conceded that the DAB is "unlikely to meet the 90-day deadline for issuing decisions in most appeals." *Id.* at 110. And this concession does not even account for the potential increase in escalations from the hundreds of thousands of appeals pending at the ALJ level. At a hearing held on July 10, 2014, before the House Committee on Oversight and Government Reform, Representative Mark Meadows recognized that escalation will not resolve the crisis.[6]

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[5] *Medicare Mismanagement Part II: Exploring Medicare Appeals Reform: Hearing Before the H. Comm. on Oversight & Gov't Reform*, at 27:00 (July 10, 2014) (statement of Chief ALJ Griswold), http://oversight.house.gov/hearing/medicare-mismanagement-part-ii-exploring-medicare-appeals-reform/ (last visited July 11, 2014) ("The interesting thing in this though, is that people have chosen not to escalate. This year we have had 152 requests to date, which I believe indicates that providers and suppliers are still finding value in our ALJ hearing process and choose to remain in the queue.")

[6] *Medicare Mismanagement Part II: Exploring Medicare Appeals Reform: Hearing Before the H. Comm. on Oversight & Gov't Reform*, at 26:47 (July 10, 2014) (statement of Rep. Meadows),

In the event of escalation, the DAB – faced with its own backlog, very limited resources, and a record lacking hearing evidence and an ALJ opinion – can take one of only four actions, all of which are inadequate to provide relief to Plaintiffs. First, the DAB may render a summary decision on the basis of only the record established before the QIC (or, in the case of a triple escalation, the MAC), which would not provide the process that is due to hospitals in the form of an ALJ hearing. 42 U.S.C. § 1395ff(d)(1)(A). Second, it may remand the appeal to the ALJ, which would simply place the hospitals in the same position where they started, waiting years for a relatively small number of ALJs to wade through an enormous and increasing backlog of appeals, only now at the back of the ALJ line. Third, the DAB may issue a notice that it, too, is unable to fulfill its statutory duty within the required timeline and thereby allow hospitals to escalate their claims to federal court. Or fourth, it may do nothing at all. None of these possible outcomes makes escalation an adequate alternative remedy to the mandamus relief that Plaintiffs seek.

2. Escalation From The DAB To The Federal Courts Is Similarly Inadequate Here Due To The Lack Of Agency Record And Prohibitive Costs.

Nor is the potential for escalation from the DAB to federal court an adequate form of relief under these circumstances. Providers can escalate their DAB appeals to U.S. District Court in the event that the DAB issues a notice conceding its inability to meet its deadlines. 42 U.S.C. § 1395ff(d)(3)(B). In the event that a hospital chose to escalate its appeal from the ALJ to the DAB and then again from the DAB to federal court – the most likely scenario during the

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http://oversight.house.gov/hearing/medicare-mismanagement-part-ii-exploring-medicare-appeals-reform/ (last visited July 11, 2014) ("So we just move the ten-year backlog up to number 4 or number 5 [level of the administrative appeals process] ? That won't work either. I mean, I've looked at their budgets.").

moratorium – the court would have before it only the record and determination made by the QIC (or the MAC) without a hearing and without the benefit of an independent ALJ's findings of fact and conclusions of law. *See, e.g.*, Wallace Decl. ¶ 15 and Exs. A-C to Wallace Decl. In that instance, the federal court might remand the matter to the agency for fact-finding. This result would leave Plaintiffs and other hospitals stuck in an endless loop of escalation and remand with no meaningful opportunity to be heard and no merits decision. Plaintiffs "are entitled to an end to [HHS's] marathon round of administrative keep-away and soon." *In re Am. Rivers*¸ 372 F.3d at 420.

Even were the federal court to fully entertain the claim, the cost of litigating would render escalation worthless in most cases. Because the amount-in-controversy requirement for escalation to federal court is relatively low (currently $1,430), hospitals must weigh the cost of federal court litigation against the total possible recovery. In circumstances in which hospitals would pay more to litigate their numerous claims than they could even recover, federal court escalation is not a viable alternative for Plaintiffs and other hospitals. *See* Wallace Decl. ¶ 16; Holleman Decl. ¶ 13; Geppi Decl. ¶ 15. They thus would be left with no adequate remedy for HHS's unlawful delays.

II. HHS'S DELAYS ARE SUFFICIENTLY EGREGIOUS TO WARRANT THIS COURT'S INTERVENTION.

HHS's delays also are sufficiently egregious that mandamus is warranted. In the case of agency inaction, courts grant mandamus relief if the agency has "unreasonably delayed" performing its duty. *In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000). In determining whether an agency delay is "unreasonable," courts in this Circuit consider the following factors, none of which is dispositive:

(1) the time agencies take to make decisions must be governed by a "rule of reason";

(2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;

(3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;

(4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;

(5) the court should also take into account the nature and extent of the interests prejudiced by delay; and

(6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'"

TRAC, 750 F.2d at 80 (internal citations and quotation marks omitted) (collectively, the "*TRAC* factors"). As discussed below, all six *TRAC* factors weigh in favor of granting mandamus relief; HHS's failure to render timely decisions is in clear violation of statute and has wide-ranging and severe impacts on human health and welfare that the Court should address.

A. HHS's Delays Are Unreasonable.

The first two *TRAC* factors require that the time for agency decisionmaking be governed by a "rule of reason." *TRAC*, 750 F.2d at 80. This "rule of reason" factor is "the first and most important of the *TRAC* factors." *In re People's Mojahedin Org. of Iran,* 680 F.3d 832, 837 (D.C. Cir. 2012) (citation omitted). HHS's years-long delays in adjudicating Medicare appeals, including at least a two-year moratorium on the assignment of appeals at the ALJ level, far outstrip the statutory time periods allotted for the process and are unreasonable.

Where Congress has provided a timetable within which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason. *TRAC*, 750 F.2d at 80. Here, Congress defined a reasonable time for each step of the Medicare appeals

process, including a ninety-day deadline for review and decision by an ALJ. The "specificity and relative brevity" of the deadlines "manifests the Congress's intent" that HHS act promptly on Medicare appeals. *People's Mojahedin*, 680 F.3d at 837. In fact, these deadlines were specifically established as part of an effort by Congress to *shorten* the statutory claim review deadlines in the Medicare Act. *See* Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub L. No. 106-554, 114 Stat. 2763.

In *People's Mojahedin*, the court held that a twenty-month failure to act on a 180-day statutory deadline "plainly frustrates the congressional intent and cuts strongly in favor of granting [the] mandamus petition." 680 F.3d at 837. This situation is even more egregious – the delay is far longer and Congress's deadline is shorter. Whereas the statutory timeframe for the entire ALJ portion of the process – including hearing and decision – is ninety days, HHS currently is exceeding that timeframe by more than four hundred percent: the average processing time for appeals in June 2014 was 463.9 days, a number that will rapidly rise each month as HHS's moratorium takes root. Ex. 4 (*Important Notice*). HHS has already acknowledged that the wait times for a hearing before an ALJ are "unacceptable." Ex. 6 ("Path Forward").

Moreover, this situation presents a uniquely unreasonable and extreme circumstance: not only is the agency currently failing to meet its deadlines, it has affirmatively declared that it will not meet its deadlines in the future and has implemented an outright moratorium on agency action. Effective July 15, 2013, HHS suspended assignment of claim appeals to ALJs, a suspension it expects to last for at least two years. *See* Ex. 3 (Griswold Memorandum). Even after the suspension is lifted and cases begin receiving assignment, HHS estimates that providers are likely to wait at least six months to receive a hearing. *Id.*

Such extraordinary measures in the face of self-admitted "unacceptable" delays clearly are not reasonable. Although there "is 'no *per se* rule as to how long is too long' to wait for agency action, . . . a reasonable time for agency action is typically counted in weeks or months, not years." *In re Am. Rivers*, 372 F.3d at 419 (quoting *In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992). Years-long delays have been held to be unreasonable. *See, e.g., Public Citizen Health Grp. v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983) (three years); *MCI Telecomms. Corp. v. FCC*¸ 627 F.2d 322, 327 (D.C. Cir. 1980) (over three years); *Midwest Gas Users Ass'n v. FERC*¸ 833 F.2d 341, 359 (D.C. Cir. 1987) (four years); *In re Am. Rivers*, 372 F.3d at 419 (six years). Further, while "[i]n certain situations, administrative delays may be unavoidable . . . , extensive or repeated delays are unacceptable and will not justify the pace of action." *Muwekma Tribe v. Babbitt*, 133 F. Supp. 2d 30, 36 (D.D.C. 2000). The extensive delay within HHS's Medicare appeals process coupled with the ALJ assignment moratorium are not the type of incidental delays that courts should tolerate; rather, they are severe delays that have effectively caused the system to grind to a halt.

B. HHS's Unreasonable Delays Cause Extreme Prejudice And Threaten Health And Welfare By Depriving Hospitals Of Funds Needed For Patient Care.

The third and fifth *TRAC* factors assess the impact of the delays and strongly counsel in favor of mandamus relief here. Under the third *TRAC* factor, courts recognize that delays that relate to health and welfare are more likely to necessitate judicial intervention than those that simply may have economic consequences. *TRAC*, 750 F.2d at 80. Under the fifth *TRAC* factor, courts consider the nature and extent of the interests prejudiced by the agency's delay. *Id.* These factors are most appropriately addressed together in this case, because the prejudice suffered by the Plaintiff hospitals is exactly the harm courts have found particularly well-suited for mandamus relief: harm to patient health and welfare.

Where an economic harm has consequences for the viability of "health services and facilities," courts find that the third and fifth *TRAC* factors weigh in favor of finding an agency's delay to be unreasonable. *Muwekma Tribe*, 133 F. Supp. 2d at 39-40 ("[T]he record discloses a nexus between human welfare and 'economic' considerations which weighs in favor of compelling agency action based on unreasonable delay."); *Air Line Pilots Ass'n, Int'l v. C.A.B.*, 750 F.2d 81, 86 (D.C. Cir. 1984) (finding that the third *TRAC* factor weighed in favor of compelling agency action because of impact on health and human welfare where the agency had delayed five years in adjudicating claims for a form of unemployment assistance payments). Both factors weigh in favor of mandamus here, where the hospitals patients turn to for care are impeded in their ability to provide it. Hospitals are deeply out-of-pocket for services they already have rendered, whether their claim denials are pre-payment – in which case hospitals never receive payment for the value of their services – or post-payment – in which case hospitals must repay the amount initially reimbursed before they ever get to the ALJ level.

The danger to health and safety is real and the scope of the problem is measureable. *Billions* of healthcare dollars hang in the balance. *See* Ex. 5 (RAC*Trac* Survey), at 47; Decl. of C. Steinberg ("Steinberg Decl.") ¶ 17. For example, Plaintiff Covenant's hospitals have approximately 1,477 appeals currently pending at the ALJ level, representing over $ 7million in denied reimbursement. Geppi Decl. ¶ 8. And Plaintiff Rutland has ninety-eight appeals pending at the ALJ level, representing more than half a million dollars in Medicare reimbursement for services that Rutland provided to its patients. Wallace Decl. ¶ 12.

For some hospitals, the situation is dire. Plaintiff Baxter has 230 claims, representing almost $3 million in reimbursement for services rendered, tied up at the ALJ level of the appeals process. Holleman Decl. ¶ 9. Because these funds are unavailable, Baxter has been unable to

purchase basic equipment for patient care, like new beds for its intensive care unit. *Id.* ¶ 14. Instead of replacing a failing roof over its surgery department at a cost of approximately $500,000, Baxter has been able only to patch it. *Id.* Baxter also has been unable to replace its twenty-year-old catheterization laboratory. *Id.* Without renovation, this laboratory will soon need to be shut down. *Id.* The cost of pursuing Baxter's numerous appeals of rehabilitation-related claim denials, combined with the high value of those claims and the delay in achieving resolution of them, has become so prohibitive that Baxter has considered whether it would be more financially prudent to *close* its rehabilitation center rather than to pursue the appeals. *Id.* ¶ 16. The unavailability of funds that remain pending in the appeals process has placed Baxter's bond rating at risk: Baxter's bond rating could easily fall to "junk bond" status if the ALJ delays continue. *Id.* ¶ 17.

Hospitals like Plaintiffs Covenant and Rutland also engage in cost-cutting measures to offset the deficits and cash flow problems caused in part by the appeals delays. Geppi Decl. ¶¶ 17-19; Wallace Decl. ¶ 19. Rutland has initiated two rounds of cost reductions, resulting in the elimination of thirty-two jobs. Wallace Decl. ¶ 19. The inability to recover the millions of dollars that are tied up in the appeals process is a major factor in Covenant's negative operating margin. Geppi Decl. ¶ 19. In some instances, hospitals may forego offering services they cannot afford to bring to their communities; in others, hospitals must face the possibility of scaling back services they have long provided. *See, e.g.*, Holleman Decl. ¶¶ 14, 16; Geppi Decl. ¶ 18.[7]

[7] The impact on patient care is significant and has been widely recognized in the industry, including in communications directly to HHS. For example, ninety-eight organizations, including the American Medical Association, warned HHS that the "often lengthy delays" "undermine the ability of physicians to deliver patient-centered care." Ex. 8 (Letter from the American Medical Association, et al., to The Honorable Nancy J. Griswold, Chief ALJ, OMHA, dated Feb. 12, 2014). The Advanced Medical Technology Association ("AdvaMed") has also noted the devastating effects of HHS's moratorium, explaining that "the policy will create

In short, the severe delays in the Medicare appeals process affect huge numbers of appeals with significant reimbursement dollars at stake. The ALJ delays are causing harm every moment they persist – crippling America's hospitals by tying up funds they need to provide facilities and patient care to the communities they serve.

C. HHS's Unreasonable Delays Are Not Justified By Competing Priorities.

HHS's unlawful delays have not been, and cannot be, justified by a supposed competing or higher priority that would render these delays reasonable. *See TRAC*, 750 F.2d at 80. Where an agency has offered no "'plea of administrative error, administrative convenience, practical difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources,'" this factor weighs heavily in favor of granting mandamus. *In re Am. Rivers*, 372 F.3d at 420 (quoting *Cutler v. Hayes*, 818 F.2d 879, 898 (D.C. Cir. 1987)). HHS can offer no such competing priorities.

HHS's announcement of the ALJ appeals moratorium stated only that "we have been unable to keep pace with the exponential growth in requests for hearing." *See* Ex. 3 (Griswold Memorandum). This explanation alludes to a problem that is of HHS's own making. The "exponential growth" in requests for ALJ hearings that is causing the unlawful ALJ delays is attributable in large part to the increasingly aggressive auditing activity of the RACs. *See* Ex. 2 (OMHA Forum Presentation), at 17 (listing "[c]ontinuing expansion of all post-payment audit programs" as a reason for increase in appeals received by OMHA); Ex. 7 (Griswold Statement of Jul. 10, 2014) at 3 (noting that "[t]he rise in the number of appeals resulted from . . . the expansion of OMHA's responsibility to adjudicate appeals resulting from new audit workloads,

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significant harm for both patients and providers." Ex. 9 (Letter from Donald May, Executive Vice President of Payment & Healthcare Delivery Policy at AdvaMed, to Kathleen Sebelius, Secretary of HHS, and Marilyn Tavenner, Administrator of CMS dated Mar. 27, 2014) at 1.

including the nationwide implementation of the Recovery Audit Program in 2010"). Although Plaintiffs do not seek to compel the Secretary to address the ALJ delays in a particular way, the very RAC activity that is creating the backlog may provide one method for resolving it – the Secretary could rein in the activity of the RACs, thereby addressing the largest driver of claim appeals at the front end.

Moreover, HHS's overall budget is sizable: for fiscal year 2014, HHS's budget authority approached a trillion dollars. *Overview*, Fiscal Year 2015 Budget in Brief, Dep't of Health & Human Servs., *available at* http://www.hhs.gov/budget/fy2015-hhs-budget-in-brief/hhs-fy2015budget-in-brief-overview.html (last visited July 11, 2014). HHS cannot insulate the Medicare claim appeals process from review by simply failing to allocate the resources it has been given by Congress to address this issue: "However many priorities the agency may have, and however modest its personnel and budgetary resources may be, there is a limit to how long it may use these justifications to excuse inaction in the face of the congressional command to act within ninety days." *In re United Mine Workers of Am. Int'l Union*¸ 190 F.3d 545, 554 (D.C. Cir. 1999) (addressing statutory requirement that the Secretary of Labor promulgate final regulations, or explain her decision not to promulgate them, within ninety days after either the certification of the record of a hearing or the close of the public comment period). Ultimately, "the Congress undoubtedly knew the enormous demands placed upon the Secretary and nonetheless limited her time to act." *People's Mojahedin*, 680 F.3d at 837.

D. Agency Impropriety Need Not Exist For Mandamus To Issue.

The sixth *TRAC* factor makes clear that mandamus does not require that the agency's delay be driven by improper conduct or motive, *TRAC*, 750 F.2d at 80; the egregiousness of the delay itself is sufficient to warrant mandamus. Thus, HHS's openness about the extent of the

problem and its stated concern for finding "new ways to work smartly and more efficiently," Ex. 3 (Griswold Memorandum), are immaterial to avoiding mandamus, because they do nothing to change the underlying fact of the unlawful and egregious delays. Indeed, HHS's own acknowledgement of the severity of the problem is an inherent concession that the delays are not reasonable.

CONCLUSION

HHS has violated, and is continuing to violate, its clear statutory obligation to adjudicate Medicare appeals within the deadlines established by the Medicare Act. HHS's unlawful delays are egregious, exceeding reasonable statutory timeframes by *years.* The only remedy for these delays and the resulting debilitating effects on hospitals' ability to provide quality patient care is for the Court to grant mandamus relief to require HHS to comply with the statutory deadlines provided in the Medicare Act, and to conduct and conclude timely hearings in the claim appeals brought by the Plaintiff hospitals. For all the foregoing reasons, Plaintiffs respectfully request that the Court grant their motion for summary judgment.

Dated: July 11, 2014

Respectfully submitted,

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REQUEST FOR ORAL HEARING

Plaintiffs respectfully request an oral hearing on their motion.

/s/ Adam K. Levin
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:14-CV-851-JEB

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Rule (7)(h)(1) of the Rules of the United States District Court for the District of Columbia, Plaintiffs the American Hospital Association ("AHA"), Baxter Regional Medical Center ("Baxter"), Covenant Health ("Covenant"), and Rutland Regional Medical Center ("Rutland") (collectively, "Plaintiffs," and Baxter, Covenant, and Rutland collectively, the "Plaintiff hospitals") submit this Statement of Undisputed Material Facts in support of their Motion for Summary Judgment.

I. Medicare

1. The Medicare program was enacted in 1965 under Title XVIII of the Social Security Act to provide health insurance primarily to individuals sixty-five years of age and older. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395-1396v).

2. The program's main objective is to ensure that its beneficiaries have access to health care services. *Id.*

3. The Plaintiff hospitals qualify as "providers of services" under Title XVIII, also known as the Medicare Act. *See* 42 U.S.C. § 1395x(u).

4. When hospitals furnish services to a Medicare beneficiary, they thereafter submit a claim for reimbursement to a Medicare Administrative Contractor ("MAC") that conducts the initial review of the claim. 42 U.S.C. § 1395ff(a)(2)(A).

5. MACs are government contractors responsible for processing Medicare claims and making payments to hospitals, doctors, and others that furnish medical care to Medicare beneficiaries. 42 U.S.C. § 1395kk-1(a)(3).

6. MACs review a hospital's claim for reimbursement and either pay the claim or deny it. *See id.* § 1395kk-1(a)(4).

7. Some claims initially paid by MACs are then subjected to an additional level of oversight. In a process known as "post-payment review," third-party contractors, including Medicare Recovery Audit Contractors ("RACs"), audit MAC payment decisions. *See* 42 U.S.C. § 1395ddd(h)(1).

8. RACs are paid based on the amount of Medicare reimbursement they recover for alleged overpayments. *Id.* § 1395ddd(h)(1).

9. RACs can audit hospital claims paid by MACs dating back three years. *See* Statement of Work for the Medicare Fee-for-Service Recovery Audit Program, at 9, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111RACFinSOW.pdf (last visited Jul. 11, 2014).

II. The Appeals Process

10. When a hospital's claim for reimbursement under Medicare is denied (by a MAC, RAC, or otherwise), the hospital has a right to file an administrative appeal under the Medicare Act. 42 U.S.C. § 1395ff(b)(1)(A).

11. Appeals of both pre- and post-payment claim denials are subject to an administrative process set forth by statute. *Id.* § 1395ff.

12. When a hospital's claim for reimbursement under Medicare is denied by a MAC, or in post-payment review by a RAC or other contractor, the first step in the administrative appeals process is for the hospital to present the denied claim to the MAC again for redetermination. *Id.* § 1395ff(a)(3)(A).

13. The MAC must render a redetermination decision within sixty days. *Id.* § 1395ff(a)(3)(C)(ii).

14. This first step of the process is overseen by the Centers for Medicare & Medicaid Services ("CMS") within the Department of Health and Human Services ("HHS").

15. If unsatisfied with the MAC's redetermination, a hospital can appeal the MAC's decision to a Qualified Independent Contractor ("QIC") for reconsideration. *Id.* § 1395ff(c).

16. QICs must render a decision within sixty days. *Id.* § 1395ff(c)(3)(C)(i).

17. This second step of the process is overseen by CMS.

18. A hospital may next request a hearing before an ALJ. *Id.* §§ 1395ff(b)(1)(E), 1395ff(d)(1)(A).

19. The ALJ is required both to hold a hearing and render a decision within ninety days. 42 U.S.C. § 1395ff(d)(1)(A); 42 C.F.R. § 405.1016(a).

20. This third step of the process is overseen by HHS's Office of Medicare Hearings and Appeals ("OMHA").

21. ALJs are independent adjudicators. *See* Medicare Modernization Act of 2003, Pub. L. No. 108-173, § 931(b)(2), 117 Stat. 2066, 2398 (2003) ("The Secretary shall assure the independence of administrative law judges . . . . In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from [CMS].")

22. Next, a hospital can appeal its claim to the Departmental Appeals Board ("DAB") within HHS. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1108(a).

23. The DAB conducts a *de novo* review of the ALJ decision and either renders its own decision or remands to the ALJ for further proceedings. *Id.*

24. In either event, the DAB must act within ninety days. *Id.*

25. The Medicare Act also provides for a process by which the QIC, ALJ, and DAB levels of review may be bypassed, known in the regulations as "escalation."

26. Specifically, if the QIC is unable to complete its review within sixty days, it must notify all parties that it cannot complete the reconsideration within the statutory timeframe and offer the hospital the opportunity to "escalate" the appeal to an ALJ. 42 U.S.C. § 1395ff(c)(3)(C)(ii); 42 C.F.R. § 405.970.

27. The QIC will continue the reconsideration process unless and until the hospital files a written escalation request. 42 C.F.R. § 405.970(c)(2).

28. Similarly, if an ALJ has not held a hearing and rendered a decision within ninety days, a hospital may bypass the ALJ level by escalating its claim to the DAB. 42 U.S.C. § 1395ff(d)(3)(A).

29. In such situations, the QIC's decision becomes the decision subject to DAB review. 42 C.F.R. § 405.1104; 42 C.F.R. § 405.1108(d).

30. If a hospital escalates from the ALJ level after having previously escalated from the QIC level, only the record from the MAC is available for consideration by the DAB.

31. The DAB may conduct additional proceedings, including a hearing, but is not required to do so. 42 C.F.R. § 405.1108.

32. Judge Constance B. Tobias, Chair of the DAB, has stated that, in escalation situations, the DAB will "NOT hold a hearing or conduct oral argument unless there is an extraordinary question of law/policy/fact." Ex. 2 (OMHA "Medicare Appellant Forum" Presentation dated Feb. 12, 2014) ("OMHA Forum Presentation") at 117.

33. The DAB has 180 days in which to act on an escalation request, rather than the ninety days it has to act on direct appeals. 42 C.F.R. § 405.1100(c)-(d).

34. If the DAB has not rendered a decision within ninety days on its review of an ALJ's decision, a hospital may bypass the DAB and seek judicial review in federal court. 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132.

35. A hospital may file an action in federal district court if the DAB notifies it that no decision will be issued and if the claim meets an amount-in-controversy requirement (currently $1,430). 42 C.F.R. § 405.1132(b); 42 C.F.R. § 405.1006(c); Notice of Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014, 78 Fed. Reg. 59702-03 (Sept. 27, 2013).

36. In cases of an initial escalation past the ALJ level, a hospital may escalate the appeal to federal court if the DAB fails to render a decision within 180 days. 42 C.F.R. § 405.1132; 42 C.F.R. § 405.1100(d).

37. In the event of "double escalation" past both the ALJ and the DAB levels, the only agency decision available to the federal court for review is the QIC's decision, made without a hearing.

38. In the event of a "triple escalation" past the QIC, the ALJ, and the DAB, only the MAC record is available for review.

III. The Delays

39. The statutory time periods governing the appeals process provide for all levels of administrative review to be completed within a total of about one year. *See* 42 U.S.C. § 1395ff.

40. Increases in the rates of appeal have caused a significant backlog at the ALJ level of the appeals process. *See* Ex. 4 (OMHA *Important Notice Regarding Adjudication Timeframes*) ("*Important Notice*").

41. These increases are due in part to providers challenging RACs' claim denials. *See* Ex. 2 (OMHA Forum Presentation) at 17.

42. In just two years (2012 and 2013), the backlog of ALJ-level appeals quintupled, growing from 92,000 to 460,000 pending claims. Ex. 3 (Mem. from Nancy J. Griswold to OMHA Medicare Appellants dated Dec. 24, 2013) ("Griswold Memorandum").

43. The workload of OMHA's sixty-five ALJs increased by almost 300 % percent from fiscal year 2012 to fiscal year 2013. *See* Ex. 2 (OMHA Forum Presentation) at 16.

44. In fiscal year 2013, of the 384,151 appeals that were filed, only 79,303 were decided. *See* Ex. 2 (OMHA Forum Presentation) at 12 (reflecting decision figures); *see* Ex. 4 (*Important Notice*) (reflecting adjusted appeals receipts figures).

45. As of December 2013, it was taking an average of sixteen months before an ALJ heard a case – approximately thirteen months longer than the ninety-day statutory deadline for an ALJ decision. *See* Ex. 2 (OMHA Forum Presentation) at 11; Ex. 3 (Griswold Memorandum).

46. As of June 2014, the average processing time for appeals was 463.9 days. Ex. 4 (*Important Notice*).

47. On December 24, 2013, HHS announced through OMHA's Chief ALJ, Nancy Griswold, that HHS had suspended the assignment of all new appeals to ALJs (other than those by Medicare beneficiaries) as of July 15, 2013. Ex. 3 (Griswold Memorandum).

48. The moratorium is expected to last for a minimum of two years. *Id.*

49. Additional post-assignment hearing wait times are expected to exceed six months when the suspension is eventually lifted. *Id*.

50. As recently as February 14, 2014, Judge Griswold stated that the wait times for a hearing before an ALJ are "unacceptable." Ex. 6 (Michelle M. Stein, *ALJs Lay Out Path Forward For Stakeholders As Appeals Backlog Continues*, Inside Health Policy, Feb. 20, 2014).

51. OMHA has received from 10,000 to 16,000 ALJ appeals per week in fiscal year 2014. Ex. 7 (Statement of N. Griswold before the U.S. House Committee on Oversight and Government Reform, Subcommittee on Energy Policy, Health Care & Entitlements on July 10, 2014) ("Griswold Statement") at 4.

52. OMHA has stated that it projects a twenty to twenty-four week delay in docketing new appeals. Ex. 4 (*Important Notice*).

53. As of July 1, 2014, 800,000 appeals were pending at the ALJ level. Ex. 7 (Griswold Statement) at 4.

54. Plaintiff Baxter currently has appeals pending at the ALJ level that have been pending longer than ninety days.

55. Plaintiff Baxter currently has appeals pending at the ALJ level that are subject to the moratorium imposed as of July 15, 2013.

56. Plaintiff Covenant currently has appeals pending at the ALJ level that have been pending longer than ninety days.

57. Plaintiff Covenant currently has appeals pending at the ALJ level that are subject to the moratorium imposed as of July 15, 2013.

58. Plaintiff Rutland currently has appeals pending at the ALJ level that have been pending longer than ninety days.

59. Plaintiff Rutland currently has appeals pending at the ALJ level that are subject to the moratorium imposed as of July 15, 2013.

60. HHS's suspension in assignment of appeals to ALJs does not alter the requirement that a hospital appeal an unfavorable QIC decision within sixty days. *See* 42 U.S.C. § 1395ff(b)(1)(D)(ii); 42 C.F.R. § 405.1014(b)(1).

61. At the end of fiscal year 2013, the DAB had 4,888 pending appeals, 112% more than it had at the end of fiscal year 2012. Ex. 2 (OMHA Forum Presentation) at 106.

62. There are four Appeals Officers responsible for DAB review of Medicare entitlement, managed care, prescription drug claims, and fee-for-service payment denials.

63. HHS projects that 7,000 DAB appeals will be received in fiscal year 2014. *Id.* at 107.

64. That number is expected to rise to over 8,000 for fiscal year 2015. *Id.*

65. As with the ALJs, the DAB is seeing an increased caseload due to the behavior of the RACs and other Medicare contractors. *Id.* at 108.

66. HHS has stated that the DAB is "unlikely to meet the ninety-day deadline for issuing decisions in most appeals." *Id.* at 110.

Respectfully submitted,

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Dated: July 11, 2014

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of July, 2014, I caused the foregoing Plaintiffs' Motion for Summary Judgment, and accompanying memorandum, Statement of Undisputed Material Facts, exhibits, and declarations to be sent by certified mail, return-receipt requested, addressed to the following:

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