NOT YET SCHEDULED FOR ORAL ARGUMENT

No. 15-5015

IN THE

United States Court of Appeals for the District of Columbia Circuit

AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL MEDICAL CENTER, RUTLAND REGIONAL MEDICAL CENTER, AND COVENANT HEALTH,

Plaintiffs-Appellants,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant-Appellee.

Appeal from the United States District Court
for the District of Columbia in
Case No.1:14-CV-851
Judge James E. Boasberg

OPENING BRIEF FOR APPELLANTS

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Dated: May 4, 2015

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici.

1. The following parties and amicus curiae appeared before the District Court:

Plaintiffs
American Hospital Association
Baxter Regional Hospital, Inc., doing business as Baxter Regional Medical Center
Covenant Health
Rutland Hospital, Inc., doing business as Rutland Regional Medical Center

Defendant
Sylvia Mathews Burwell, in her official capacity as Secretary of Health and Human Services

Amicus Curiae
Fund for Access to Inpatient Rehabilitation

2. The following parties currently appear before this Court:

Appellants
American Hospital Association
Baxter Regional Hospital, Inc., doing business as Baxter Regional Medical Center
Covenant Health
Rutland Hospital, Inc., doing business as Rutland Regional Medical Center

Appellee
Sylvia Mathews Burwell, in her official capacity as Secretary of Health and Human Services

Amicus Curiae
Fund for Access to Inpatient Rehabilitation

3. Appellants make the following disclosures:

The American Hospital Association is a national non-profit corporation that represents more than 5,000 hospitals, health care systems, and other healthcare organizations, plus nearly 43,000 individual members, in matters before Congress, the executive branch, and courts. It has no parent companies and no publicly held company has a 10% or greater ownership interest (such as stock or partnership shares) in the entity.

Baxter Regional Medical Center is a 268-bed regional hospital located in Mountain Home, Arkansas. It has no parent companies and no publicly held company has a 10% or greater ownership interest (such as stock or partnership shares) in the entity.

Covenant Health is a community-owned health system located in East Tennessee, consisting of nine individual hospitals. It has no parent companies and no publicly held company has a 10% or greater ownership interest (such as stock or partnership shares) in the entity.

Rutland Regional Medical Center is a 133-bed, community-owned rural hospital located in Rutland, Vermont. It has no parent companies and no publicly held company has a 10% or greater ownership interest (such as stock or partnership shares) in the entity.

B. Ruling Under Review.

The decision on review is *American Hospital Association v. Burwell*, __ F. Supp. 3d __, 2014 WL 7205335 (D.D.C. Dec. 18, 2014) (Boasberg, J.), reproduced at JA166-JA186.

C. Related Cases.

There is one related case of which undersigned counsel is aware: *Cumberland County Hospital v. Sylvia Burwell*, No. 15-1393, currently pending in the United States Court of Appeals for the Fourth Circuit. That case, like this one, is brought by a hospital system and presents the issue whether mandamus should issue because HHS has breached its duty to hold hearings and render administrative law judge (ALJ) decisions within 90 days. The opening brief in that case currently is due on May 26, 2015.

Dated: May 4, 2015

/s/ Catherine E. Stetson
Catherine E. Stetson

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GLOSSARY

AHA	The American Hospital Association
CMS	Centers for Medicare & Medicaid Services
DAB	Departmental Appeals Board
HHS	Department of Health and Human Services
MAC	Medicare Administrative Contractor
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
OMHA	Office of Medicare Hearings and Appeals
QIC	Qualified Independent Contractor
RAC	Medicare Recovery Audit Contractor

INTRODUCTION

The Department of Health and Human Services (HHS) is required by statute to decide hospitals' Medicare claim appeals within a certain period of time. HHS does not. It does not even come close. And as the District Court recognized below, the Department's egregious delays force hospitals' claims to "languish[] in an administrative process that is unable to manage an ever-growing backlog of appeals." JA166.

One significant reason for the backlog—and the resulting delays—is that HHS's Medicare contractors have pursued increasingly aggressive auditing practices, calculated to earn them the largest contingent fees. This aggressive auditing activity has led hospitals and other health care providers to appeal vastly increasing numbers of improperly denied claims, which are very frequently found to be meritorious. This dramatic increase in appeals further contributes to HHS's violating its statutory deadlines, often by years.

HHS has no incentive, short of judicial fiat, to hasten the process. In fact, HHS has every incentive to let the appeals backlog grow: The Department retains the funds attributable to improperly denied claims during the entire pendency of a hospital's appeal. In the meantime, as they wait, hospitals all over the country are forced to make increasingly difficult decisions about how to continue to provide quality patient care with less and less money.

Despite these egregious delays and the resultant severe detrimental effects on hospitals, the District Court concluded that it was not yet time for it to "intermeddle" in HHS's processes. According to the District Court, the hospitals must "wait along with everyone else" for HHS to do its job.

The hospitals have waited quite long enough. HHS's delays violate a clear statutory mandate, they violate that mandate by a mile, and its delays cannot be excused or outweighed by the Department's competing priorities.

Mandamus should issue.

STATEMENT OF JURISDICTION

This appeal is from a final judgment that disposes of all parties' claims. The District Court had jurisdiction over this action pursuant to 28 U.S.C. § 1361. The District Court entered its final judgment on December 18, 2014. JA165. A timely notice of appeal was filed in this Court on January 16, 2015. JA187. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATUTES AND REGULATIONS

The relevant statutes and regulations are reprinted in the addendum to this brief.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

Whether the District Court erred in denying Appellants mandamus relief,

despite recognizing that HHS is violating its statutory deadlines, despite recognizing that the Department's delays are causing consequences to health and welfare, and despite the fact that mandamus is the only meaningful means of relief available to the hospitals.

STATEMENT OF THE CASE

When a provider of hospital services treats a Medicare beneficiary, it submits a claim for reimbursement to a contractor acting under the supervision of HHS. That claim may be approved or denied—and sometimes, it may be approved only to be later clawed back by an HHS contractor. If a claim is denied or clawed back, the hospital may pursue a four-step administrative appeals process that the Medicare Act requires be completed within one year.

That is how the system is *supposed* to work, in theory. In practice, HHS has allowed these deadlines to pass by years without providing a hearing or rendering a decision.

I. Medicare

The Medicare program was enacted in 1965 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 hospital appellants qualify as

providers of inpatient hospital services under Title XVIII of the Social Security Act, also known as the Medicare Act.

When hospitals treat a Medicare beneficiary, they submit a claim for reimbursement to a Medicare Administrative Contractor (MAC). 42 U.S.C. § 1395ff(a)(2)(A). MACs are government contractors; they are 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 conduct the initial review of a hospital's claim for reimbursement, and they either pay the claim or deny it.

Some of the claims MACs pay are subjected to an additional level of oversight. In a process known as "post-payment review," third-party contractors, including entities called "Medicare Recovery Audit Contractors" (RACs), audit MAC payment decisions, sometimes reaching back as much as three years. *See* 42 U.S.C. § 1395ddd(h)(1).[1] RACs are supposed to "identify and correct Medicare improper payments."[2] But RACs are compensated based on the amount of money they recover from hospitals and other providers for purportedly "improper" Medicare payments. In other words, RACs work on a contingent fee. And

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[1] *See* HHS, CMS, *Statement of Work for the Medicare Fee-for-Service Recovery Audit Program* 1, 9, http://goo.gl/HtwGt8.

[2] HHS, CMS, *Recovery Audit Program*, http://goo.gl/T33Df0 (last visited May 2, 2015).

because RACs work on a contingent-fee basis, it should come as no great surprise that they engage in shrewdly targeted audits of Medicare claims, frequently question the medical judgment of health care providers, and frequently claw back payments—especially for services that qualify for the largest amount of reimbursement. The value of appealed, RAC-denied claims alone currently exceeds $1.8 *billion*. JA43.

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 statutorily prescribed four-step administrative process. *See* 42 U.S.C. § 1395ff. The first two steps are overseen by the Centers for Medicare & Medicaid Services (CMS) within HHS; the third (the ALJ level) is overseen by the Office of Medicare Hearings and Appeals (OMHA); and the fourth is overseen by the Departmental Appeals Board (DAB) within HHS.[3] The four appeals steps are:

Step 1. When a hospital's claim for Medicare payment is denied by a MAC, or in post-payment review by a RAC or other contractor, the first step in the

[3] The DAB division that conducts the fourth level of administrative review is called the Medicare Appeals Council, and the Medicare regulations refer to this division as the "MAC." This brief uses the shorthand "DAB" instead of "MAC" to avoid possible confusion with the Medicare Administrative Contractors that conduct initial determinations and redeterminations.

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). The ALJ is required to both hold a hearing and render a decision within ninety days. *Id.*; 42 C.F.R. § 405.1016(a). At the hearing, hospitals can present evidence, respond to questions posed by the ALJ in real time, and explain the written materials in the record. JA75; JA70; JA84. The ALJ stage provides the first opportunity for a hospital to obtain an independent review of its claim. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), 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]."). Not unrelatedly, 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.*, JA75.

Step 4. Finally, a hospital can appeal an adverse ALJ ruling to the DAB. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1108(a). 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. 42 U.S.C. § 1395ff(d)(2). 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 (steps 2-4) may be bypassed, known as "escalation." *See* 42 C.F.R. § 405.970(c)(2) (escalation to ALJ); 42 C.F.R. § 405.1106(b) (escalation to DAB); 42 C.F.R. § 405.1132 (escalation to federal court). Congress added the escalation provisions to the Medicare Act in 2000 as part of an overall reform to the appeals process designed (among other things) to shorten decision deadlines. Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763, § 521; *see Medicare Program: Changes to the Medicare Claims Appeal Procedures*, 67 Fed. Reg. 69,312 (Nov. 15, 2002) (noting "the establishment of drastically reduced mandatory time frames for appeals decisions"). Under the escalation provisions, if the QIC (at step 2) is unable to complete its review within sixty days, it must so notify all parties and offer the hospital the opportunity to "escalate" the appeal to an ALJ (step 3). 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 (step 4). 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 by the DAB. 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 where a hospital has escalated its claim, the DAB will "NOT hold a hearing or conduct oral argument unless there is an extraordinary question of law/policy/fact"—forcing a hospital to make a difficult tactical choice. JA35. If it escalates, a hospital forfeits its right to a hearing. If it does not, the hospital must bide its time until an ALJ is available to hear and decide its appeal, which could be years later.

Finally, 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 $1,460). 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 2015, 79 Fed. Reg. 57,933, 57, 934, 57, 935 (Sept. 26, 2014). Hospitals having claims that do not meet the amount-in-controversy requirement for escalation, however, do not have that option to jump-start the federal court process. They must wait out the delays.[4]

III. The Delays

The statutory time periods governing the appeals process provide for all levels of administrative review—collectively—to be completed within a total of about one year. But the statutory rule is honored only in the breach. In practice, the time it takes to pursue a claim appeal through HHS grossly exceeds the timeframes established by the Medicare Act.

A massive appeal backlog exists at the ALJ level. As OMHA's Chief ALJ, Nancy Griswold, reported at the end of 2013, in just two years (2012 and 2013),

[4] 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 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.

the backlog of ALJ-level appeals *quintupled*, growing from 92,000 to 460,000 pending claims. JA23. That backlog currently exceeds 800,000 appeals.[5] And the ALJs have not come close to keeping up with the growing volume of appeals because the receipt of new appeals is far outpacing the number of decisions issued. In fiscal year 2014, for example, only 87,266 appeals were decided (many of which had been carried over from previous years' filings).[6] In comparison, OMHA received nearly five times that many new appeals that year—395,000. *Id.*

Indeed, as of December 2013, it was taking an average of sixteen months before an ALJ even *heard* a case—over a year longer than the ninety-day statutory deadline for an ALJ *decision*. *See* JA23. When OMHA prepared its budget justification for fiscal year 2016, the average age of pending appeals at OMHA was 647 days—557 days too many.[7] More than a year ago, when the delays were less severe than hospitals face today, Judge Griswold observed that the wait times for an ALJ hearing were "unacceptable" even then. JA46.

HHS acknowledges that "[f]or the past three years, OMHA has failed to

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[5] HHS, OMHA, Justification of Estimates for Appropriations Committees, Fiscal Year 2016, 6 (2015) http://goo.gl/jGTfj8 ("FY2016 Budget Justification") (last visited Apr. 28, 2015).

[6] *See* OMHA, October Appellant Forum, 9 (Oct. 29, 2014), *available at* http://goo.gl/VtO4oV("OMHA October Forum").

[7] FY2016 Budget Justification, *supra* n.5, at 7.

issue decisions in 90 days."[8] That continuing statutory violation is not likely to be cured any time soon, either: On December 24, 2013, Judge Griswold announced that as of July 15, 2013, HHS had *suspended* the assignment to ALJs of all new appeals (other than those by Medicare beneficiaries) for a minimum of two years. JA23. According to HHS's website, it is only now assigning a "limited number" of non-beneficiary appeals received between April and June 2013.[9] As of October 29, 2014, OMHA was only then entering appeals from July 2014 into its docketing system.[10]

But 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 continues to increase dramatically as appeals 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). In fiscal year 2014 alone, OMHA received 395,000 new appeals.[11] According to HHS's own data, none of those new appeals has even been assigned to an ALJ.

Hospitals lodging new appeals from the QIC to the ALJ thus can realistically expect to wait close to *three years*, and probably longer, even to obtain a hearing—

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8 FY2016 Budget Justification, *supra* n.5, at 7.

9 OMHA, *Important Notice Regarding Adjudication Timeframes*, *available at* http://goo.gl/a7Lvus (last visited May 2, 2015).

10 OMHA October Forum, *supra* n. 6, at 14.

11 OMHA October Forum, *supra* n. 6, at 9.

let alone a decision.[12]

The situation is getting worse instead of better: OMHA currently receives more than one year's worth of claim appeals every eight weeks.[13] And the delays begin at the beginning: OMHA projects a twenty to twenty-four week delay even in docketing new appeals.[14] From there, the new appeals will await ALJ assignment indefinitely, while the moratorium persists. All of this has led to the current state of affairs: As of July 1, 2014, 800,000 appeals were pending at the ALJ level. JA51. And given HHS's suspension of assignments, and the clip of approximately 48,000 ALJ appeals filed each month of fiscal year 2014, on average, we can predict that the backlog now is even larger.

The DAB—the last level of administrative review—is similarly inundated. The DAB has just four Appeals Officers responsible for DAB review of Medicare entitlement, managed care, and prescription drug claims, in addition to claims from providers challenging payment denials. *See* JA31-32. And at the end of fiscal year 2014, the DAB had before it 7,394 pending appeals, a 43% increase over fiscal year 2013.[15] That number is expected to rise to over 8,000 for fiscal year 2015.

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12 *See* HHS, OMHA, *Data—Current Workload*, *available at* http://goo.gl/d6usKM ("Current Workload") (last visited May 2, 2015).

13 FY2016 Budget Justification, *supra* n. 5, at 1.

14 Current Workload, *supra* n. 12.

15 OMHA October Forum, *supra* n. 6, at 56.

JA33. In a triumph of understatement, HHS has conceded that the DAB is "unlikely to meet the 90-day deadline for issuing decisions in most appeals."[16]

HHS thus has recognized for some time the severity of the problem. But the Department has not resolved it. The moratorium on assigning appeals to ALJs has been in place for over a year and a half. The attendant delays in the appellate process continue to worsen from month to month.[17] And in the meantime, RACs seeking to maximize their own contingent-fee revenues continue their aggressive auditing practices, forcing more and more hospitals to appeal more and more denied and clawed-back claims. Fifty-seven percent of all appeals received by OMHA in fiscal year 2014 were RAC appeals.[18] Data reported to the AHA through the first quarter of 2014 show that RAC denials of hospitals' claims were overturned 66% of the time on appeal. JA42, JA45.

In the first quarter of 2014, 93% percent of the AHA's (over one thousand) reporting hospitals experienced at least one delay longer than the statutory limit of ninety days for an ALJ determination to be issued. JA44. Without any options left, with no end in sight to the delays, and with delays worsening every month, the AHA and several hospitals filed this lawsuit. The appellant hospitals represent only a handful of those that have been hardest hit:

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16 OMHA October Forum, *supra* n. 6, at 60.
17 Current Workload, *supra* n. 12.
18 OMHA October Forum, *supra* n. 6, at 9, 11.

Baxter. Baxter Regional Medical Center is a 268-bed regional hospital located in Mountain Home, Arkansas. JA68. It has served the residents of North-Central Arkansas and South-Central Missouri for over fifty years. JA69. In 2013, Baxter was identified as America's fifth-most Medicare-dependent hospital, with Medicare responsible for 65% of its gross revenue. *Id.*

Baxter has millions of dollars in Medicare reimbursement tied up in the appeals process. *See id.* These delays have crippled Baxter's cash flow and harmed its operations. Baxter has been unable to purchase basic replacement equipment, like beds for its intensive-care unit. JA70. In fact, Baxter's cash position is so weak that its bond rating could easily fall to "junk bond" status if the delays continue. JA71.

The large volume of rehabilitation-related Medicare claim denials, and resulting large sums tied up in the appeals process, have caused Baxter to evaluate whether it would be more financially prudent to close its rehabilitation center rather than to continue to pursue its administrative appeals. *Id.* That in turn would mean residents of North-Central Arkansas and South-Central Missouri could face a one- to two-hour drive to obtain such services elsewhere. JA68-69.

Covenant. Covenant Health is a community-owned health system of nine hospitals located in East Tennessee. JA72-73. Medicare payments account for fully 55% of Covenant's gross revenue, and Covenant has millions of dollars in

claims pending system-wide in the Medicare appeals process. *See* JA73.

These delays have significantly impaired Covenant's cash flow. JA75-76. From January through May of 2014, Covenant's overall operating margin was negative 1.8%. JA76. Because of this operating margin deficit, due in major part to funds tied up in the appeals process, Covenant is evaluating the scope of services provided to its patients to determine whether cuts need to be made. *Id.* And harm to Covenant does not harm only its patients: It also is the largest private employer in the region. JA73.

Rutland. Rutland Regional Medical Center is a small, community-owned rural hospital in Rutland, Vermont. JA82. In addition to providing a full scope of community hospital services and maintaining several outpatient specialty clinics, Rutland provides services that are uniquely important to the community it serves, including an addiction-treatment facility.[19] *Id.* In 2011, Rutland served a critical function by expanding its inpatient psychiatric services and assuming responsibility for patients displaced when Vermont's psychiatric hospital for the most seriously ill patients closed after flooding from Hurricane Irene. *Id.*

The Secretary has designated Rutland a "Rural Referral Center" because of

[19] Vermont ranks in the top ten states for several measures of substance abuse, and Rutland itself has been the subject of a front-page New York Times article discussing the small city's rampant heroin epidemic. *See* Katharine Q. Seelye, *A Call to Arms on a Vermont Heroin Epidemic*, N.Y. Times, Feb. 27, 2014, at A1, *available at* http://goo.gl/pSy1zE).

the severity of cases it treats and the specialized physicians the hospital provides to treat those cases. JA82-83. The Secretary also has designated Rutland a "sole community hospital" pursuant to 42 U.S.C. § 1395ww(d)(5)(D)(iii) and 42 C.F.R. § 412.92. *Id.* The "sole community hospital" program is intended to maintain access to quality patient care and hospital services for Medicare beneficiaries in geographically isolated areas. *Id.*

Rutland's community is aging; it thus has a large proportion of Medicare beneficiaries. In fiscal year 2013, Rutland depended on Medicare for 47% of its gross revenues. JA83. As of July 11, 2014, Rutland had over half a million dollars tied up in the appeals process—all but a tiny fraction of it at the ALJ level. *Id.* In response, Rutland had had to implement a number of cost-cutting measures: It initiated two rounds of cost reductions and eliminated thirty-two jobs. JA85. These job losses and Rutland's impaired ability to serve patients have negatively affected the hospital's community. *Id.*

IV. The District Court's Opinion

Out of both money and options, the Baxter, Covenant, and Rutland hospitals, joined by the AHA, filed a complaint in federal district court for mandamus relief, and sought summary judgment. As they explained, massive delays in the Medicare appeals process have postponed by years the prompt adjudications to which they are statutorily entitled, while the Department retains millions of dollars in

improperly denied Medicare payments. Mot. Summ. J. 6-9. The hospitals detailed the severe consequences they have suffered as a result of HHS's delays. *Id.* at 21-24. These harms are emblematic of those suffered by hospitals across the country: The AHA has received reports from its member hospitals that the value of appealed, RAC-denied claims alone exceeds $1.8 billion. JA43. And they offered several avenues the Secretary could pursue to address the delays: For example, the Secretary could rein in the audit practices of rampant and overzealous RACs, Mot. Summ. J. 18; could seek greater appropriations for OMHA, *id.* at 17; could use funds within HHS to hire more ALJs, *id.* at 16; and could reprogram funds to address the backlog, *id.* at 17.

HHS, for its part, moved to dismiss. As the Department saw things, it had not even violated the Medicare Act. Mot. To Dismiss at 15-17. That was so, the Department argued, because the availability of escalation meant that Congress "contemplated that the administrative appeal timeframes would not always be met." *Id.* at 17. HHS went on to cite its "other agency priorities" to explain why it could not meet its statutory deadlines. *Id.* at 22, 25. Also according to HHS, escalation is the exclusive "remedy" for violations of the Medicare Act's decision deadlines, meaning that mandamus should not issue. *Id.* at 26-32.

The District Court granted the Secretary's motion to dismiss and denied the hospitals' motion for summary judgment without a hearing. JA166. The court

considered the question of its jurisdiction and the merits of the claim together because "whether HHS's delay is so unreasonable as to warrant relief requires the same analysis as whether the Court has jurisdiction to grant that relief." JA174.

The court then addressed the six *TRAC* factors—the factors this Court applies in evaluating whether an agency delay is actionable in mandamus. JA175. The factors are:

> (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.

Telecommunications Research & Action Ctr. v. FCC, 750 F.2d 70, 79 (D.C. Cir. 1984) ("*TRAC*") (internal quotation marks and citations omitted).

As to the first two factors, the court observed that the "Secretary concedes that the 90-day statutory 'timetable supplies the applicable rule of reason' in this case," and that the Secretary "does not deny that ALJs are in violation of this rule." *Id.* (citing Reply Br. at 14). The court thus agreed with the plaintiffs that "HHS has violated its statutory framework." JA177; *see also* JA184 (observing that "OMHA has been saddled with a workload it cannot, at present, possibly

manage").

The District Court then turned its attention to the consequences of non-intervention, addressing factors three and five. JA177-179. The court acknowledged that Covenant's hospitals alone had over $7 million worth of appeals pending at the ALJ level. JA177 (citing JA73). It acknowledged Baxter's undisputed inability to update its equipment or provide necessary repairs to its facilities, as well as the precariousness of Baxter's bond rating. JA177-178 (citing JA70-71). It noted that rehabilitation facilities have been "forced to avoid admitting certain types of patients." JA178. And the court acknowledged that "[o]verall, the holdups have forced health-care providers to reduce costs, eliminate jobs, forgo services, and substantially scale back." *Id.*

As the District Court put it, "these are real consequences to health and welfare." *Id.* And yet the court found those health-and-welfare consequences to be "not the kind of immediate and undisputed dangers that have weighed heavily in the *TRAC* analysis." *Id.* As the court saw things, "[n]early everything HHS does affects human health and welfare"—meaning that these documented, undisputed, and widespread harms to hospitals "weigh, if at all, only very lightly in favor of granting relief." JA179.

What the court instead found more compelling than the "real consequences to health and welfare" occasioned by the delays in reimbursing hospitals for the

care they furnish, JA178, was the Secretary's argument that she is generally "constrained by budgetary concerns and competing agency priorities." JA180. That is true enough—which is why the hospitals proposed multiple methods for remedying the problem. But the District Court dismissed each out of hand. JA181-182.

The District Court acknowledged that it could not "predict whether, over time, if HHS and Congress cannot adequately address the overflow of appeals, the *TRAC* factors might shift toward Plaintiffs," JA185-186. And it observed that "[h]ospitals that are owed reimbursement should not be indefinitely deprived of funds." JA185. But for now, the court told the hospitals, they must tough it out and "wait along with everyone else." JA186.

V. The Current State of Affairs

Since the District Court issued its decision, the Secretary has engaged in several half-hearted initiatives in response to delays in processing Medicare claim appeals. None of them has resulted in HHS meeting its statutory deadlines. In fact, none of those attempts has moved the needle in any appreciable respect.[20]

[20] Effective August 29, 2014, CMS offered a remarkably limited settlement to pay sixty-eight cents on the dollar to certain hospitals for a subset of their appeals involving one issue—a dispute over whether a patient should have been admitted as an inpatient—in exchange for withdrawal of those appeals. CMS, *Hospital Participant Settlement Instructions*, *available at* http://goo.gl/LLkRwW. This offer was limited to one provider type, one type of claim, and only those claims for

The most recent information available is that, as of February 2015, the ALJ decisions issued in that month came—on average—619.7 days after they had been filed.[21] In other words, on average, a case filed in May or June 2013 *might* be decided in February 2015. That is a delay of nearly *seven times* the statutory mandate, and it does not even account for delays at the other three levels of the appeals process.

There is no end in sight: RACs and other Medicare contractors continue to deny claims improperly. Adding ALJs, as HHS proposes to do, does nothing to stem the tide of incoming appeals. Nor can it clear the existing backlog expeditiously: even if HHS receives every penny of a recently requested budget increase, it would take five years for the Department to clear the existing backlog alone, assuming (absurdly) that not a single new appeal is filed in the meantime.

And in the meantime, as the hospitals "wait along with everyone else," they are forced to get by with less and less, which will carry more and more grave consequences to health and welfare.

This impasse calls for mandamus relief.

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services furnished before October 1, 2013. As a result, even after settling some of their claim appeals, Baxter and Covenant still have millions of dollars each tied up in the Medicare appeals process. Rutland did not pursue the settlement for any of its pending claims and still has more than half a million dollars tied up there.

[21] Current Workload, *supra* n. 12.

SUMMARY OF ARGUMENT

HHS's delays are in violation of a clear statutory mandate. Left uncorrected, those violations threaten harm to health and welfare. Indeed, the District Court acknowledged as much. Yet the court adopted HHS's say-so that other competing priorities completely restricted the Department from offering a constructive solution to the impasse, and instructed the hospitals simply to continue to bide their time.

That was error. It cannot be an answer, once a court has found both a statutory violation *and* consequences to health and welfare, for the government simply to point to competing budget priorities in order to neutralize a mandamus request. And what is more, by focusing solely on other budget priorities, HHS (and the District Court) ignored other approaches that do not require a large investment of funds and could remedy the problem at its source—for example, revising RAC auditing practices to cut down on the number of improperly denied claims.

Staring down an endless wait and an unsustainable drain on their cash flow, struggling to avoid making decisions that could harm patient care, hospitals have come to the courts for relief. Relief should be granted.

ARGUMENT

I. STANDARD OF REVIEW

This Court reviews the District Court's jurisdictional determination under 28 U.S.C. § 1361 *de novo*. *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807 (D.C. Cir. 2001); *Baptist Mem. Hosp. v. Sebelius*, 603 F.3d 57, 62 (DC. Cir. 2010). The hospital-appellants in this case are entitled to mandamus relief because (1) they have a clear and indisputable right to relief; (2) the Department has a clear duty to act; and (3) they have 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. 2002)). When a mandamus claim is based on agency delay, the court also considers whether that delay is "so egregious as to warrant mandamus." *TRAC*, 750 F.2d at 79. Where these legal standards have been met and "compelling . . . equitable grounds" exist, mandamus should issue. *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005) (citation omitted).

II. HHS'S VIOLATION OF ABSOLUTE STATUTORY DEADLINES IS EGREGIOUS.

"When an agency's recalcitrance, inertia, laggard pace or inefficiency sorely disadvantages the class of beneficiaries Congress intended to protect, judicial review, we have several times acknowledged, is in order." *In re Am. Federation of Government Employees, AFL-CIO*, 790 F.2d 116, 117 (D.C. Cir. 1986) (internal quotation marks and citation omitted). This Court grants mandamus relief if an

agency has "unreasonably delayed" performing its duty. *In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000) (granting mandamus relief against the Coast Guard for its failure to undertake for nine years a rulemaking that should have taken place within in one year).

In determining whether agency delay is "unreasonable," this Court considers the following factors:

> (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 79 (internal quotation marks and citations omitted). Each supports mandamus here.

A. Congress Provided Mandatory Deadlines In Which HHS Is Required To Act On Medicare Appeals.

The first two *TRAC* factors are undisputed, and indisputably counsel in the hospitals' favor. After all, as the District Court noted, the Secretary "concedes that the 90-day statutory 'timetable supplies the applicable rule of reason' in this case and she does not deny that ALJs are in violation of this rule." JA176. The court

thus concluded that "HHS has violated its statutory framework." JA177.

1. The Plain Text Of The Statute Sets A Mandatory Deadline.

The Secretary contended in the District Court that the Medicare Act "does not establish an absolute deadline of 90 days for all ALJ decisions and hearings or for all Appeals Council decisions or remand orders." Mot. To Dismiss at 16. The District Court quickly dispatched that argument, and for good reason: the statutory deadlines provided in the Medicare Act plainly are mandatory. "[A]n administrative law judge *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). And "[t]he Departmental Appeals Board . . . *shall* conduct and conclude a review of the decision on a hearing . . . and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed," *id.* § 1395ff(d)(2)(A). "[T]he mandatory 'shall[]' . . . normally creates an obligation impervious to judicial discretion." *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). And this Court has found, when Congress sets forth a specific and mandatory deadline, that "Congress meant what it said." *In re United Mine Workers of Am. Int'l Union*, 190

F.3d 545, 551 (D.C. Cir. 1999).[22]

But even if this Court does not agree that the statutory deadlines are mandatory, it still is clear that the "rule of reason" established by those deadlines has been transgressed where an ALJ hearing and decision that is supposed to take *ninety* days instead takes, on average, *six hundred and nineteen* days. *See United Mine Workers*, 190 F.3d at 551 (noting that "[t]he eight-year delay here is simply not in the same ballpark as the ninety-day period contained in the statute"). As in *United Mine Workers*, "Congress did not expect [the agency] to tarry for years over" these appeals. 190 F.3d at 551. In fact, the "specificity" and "relative brevity" of the ninety-day deadlines at both the ALJ- and DAB-levels of the appeals process "manifest[] the Congress's intent that [HHS] act promptly" on Medicare appeals. *In re People's Mojahedin Org. of Iran*, 680 F.3d 832, 837 (D.C. Cir. 2012).

Thus, "even if [the Court] were to read the statute not as specifying an express 'timetable' for decision, but as merely providing an 'indication of the speed with which [Congress] expects the agency to proceed, it would still be clear that the agency has transgressed congressional expectations." *United Mine*

[22] *See also* HHS, OMHA, Justification of Estimates for Appropriations Committees, Overview of Performance, Fiscal Year 2015, 7 (2014), *available at* http://goo.gl/RLN0FF (acknowledging that the 90-day ALJ adjudication period is "*mandated* by the Benefits Improvement and Protection Act (BIPA) [of] 2000").

Workers, 190 F.3d at 551 (quoting *TRAC*, 750 F.2d at 80).

2. "Escalation" Does Not Render The Statutory Deadline Flexible.

The structure of the statute reinforces the text.

Before the District Court, HHS also took the position that the option for a Medicare appellant to escalate its claims from the QIC, ALJ, or DAB levels was an indication that "the Medicare statute does not establish an absolute deadline of 90 days for all ALJ decisions and hearings or for all Appeals Council decisions or remand orders." Mot. To Dismiss at 16. But the decision whether to escalate an appeal is always squarely within the discretion of the Medicare appellant—not HHS. An appellant's option to escalate does not make Congress's statutory deadlines optional for HHS. If Congress meant for the escalation option to render its statutory deadlines permissive, surely it would have made escalation automatic or, at the very least, within *HHS's* discretion. It did not do so. Indeed, nothing in the governing statute allows the Secretary any "flexibility to set aside statutory deadlines," *see United Mine Workers*, 190 F.3d at 550 (explaining that such a provision was "the main reason" a deadline was held to be non-mandatory in a previous case).

B. The Department's Delays Place Human Health And Welfare At Risk.

The District Court acknowledged that these delays carry real health and welfare consequences for hospitals. JA178. But according to the court, those

consequences were not the right *sort* of health and welfare consequences, because they did not pose an "immediate and undisputed danger," and apparently because they are in the first instance "economic" consequences. *Id.*

There are a few different problems with that analysis. To begin with, in requiring some kind of "immediate and undisputed danger," the District Court appears to have conflated mandamus relief with emergency relief. *See Winter v. Natural Res. Def. Council*, 555 U.S. 7, 21 (2008) (a plaintiff seeking a preliminary injunction must establish, among other things "that he is likely to suffer irreparable harm in the absence of preliminary relief"). That was error. A party can prove its entitlement to mandamus relief in the absence of "immediate danger." *See In re Core Communications, Inc.*, 531 F.3d 849 (D.C. Cir. 2008) (granting mandamus in an FCC action presenting no semblance of an "immediate danger").

What is more, the cases the District Court cited do not, in fact, require that a plaintiff suffer some kind of "immediate and undisputed danger" before seeking judicial enforcement of an agency's statutory duty. *See* JA178. In *Public Citizen Health Research Group v. Commissioner, Food & Drug Administration*, 740 F.2d 21 (D.C. Cir. 1984), this Court instructed the district court on remand to consider "the nature and extent of the interests prejudiced by delay, the agency justification for the pace of decision, and the context of the statutory scheme out of which the dispute arises." *Id.* at 35. That case makes no mention of an "immediate and

undisputed danger" standard for mandamus—although it does explain that "immediate *impact*" must be considered when the court evaluates finality and ripeness for exhaustion purposes. *Id.* at 30 (emphasis added). *See also Public Citizen v. Heckler*, 602 F. Supp. 611, 613 (D.D.C. 1985) (quoting same standard as *Public Citizen*).

The "immediate and undisputed danger" standard the District Court applied to the hospitals' mandamus request is not just new; it also would impose an impossible burden on hospitals of having to demonstrate concrete and actual harm to patients stemming from the unavailability of Medicare funds. That is too much to ask of them. Hospitals prioritize patient care, and they have consistently found ways to do more with less in the face of HHS's inability to make timely determinations on hospitals' entitlement to reimbursement. But the hospitals should not be punished for their ingenuity in managing to avoid—so far—causing direct and immediate harm to patients as an outgrowth of lack of Medicare funds.

Moreover, even if the District Court's novel standard were supported in the case law, the hospitals have met that burden, too, by demonstrating that years-long delays in adjudications of their Medicare appeals pose a daily threat to services, infrastructure, and jobs. Baxter's ability to purchase replacement equipment, like beds for its intensive care unit, JA70, Covenant's ability to provide a full scope of services to its patients, JA76, and Rutland's ability to retain a full staff and

enhance patient care through clinics and programs, JA85, all hang in the balance. HHS never disputed in the District Court that these harms have occurred. Given that Baxter's bond rating is on the brink, JA71, Covenant's operating margin already is negative, JA76, and Rutland already has had to impose two rounds of job cuts, JA85, the immediacy of this danger also is beyond debate.

Under either standard, the District Court failed to appreciate the close (indeed, inexorable) tie between economic harm to hospitals and the attendant risk of harm to health and welfare if the Department's rampant delays are not remedied. But HHS itself understands this connection. In OMHA's budget justification documents, the Department explains: "Ensuring that providers and suppliers have a forum for independent and timely resolution of their disputes over Medicare payments also contributes to the security of the Medicare system by encouraging them to continue to provide services and supplies to Medicare beneficiaries."[23] Hospitals across America are struggling to develop financial work-arounds to account for the millions of dollars in funds tied up in the Medicare appeals process: the AHA's quarterly survey reflects that among the hospitals responding, the value of appealed, RAC-denied claims *alone* exceeded $1.8 billion. JA43. That staggering number does not even include the value of other appealed claims, which also are subject to the ALJ moratorium. JA80. Where well over $1.8 billion in

[23] FY2016 Budget Justification, *supra* n. 5, at 16.

funds are unavailable to support patient care and necessary upkeep of medical facilities, patient health and welfare cannot help but be threatened.

C. HHS's Failure To Address These Delays Cannot Be Excused By Competing Priorities.

The Secretary's response to the hospitals' showing of both a statutory violation and threatened harm to health and welfare was to point to the Department's "competing priorities," which in the Secretary's view should not be "reorder[ed]" to remedy a continuing statutory violation. Mot. To Dismiss at 25-26.[24] The District Court accepted that argument. JA181.

But nothing in the Medicare "statute authorizes the Secretary to adopt a position of impossibility." *Ganem v. Heckler*, 746 F.2d 844, 854 (D.C. Cir. 1984). As this Court has explained,"[h]owever many priorities the agency may have, and however modest its personnel and budgetary resources may be, there is a limit to

[24] When pressed, HHS identified three competing priorities in its reply brief. Reply Br. at 17. Two of those priorities were one-time transfers of funds during fiscal year 2014 to address the health insurance Marketplaces and the issue of unaccompanied children arriving in the United States. *Id.* The third priority HHS identified was Medicare beneficiary appeals, *id.*, but that priority would be helped, not harmed, by an order granting mandamus relief in this case. After all, these hospitals seek an order compelling the Secretary to comply with its statutory mandate in *all* Medicare appeals, both for beneficiaries and providers. *See* JA21-22; Resp. To Mot. To Dismiss 14. The District Court's reliance on *In re Barr Laboratories, Inc.*, 930 F.2d 72 (D.C. Cir. 1991), thus is misplaced. *See id.* at 75 (denying mandamus where "putting [the plaintiff] at the head of the queue simply moves all others back one space and produces no net gain.").

how long it may use these justifications to excuse inaction in the face of the congressional command to act within ninety days." *United Mine Workers*, 190 F.3d at 554.

And this delay is too long. 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 and Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004) (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). And although "[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).[25] In other words, an agency's complete and continuing failure to comply with a statutory mandate cannot be excused by protests that the agency

[25] Query, too, how much of these delays are "unavoidable." Given the RAC clawback process and contingent-fee based method of payment, HHS knew (or reasonably should have known) that the amount of claim appeals would skyrocket. The Department cannot claim surprise, just as it cannot claim impossibility.

must make hard budgetary choices. But that is exactly the argument the Secretary sold here—and the District Court bought it.

D. HHS Can Address These Delays—But It Has No Incentive To Do So Absent Court Intervention.

The sixth *TRAC* factor makes clear that there need not be a finding of bad faith or "impropriety" for mandamus to issue. But one can question whether an agency can be seen as acting in "good faith" when the complained-of statutory violation has persisted, visibly and unremedied, for a period of years. *Cf. In re Barr Labs.*, 930 F.2d at 76 ("[w]here the agency has manifested bad faith, as by . . . asserting utter indifference to a congressional deadline, the agency will have a hard time claiming legitimacy for its priorities."); *In re Aiken Cnty.*, 725 F.3d 255, 267 n.12 (D.C. Cir. 2013) ("In the face of such deliberate and continued agency disregard of a statutory mandate, our precedents strongly support a writ of mandamus."). But even if HHS's concededly inadequate response to these egregious delays could be taken in good faith, the Department cannot in good faith assert that it is unable to address at least one major root cause of the problem: It can rein in the out-of-control RACs.

HHS claimed before the District Court that OMHA's increased workload is due to a "combination of factors," including "more beneficiaries; increased utilization of Medicare-covered services . . . ; [and] increased Medicaid State Agency appeals." Mot. To Dismiss at 6-7. But the most significant contributor to

the morass in which the Secretary finds herself is "the additional appeals from audits conducted under the RAC Program," Mot. To Dismiss at 6-7; *see also* JA117 (DAB Chair acknowledging that the unprecedented increase in appeals is due "in large part" to RAC audit activities). In fact, the President of a MAC testified just last week before the United States Senate Committee on Finance, explaining that "[t]he most significant contributor to changes in the volume of appeals has been the [RACs]."[26] And HHS does have significant control over that.

In fiscal year 2009—the last full fiscal year before the permanent RAC program was instituted—there were 35,831 ALJ appeals, total. JA36. In fiscal year 2013, after the implementation of the RACs, 384,151 appeals were filed at the ALJ level—a ten-fold increase over appeals figures only four years earlier. *Id.* In justifying her fiscal year 2016 budget request to Congress, the Secretary reported an increase in appeals of a similar order of magnitude: She stated that OMHA received only 20,000 appeals of RAC determinations through fiscal year 2009, but received nearly 195,000 in fiscal year 2013 alone.[27]

And RACs do not prompt just more appeals; they prompt more *meritorious*

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[26] *Creating a More Efficient and Level Playing Field: Audit and Appeals Issues in Medicare Before the S. Comm. On Finance*, 114th Cong. (2015) (Statement of Sandy Coston, CEO and President, Diversified Service Options, Inc.), *available at* http://goo.gl/1DxT6k (noting the overall percent of appeals driven by RAC decisions "jumped from 7% in 2011 to 63% in 2013" before her MAC).

[27] FY2016 Budget Justification, *supra* n. 5, at 7.

appeals. Data provided to the AHA through the first quarter of 2014 show hospitals reporting that RAC denials were overturned sixty-six percent of the time on appeal. JA42, JA45. Perhaps recognizing the high error rate of the RACs, CMS recently offered to make a partial payment –sixty-eight cents on the dollar— for the net payable amount of certain denied inpatient status determination claims.[28]

As described above, however, HHS retains the funds recovered by Medicare contractors during the entire pendency of the appeals process. *See supra* at 4-5. So the Secretary has no incentive to expedite that process to bring it into line with statutory deadlines.

But that is not to say that she does not have the *power* to do so. To begin, the Secretary could consider any number of partial interim solutions to help eliminate the backlog that has already accumulated or to mitigate the financial strain the prolonged delays impose on hospitals. For example, CMS could offer more widespread settlements of claims for hospitals and other Medicare providers and suppliers. Or it could change the timeframes for when interest on the dollar amounts of denied claims begins to accumulate and when CMS begins to recoup

[28] CMS, *Hospital Participant Settlement Instructions*, *available at* http://goo.gl/LLkRwW; *see supra* n. 20 (noting that settlement was limited to one provider type, one type of claim, and only those claims for services furnished before October 1, 2013).

the funds associated with denied claims, such that hospitals are no longer deprived of those funds during the many years that their appeals are pending.

The Secretary also has control over the RACs; Congress tasked the Secretary with implementing the program. *See* Medicare Modernization Act of 2003, Pub. L. No. 108-173 § 306, 117 Stat. 2066, 2256-57; Pub. L. 109-432, 120 Stat. 2922 (2006) (codified at 42 U.S.C. § 1395ddd). And Congress has encouraged the Secretary to use that authority, directing the Secretary to "work with providers at the early stages of the audit process so that only a small number of cases are ultimately appealed and the loss of provider time, energy, and resources due to incorrect audit results are limited."[29] Exactly right. As the Medicare Payment Advisory Commission has explained, "if the RACs aren't reformed, there could be similar problems with the appeals process down the road." *See* Michelle M. Stein, *MedPAC Takes on Short Hospital Stays, SNF Qualifying Stays, RAC Audits*, 17 Inside CMS, No. 38 (Sept. 18, 2014). In fact, MedPAC has adopted recommendations to reform the RAC program, which would require the Secretary to modify the RACs' contingency fees so they would be based, in part, on their claim denial overturn rate. *See* Michael D. Williamson, *MedPAC Approves Draft Recommendations Affecting RACs' Audits*, Medicare Rep. (BNA), No. 26, at 310 (Mar. 13, 2015).

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[29] Sen. Rep. No. 113-71, at 149 (2013), *available at* http://goo.gl/5hreBz.

And the Secretary has other options of which she has not availed herself. First, HHS is a large department with substantial resources. Congress explicitly granted the Secretary authority to transfer funds from other HHS appropriations to OMHA up to a capped amount. HHS Appropriations Act, 2014, Pub. L. No. 113-76 Div. H, Title II, 128 Stat. 363, 382 (Jan. 17, 2014). In 2013, Secretary Sebelius used this authority to transfer *$113 million* to implement the Affordable Care Act. Brett Norman and David Nather, *The Obamacare Money Under the Couch*, Politico, Mar. 7, 2014.

The Secretary waited until 2014, after this lawsuit was filed, to request additional funds to address the snowballing Medicare appeals backlog. Long before then, as reflected on HHS's own website, the backlog was huge and growing.[30] And the additional appropriation she requested still is insufficient. OMHA's own budget justification documents estimate that it will be able to adjudicate only 200,000 complex appeals annually, even if it receives the full extent of the appropriations request.[31] HHS recognizes that, with these funds, the Department will only "begin to *slow the growth* of its increasing backlog, which currently exceeds 800,000 appeals."[32] Slowed growth is cold comfort for those

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[30] *See* OMHA October Forum, *supra* n. 6, at 9 (reflecting appeals received and decided in fiscal years 2007-2014).

[31] FY2016 Budget Justification, *supra* n. 5, at 7.

[32] *Id.* (emphasis added).

hospitals that already have waited years to have their appeals adjudicated.

In any event, "[f]ederal agencies may not ignore statutory mandates simply because Congress has not yet appropriated all of the money necessary to complete a project." *In re Aiken Cnty.*, 725 F.3d at 260.

The District Court accepted the Secretary's assertion that she was essentially powerless to remedy the current continuing statutory violation that all concede exists. It should not have done so. The Secretary plainly has the power to—among other things—rein in the RACs that are creating the greatest proportion of appeals. And if this Court orders the Secretary to remedy the statutory violation, appellants have every confidence that the Secretary will find a way, or face the consequences.

III. APPELLANTS HAVE NO ADEQUATE REMEDY OTHER THAN MANDAMUS.

Before mandamus may issue, a petitioner must show that there is no other adequate remedy of which it can avail itself. *Monzel*, 641 F.3d at 534. In its briefing before the District Court, the only adequate remedy the Secretary suggested other than mandamus was the escalation process. Mot. To Dismiss at 27-32. The District Court was not persuaded. JA171 ("escalation does not provide sufficient relief"). Neither should this Court be, for three reasons. First, escalating an appeal just moves it from one delay to the next. Second, where a hospital seeks escalation from the ALJ to the DAB, the hospital forfeits its right to a hearing at

which it can present testimony in support of its appeal. And third and in any event, escalation is at the option of the Medicare appellant, not HHS. It thus is not a remedy for the Department's statutory violation at all; it is merely an option for the Medicare appellant to exercise, after weighing the consequences of that choice.

1. The Medicare appeals system is wildly and demonstrably overloaded at every level. *See supra* at 9-16. If a hospital escalates its appeal to avoid the delay at the QIC level, it will be relegated to wait in the well-documented, years- long queue before receiving an ALJ hearing and decision. If a hospital seeks to escalate to the DAB to avoid the egregious delays at the ALJ level, it will simply be waiting in a third interminable line. *See supra* at 7-9.[33] Escalation thus is not a solution to the delay; it just moves the delay to a different point. Even if escalation could permit a hospital to bypass one level's delay, moreover, one interminable line is still too long. Hospitals have a statutory entitlement to expeditious resolution of the Medicare appeals process. Whether they are forced to wait in one endless line or three, hospitals are not receiving anything close to the timely adjudication to which they are entitled.

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[33] *See 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), *available at* http://goo.gl/2LDVTS (last visited Apr. 27, 2015) ("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.").

2. Escalation also forfeits a hospital's statutory right to a hearing—a critical stage in the process that allows hospitals their first "opportunity to present testimony based on clinical factors that are critical to accurate decisions in denial of complex hospital claims." JA70; *see* JA84; JA75. HHS itself has recognized both the fact of forfeiture and its consequences, advising Medicare appellants to "carefully consider the type of review that is best to resolve their case before deciding to escalate an appeal" and explaining that "when a case is escalated from the ALJ level to the [DAB], an appellant will lose the right to present his or her case during an oral hearing." 67 Fed. Reg. at 69,329. What is more, HHS conceded before the District Court that "hospitals are most likely to succeed in their appeals at the ALJ level." Mot. To Dismiss at 30. The District Court made the same observation. JA171 ("[H]ospitals find that they are most likely to succeed on their appeals at the ALJ level.") Requiring hospitals to forfeit ALJ review thus is not an adequate remedy, by any stretch.

Third, by statute, escalation is available entirely at the election of the Medicare appellant. In other words, it is for a hospital to decide whether a particular case is appropriate for escalation in certain circumstances. That discretionary decision on the hospital's part does not support the conclusion that escalation is an adequate remedy in *all* circumstances.

In its briefing before the District Court, escalation was the only available "remedy" HHS identified. Mot. To Dismiss 26-32. Because escalation plainly is inadequate, hospitals are left only with this remedy: mandamus.

CONCLUSION

As the Department's delays stretch ever further, hospitals across the country are having to make do without the money they need to continue to provide quality patient care. And in the meantime, HHS ambles along.

The District Court led off its decision by observing that "[n]o one likes the waiting game." But this is not a game. Hospitals across the country are making hard choices about how (or whether) they can continue to provide quality patient care, while nearly *two billion* dollars remains indefinitely tied up in the administrative appeals process.

The District Court's judgment should be reversed, and mandamus should issue.

Respectfully submitted,

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May 4, 2015

ADDENDUM

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28 U.S.C. § 1361

§ 1361. Action to compel an officer of the United States to perform his duty

The 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.

42 U.S.C. § 1395ff(a)-(d)

§ 1395ff. Determinations; Appeals

(a) Initial determinations

(1) Promulgations of regulations

The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A of this subchapter or part B of this subchapter in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a quality improvement organization under section 1320c-3(a)(2) of this title, and an initial determination made by an entity pursuant to a contract (other than a contract under section 1395w-22 of this title) with the Secretary to administer provisions of this subchapter or subchapter XI of this chapter.

(2) Deadlines for making initial determinations

(A) In general

Subject to subparagraph (B), in promulgating regulations under paragraph (1), initial determinations shall be concluded by not later than the 45-day period beginning on the date the fiscal intermediary or the carrier, as the case maybe, receives a claim for benefits from an individual as described in paragraph (1). Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 45-day period.

(B) Clean claims

Subparagraph (A) shall not apply with respect to any claim that is subject to the requirements of section 1395h(c)(2) or 1395u(c)(2) of this title.

(3) Redeterminations

(A) In general

In promulgating regulations under paragraph (1) with respect to initial determinations, such regulations shall provide for a fiscal intermediary or a carrier to make a redetermination with respect to a claim for benefits that is denied in whole or in part.

(B) Limitations

(i) Appeal rights

No initial determination may be reconsidered or appealed under subsection (b) of this section unless the fiscal intermediary or carrier has made a redetermination of that initial determination under this paragraph.

(ii) Decisionmaker

No redetermination may be made by any individual involved in the initial determination.

(C) Deadlines

(i) Filing for redetermination

A redetermination under subparagraph (A) shall be available only if notice is filed with the Secretary to request the redetermination by not later than the end of the 120-day period beginning on the date the individual receives notice of the initial determination under paragraph (2).

(ii) Concluding redeterminations

Redeterminations shall be concluded by not later than the 60-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a request for a redetermination. Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 60-day period.

(D) Construction

For purposes of the succeeding provisions of this section a redetermination under this paragraph shall be considered to be part of the initial determination.

(4) Requirements of notice of determinations

With respect to an initial determination insofar as it results in a denial of a claim for benefits--

(A) the written notice on the determination shall include--

(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(5) Requirements of notice of redeterminations

With respect to a redetermination insofar as it results in a denial of a claim for benefits--

(A) the written notice on the redetermination shall include--

(i) the specific reasons for the redetermination;

(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(b) Appeal rights

(1) In general

(A) Reconsideration of initial determination

Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) of this section shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and, subject to paragraph (2), to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security Administration" in subsection (g) or (1) of section 405 of this title shall be considered a reference to the "Secretary" or the "Department of Health and Human Services", respectively.

(B) Representation by provider or supplier

(i) In general

Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this section by a person that furnishes or supplies the individual, directly or indirectly, with services or items, solely on the basis that the person furnishes or supplies the individual with such a service or item.

(ii) Mandatory waiver of right to payment from beneficiary

Any person that furnishes services or items to an individual may not represent an individual under this section with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal.

(iii) Prohibition on payment for representation

If a person furnishes services or items to an individual and represents the individual under this section, the person may not impose any financial liability on such individual in connection with such representation.

(iv) Requirements for representatives of a beneficiary

The provisions of section 405(j) of this title and of section 406 of this title (other than subsection (a)(4) of such section) regarding representation of claimants shall apply to representation of an individual with respect to appeals under this section in the same manner as they apply to representation of an individual under those sections.

(C) Succession of rights in cases of assignment

The right of an individual to an appeal under this section with respect to an item or service may be assigned to the provider of services or supplier of the item or service upon the written consent of such individual using a standard form established by the Secretary for such an assignment.

(D) Time limits for filing appeals

(i) Reconsiderations

Reconsideration under subparagraph (A) shall be available only if the individual described in subparagraph (A) files notice with the Secretary to request reconsideration by not later than the end of the 180-day period beginning on the date the individual receives notice of the redetermination under subsection (a)(3) of this section, or within such additional time as the Secretary may allow.

(ii) Hearings conducted by the Secretary

The Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 405 and 406 of this title.

(E) Amounts in controversy

(i) In general

A hearing (by the Secretary) shall not be available to an individual under this section if the amount in controversy is less than $100, and judicial review shall not be available to the individual if the amount in controversy is less than $1,000.

(ii) Aggregation of claims

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve--

(I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or

(II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

(iii) Adjustment of dollar amounts

For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(F) Expedited proceedings

(i) Expedited determination

In the case of an individual who has received notice from a provider of services that such provider plans--

(I) to terminate services provided to an individual and a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk, or

(II) to discharge the individual from the provider of services,

the individual may request, in writing or orally, an expedited determination or an expedited reconsideration of an initial determination made under subsection (a)(1) of this section, as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

(ii) Reference to expedited access to judicial review

For the provision relating to expedited access to judicial review, see paragraph (2).

(G) Reopening and revision of determinations

The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

(2) Expedited access to judicial review

(A) In general

The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, who has filed an appeal under paragraph (1) (other than an appeal filed under paragraph (1)(F)(i)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

(B) Prompt determinations

If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

(C) Access to judicial review

(i) In general

If the appropriate review entity--

(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B), then the appellant may bring a civil action as described in this subparagraph.

(ii) Deadline for filing

Such action shall be filed, in the case described in--

(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) Venue

Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the District Court for the District of Columbia.

(iv) Interest on any amounts in controversy

Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this subchapter.

(D) Review entity defined

For purposes of this subsection, the term "review entity" means an entity of up to three reviewers who are administrative law judges or members of the Departmental

Appeals Board selected for purposes of making determinations under this paragraph.

(3) Requiring full and early presentation of evidence by providers

A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c) of this section, unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

(c) Conduct of reconsiderations by independent contractors

(1) In general

The Secretary shall enter into contracts with qualified independent contractors to conduct reconsiderations of initial determinations made under subparagraphs (B) and (C) of subsection (a)(1) of this section. Contracts shall be for an initial term of three years and shall be renewable on a triennial basis thereafter.

(2) Qualified independent contractor

For purposes of this subsection, the term "qualified independent contractor" means an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1) of this section, and that meets the requirements established by the Secretary consistent with paragraph (3).

(3) Requirements

Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) In general

The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient medical, legal, and other expertise (including knowledge of the program under this subchapter) and sufficient staffing to make reconsiderations under this subsection.

(B) Reconsiderations

(i) In general

The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.

(ii) Effect of national and local coverage determinations

(I) National coverage determinations

If the Secretary has made a national coverage determination pursuant to the requirements established under the third sentence of section 1395y(a) of this title, such determination shall be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section.

(II) Local coverage determinations

If the Secretary has made a local coverage determination, such determination shall not be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section. Notwithstanding the previous sentence, the qualified independent contractor shall consider the local coverage determination in making such decision.

(III) Absence of national or local coverage determination

In the absence of such a national coverage determination or local coverage determination, the qualified independent contractor shall make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence.

(C) Deadlines for decisions

(i) Reconsiderations

Except as provided in clauses (iii) and (iv), the qualified independent contractor shall conduct and conclude a reconsideration under subparagraph (B), and mail the notice of the decision with respect to the reconsideration by not later than the

end of the 60-day period beginning on the date a request for reconsideration has been timely filed.

(ii) Consequences of failure to meet deadline

In the case of a failure by the qualified independent contractor to mail the notice of the decision by the end of the period described in clause (i) or to provide notice by the end of the period described in clause (iii), as the case may be, the party requesting the reconsideration or appeal may request a hearing before the Secretary, notwithstanding any requirements for a reconsidered determination for purposes of the party's right to such hearing.

(iii) Expedited reconsiderations

The qualified independent contractor shall perform an expedited reconsideration under subsection (b)(1)(F) of this section as follows:

(I) Deadline for decision

Notwithstanding section 416(j) of this title and subject to clause (iv), not later than the end of the 72-hour period beginning on the date the qualified independent contractor has received a request for such reconsideration and has received such medical or other records needed for such reconsideration, the qualified independent contractor shall provide notice (by telephone and in writing) to the individual and the provider of services and attending physician of the individual of the results of the reconsideration. Such reconsideration shall be conducted regardless of whether the provider of services or supplier will charge the individual for continued services or whether the individual will be liable for payment for such continued services.

(II) Consultation with beneficiary

In such reconsideration, the qualified independent contractor shall solicit the views of the individual involved.

(III) Special rule for hospital discharges

A reconsideration of a discharge from a hospital shall be conducted under this clause in accordance with the provisions of paragraphs (2), (3), and (4) of section 1320c-3(e) of this title as in effect on the date that precedes December 21, 2000.

(iv) Extension

An individual requesting a reconsideration under this subparagraph may be granted such additional time as the individual specifies (not to exceed 14 days) for the qualified independent contractor to conclude the reconsideration. The individual may request such additional time orally or in writing.

(D) Qualifications for reviewers

The requirements of subsection (g) of this section shall be met (relating to qualifications of reviewing professionals).

(E) Explanation of decision

Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, be written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include (to the extent appropriate), and shall include [34] a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and[35] a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section[36] and[3] in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title)[3] an explanation of the medical and scientific rationale for the decision.

(F) Notice requirements

Whenever a qualified independent contractor makes a decision with respect to a reconsideration under this subsection, the qualified independent contractor shall promptly notify the entity responsible for the payment of claims under part A of this subchapter or part B of this subchapter of such decision.

(G) Dissemination of decisions on reconsiderations

Each qualified independent contractor shall make available all decisions with respect to reconsiderations of such qualified independent contractors to fiscal intermediaries (under section 1395h of this title), carriers (under section 1395u of this title), quality improvement organizations (under part B of subchapter XI of this

[34] So in original.
[35] So in original. The word "and" probably should not appear.
[36] So in original. Probably should be followed by a comma.

chapter), Medicare+Choice organizations offering Medicare+Choice plans under part C of this subchapter, other entities under contract with the Secretary to make initial determinations under part A of this subchapter or part B of this subchapter or subchapter XI of this chapter, and to the public. The Secretary shall establish a methodology under which qualified independent contractors shall carry out this subparagraph.

(H) Ensuring consistency in decisions

Each qualified independent contractor shall monitor its decisions with respect to reconsiderations to ensure the consistency of such decisions with respect to requests for reconsideration of similar or related matters.

(I) Data collection

(i) In general

Consistent with the requirements of clause (ii), a qualified independent contractor shall collect such information relevant to its functions, and keep and maintain such records in such form and manner as the Secretary may require to carry out the purposes of this section and shall permit access to and use of any such information and records as the Secretary may require for such purposes.

(ii) Type of data collected

Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) Specific claims that give rise to appeals.

(II) Situations suggesting the need for increased education for providers of services, physicians, or suppliers.

(III) Situations suggesting the need for changes in national or local coverage determination.

(IV) Situations suggesting the need for changes in local coverage determinations.

(iii) Annual reporting

Each qualified independent contractor shall submit annually to the Secretary (or otherwise as the Secretary may request) records maintained under this paragraph for the previous year.

(J) Hearings by the Secretary

The qualified independent contractor shall (i) submit such information as is required for an appeal of a decision of the contractor, and (ii) participate in such hearings as required by the Secretary.

(K) Independence requirements

(i) In general

Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity--

(I) is not a related party (as defined in subsection (g)(5) of this section);

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party.

(ii) Exception for reasonable compensation

Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) Limitations on entity compensation

Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) Number of qualified independent contractors

The Secretary shall enter into contracts with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection.

(5) Limitation on qualified independent contractor liability

No qualified independent contractor having a contract with the Secretary under this subsection and no person who is employed by, or who has a fiduciary relationship with, any such qualified independent contractor or who furnishes professional services to such qualified independent contractor, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this subsection or to a valid contract entered into under this subsection, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(d) Deadlines for hearings by the Secretary; notice

(1) Hearing by administrative law judge

(A) In general

Except as provided in subparagraph (B), an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) of this section 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.

(B) Waiver of deadline by party seeking hearing

The 90-day period under subparagraph (A) shall not apply in the case of a motion or stipulation by the party requesting the hearing to waive such period.

(2) Departmental Appeals Board review

(A) In general

The Departmental Appeals Board of the Department of Health and Human Services shall conduct and conclude a review of the decision on a hearing described in paragraph (1) and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.

(B) DAB hearing procedure

In reviewing a decision on a hearing under this paragraph, the Departmental Appeals Board shall review the case de novo.

(3) Consequences of failure to meet deadlines

(A) Hearing by administrative law judge

In the case of a failure by an administrative law judge to render a decision by the end of the period described in paragraph (1), the party requesting the hearing may request a review by the Departmental Appeals Board of the Department of Health and Human Services, notwithstanding any requirements for a hearing for purposes of the party's right to such a review.

(B) Departmental Appeals Board review

In the case of a failure by the Departmental Appeals Board to render a decision by the end of the period described in paragraph (2), the party requesting the hearing may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review.

(4) Notice

Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include--

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

* * *

42 U.S.C. § 1395kk-1(a)(3)

§ 1395kk-1(a)(3). Contracts with Medicare Administrative Contractors.

(3) Medicare administrative contractor defined

For purposes of this subchapter and subchapter XI of this chapter--

(A) In general

The term "Medicare administrative contractor" means an agency, organization, or other person with a contract under this section.

(B) Appropriate Medicare administrative contractor

With respect to the performance of a particular function in relation to an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the "appropriate" Medicare administrative contractor is the Medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

42 U.S.C. § 1395ddd(h)(1)

§ 1395ddd(h)(1). Medicare Integrity Program.

(h) Use of recovery audit contractors

(1) In general

Under the Program, the Secretary shall enter into contracts with recovery audit contractors in accordance with this subsection for the purpose of identifying underpayments and overpayments and recouping overpayments under this subchapter with respect to all services for which payment is made under this subchapter. Under the contracts—

(A) payment shall be made to such a contractor only from amounts recovered;

(B) from such amounts recovered, payment;

(i) shall be made on a contingent basis for collecting overpayments; and

(ii) may be made in such amounts as the Secretary may specify for identifying underpayments; and

(C) the Secretary shall retain a portion of the amounts recovered which shall be available to the program management account of the Centers for Medicare & Medicaid Services for purposes of activities conducted under the recovery audit program under this subsection.

42 U.S.C. § 1395ww(d)(5)(D)(iii)

§ 1395ww(d)(5)(D)(iii). Payments to Hospitals for Inpatient Hospital Services.

(iii) for purposes of this subchapter, the term "sole community hospital" means any hospital

(I) that the Secretary determines is located more than 35 road miles from another hospital,

(II) that, by reason of factors such as the time required for an individual to travel to the nearest alternative source of appropriate inpatient care (in accordance with standards promulgated by the Secretary), location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under part A of this subchapter, or

(III) that is located in a rural area and designated by the Secretary as an essential access community hospital under section 1395i-4(i)(1) of this title as in effect on September 30, 1997.

Pub. L. No. 108-173 Section 306

Pub. L. No. 108-173 Section 306. Demonstration Project For Use Of Recovery Audit Contractors.

(a) IN GENERAL.—The Secretary shall conduct a demonstration project under this section (in this section referred to as the "project") to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recouping overpayments under the Medicare program for services for which payment is made under part A or B of title XVIII of the Social Security Act. Under the project—

(1) payment may be made to such a contractor on a contingent basis;

(2) such percentage as the Secretary may specify of the amount recovered shall be retained by the Secretary and shall be available to the program management account of the Centers for Medicare & Medicaid Services; and

(3) the Secretary shall examine the efficacy of such use with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

(b) SCOPE AND DURATION.—

(1) SCOPE.—The project shall cover at least 2 States that are among the States with—

(A) the highest per capita utilization rates of Medicare services, and

(B) at least 3 contractors.

(2) DURATION.—The project shall last for not longer than 3 years.

(c) WAIVER.—The Secretary shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) QUALIFICATIONS OF CONTRACTORS.—

(1) IN GENERAL.—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has the appropriate clinical knowledge of and experience with the payment rules and regulations under

the Medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff.

(2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act.

(3) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency for cost control or recovery audits with private insurers, health care providers, health plans, or under the Medicaid program under title XIX of the Social Security Act.

(e) CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.—A recovery of an overpayment to a provider by a recovery audit contractor shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(f) REPORT.—The Secretary shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the Medicare program and recommendations on the cost-effectiveness of extending or expanding the project.information’ means information about a conviction for a relevant crime or a finding of patient or resident abuse.

Pub. L. No. 108-173 Section 931(b)(2)

Pub. L. No. 108-173 Section 931(b)(2). Transfer of Adjudication Authority.

(2) ASSURING INDEPENDENCE OF JUDGES.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report to, or be subject to supervision by, another officer of the Department of Health and Human Services.

42 C.F.R § 405.970(c)(2)

§ 405.970(c). Timeframe for Making a Reconsideration.

(c) Responsibilities of the QIC. Within 60 calendar days of receiving a request for a reconsideration, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

* * *

(2) Notify the parties that it cannot complete the reconsideration by the deadline specified in paragraph (b) of this section and offer the appellant the opportunity to escalate the appeal to an ALJ. The QIC continues to process the reconsideration unless it receives a written request from the appellant to escalate the case to an AU after the adjudication period has expired.

42 C.F.R. § 405.1006(c)

§ 405.1006(c). Amount in Controversy Required to Request an ALJ Hearing and Judicial Review.

(c) Judicial review. To be entitled to judicial review, a party must meet the amount in controversy requirements of this subpart at the time it requests judicial review.

(1) For review requests, the required amount remaining in controversy must be $1,000 or more, adjusted as specified in paragraphs (b)(1) and (b)(2) of this section.

(2) [Reserved]

42 C.F.R. § 405.1014(b)(1)

§ 405.1014(b)(1). Request for an ALJ Hearing.

(1) For ALJ hearing requests, the required amount remaining in controversy must be $100 increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

42 C.F.R. § 405.1016(a)

§ 405.1016. Time Frames for Deciding an Appeal Before an ALJ.

(a) When a request for an AU hearing is filed after a QIC has issued a reconsideration, the AU must issue a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the entity specified in the QIC's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

42 C.F.R. § 405.1100(d)

§ 405.1100(d). Medicare Appeals Council Review: General.

(d) When deciding an appeal that was escalated from the AU level to the MAC, the MAC will issue a final decision or dismissal order or remand the case to the AU within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

42 C.F.R. § 405.1104

§ 405.1104. Request for MAC Review When an ALJ Does Not Issue a Decision Timely.

(a) Requesting escalation. An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period under § 405.1016 may request MAC review if—

(1) The appellant files a written request with the ALJ to escalate the appeal to the MAC after the adjudication period has expired; and

(2) The ALJ does not issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016.

(b) Escalation.

(1) If the ALJ is not able to issue a decision, dismissal order, or remand order within the time period set forth in paragraph (a)(2) of this section, he or she sends notice to the appellant.

(2) The notice acknowledges receipt of the request for escalation, and confirms that the ALJ is not able to issue a decision, dismissal order, or remand order within the statutory timeframe.

(3) If the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of this section or does not send the required notice to the appellant, the QIC decision becomes the decision that is subject to MAC review consistent with § 405.1102(a).

(c) No escalation. If the ALJ's adjudication period set forth in § 405.1016 expires, the case remains with the ALJ until a decision, dismissal order, or remand order is issued or the appellant requests escalation to the MAC.

42 C.F.R. § 405.1106(b)

§ 405.1106(b). Where a Request for Review or Escalation May be Filed.

(a) When a request for a MAC review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALYs action. The appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal who received a copy of the hearing decision under § 405.1046(a) or a copy of the notice of dismissal under § 405.1052(b). Failure to copy the other parties tolls the MAC's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for MAC review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the MAC's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALYs action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALYs action, the MAC sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the MAC level because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under § 405.1016, the request for escalation must be filed with both the ALJ and the MAC. The appellant must also send a copy of the request for escalation to the other parties. Failure to copy the other parties tolls the MAC's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for MAC review. In a case that has been escalated from the ALJ, the MAC's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the MAC.

42 C.F.R. § 405.1108

§ 405.1108. MAC Actions When Request for Review or Escalation is Filed.

(a) Except as specified in paragraphs (c) and (d) of this section, when a party requests that the MAC review an ALYs decision, the MAC will review the ALJ's decision de novo. The party requesting review does not have a right to a hearing before the MAC. The MAC will consider all of the evidence in the administrative record. Upon completion of its review, the MAC may adopt, modify, or reverse the ALYs decision or remand the case to an ALJ for further proceedings.

(b) When a party requests that the MAC review an ALYs dismissal, the MAC may deny review or vacate the dismissal and remand the case to the ALJ for further proceedings.

(c) The MAC will dismiss a request for review when the party requesting review does not have a right to a review by the MAC, or will dismiss the request for a hearing for any reason that the ALJ could have dismissed the request for hearing.

(d) When an appellant requests escalation of a case from the ALJ level to the MAC, the MAC may take any of the following actions:

(1) Issue a decision based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ before the case was escalated.

(2) Conduct any additional proceedings, including a hearing, that the MAC determines are necessary to issue a decision.

(3) Remand the case to an ALJ for further proceedings, including a hearing.

(4) Dismiss the request for MAC review because the appellant does not have the right to escalate the appeal.

(5) Dismiss the request for a hearing for any reason that the ALJ could have dismissed the request.

42 C.F.R. § 405.1132

§ 405.1132. Request for Escalation to Federal Court.

(a) If the MAC does not issue a decision or dismissal or remand the case to an ALJ within the adjudication period specified in § 405.1100, or as extended as provided in this subpart, the appellant may request that the appeal, other than an appeal of an ALJ dismissal, be escalated to Federal district court. Upon receipt of a request for escalation, the MAC may-

(1) Issue a decision or dismissal or remand the case to an ALJ, if that action is issued within the latter of 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period set forth in § 405.1100; or

(2) If the MAC is not able to issue a decision or dismissal or remand as set forth in paragraph (a)(1) of this section, it will send a notice to the appellant acknowledging receipt of the request for escalation and confirming that it is not able to issue a decision, dismissal or remand order within the statutory time frame.

(b) A party may file an action in a Federal district court within 60 calendar days after the date it receives the MAC's notice that the MAC is not able to issue a final decision, dismissal order, or remand order unless the party is appealing an ALJ dismissal.

42 C.F.R. § 412.92(a)

§ 412.92. Special Treatment: Sole Community Hospitals.

(a) Criteria for classification as a sole community hospital. CMS classifies a hospital as a sole community hospital if it is located more than 35 miles from other like hospitals, or it is located in a rural area (as defined in § 412.64) and meets one of the following conditions:

(1) The hospital is located between 25 and 35 miles from other like hospitals and meets one of the following criteria:

(i) No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35—mile radius of the hospital, or, if larger, within its service area;

(ii) The hospital has fewer than 50 beds and the intermediary certifies that the hospital would have met the criteria in paragraph (a)(1)(i) of this section were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital; or

(iii) Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(2) The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(3) Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.

* * *

CERTIFICATE OF COMPLIANCE

I, Catherine E. Stetson, hereby certify that the foregoing brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 9,838 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman.

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I, Catherine E. Stetson, hereby certify that on this 4th day of May 2015, I caused the foregoing opening brief to be delivered via CM/ECF to the following:

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