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

REPLY BRIEF FOR APPELLANTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

*Authorities on which we chiefly rely are marked with an asterisk.

Page(s)

STATUTES (CONTINUED)

LEGISLATIVE MATERIALS

REGULATIONS

OTHER AUTHORITIES

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
OMHA	Office of Medicare Hearings and Appeals
QIC	Qualified Independent Contractor
RAC	Medicare Recovery Audit Contractor

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in appellants' opening brief.

INTRODUCTION

HHS's responsive brief is a curiosity; it agrees with the appellants more than it disagrees. HHS readily admits that "HHS adjudicators have been unable to resolve appeals within the timeframes contemplated by the Medicare statute." HHS Br. 1. The Department just as readily acknowledges that the request made in this proceeding is a straightforward application of the purpose for which mandamus exists: "Plaintiffs seek a writ of mandamus that would require HHS to meet the statutory timetables." HHS Br. 1. HHS all but overtly concedes that its delays are egregious, noting the 800,000-strong backlog in appeals before its ALJs, HHS Br. 10, and the 9,850-strong one before the DAB, HHS Br. 11.[1] And the Department does not contest the health and welfare consequences of those delays, which the hospitals and AHA detailed in their opening brief. *See* AHA Br. 13-16, 27-31 (explaining that Baxter's ability to purchase basic replacement equipment,

[1] Indeed, the Department's own website notes that ALJ decisions currently are taking an average of nearly *two years*, when they should be conducted and concluded in *ninety days*. OMHA, Data, Current Workload, http://goo.gl/eRtr7D (last visited July 15, 2015). That is to say nothing of the delays at other stages of the Medicare appeals process, which also stretch far beyond their mandatory statutory deadlines.

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 improve patient care through clinics and programs, JA85, all are at risk).

The parties part ways, however, at the point where the Secretary, despite acknowledging the Department's egregious statutory violations, throws up her hands and claims that "it is currently impossible . . . to adjudicate claims" in accordance with statutory deadlines, HHS Br. 1. The Secretary has many options available to her to resolve this backlog. *See, e.g.*, AHA Br. 33-38. And in any event, this Court has flatly rejected such fatalism in the past: "Nothing in the statute authorizes the Secretary to adopt a position of impossibility." *Ganem v. Heckler*, 746 F.2d 844, 854 (D.C. Cir. 1984). There is no "impossibility" exception to mandamus.

Mandamus requires that a plaintiff demonstrate three things: the plaintiff's clear right to relief; the Department's clear duty to Act; and the absence of another 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)). Once those legal requirements are satisfied, mandamus should issue if the delay is "so egregious as to warrant intervention." *Telecommunications Research & Action Ctr. v. FCC* (*TRAC*), 750 F.2d 70, 79 (D.C. Cir. 1984). The District Court agreed that the AHA and the hospitals that have brought this appeal—Baxter, Covenant, and Rutland—

satisfied *each* of those three legal requirements, JA171, JA176-177, but nonetheless denied mandamus relief because it concluded that the delays were not yet "so egregious as to warrant intervention." JA166. Seven months later, the delays—at least *six years* in the making—persist unabated. It is time.

The Secretary soothingly assures the Court in her brief that hospitals have *some* remedy for those delays—after all, she says, they can simply "escalate" their claims to the next level (forfeiting the attendant opportunities to develop a full record in support of their arguments). But as the District Court correctly recognized, that remedy is no remedy at all. It is not a solution to the Department's outsized delays to move the entire queue from one backlogged forum to another.

While HHS claims impossibility, hospitals across the country are forced to do more and more with less and less, so as not to compromise patient care while millions of dollars in Medicare reimbursement funds are tied up in the appeals process. These hospitals—and others across the country—cannot much further endure an endless loop of waiting for the Secretary to adjudicate their appeals.

Mandamus should issue.

SUMMARY OF ARGUMENT

The Secretary offers three responses to avoid mandamus. *First*, she characterizes the Medicare Act's mandatory statutory deadlines as "discretionary

policy judgments" best left to the Secretary. HHS Br. 21-31. *Second*, she claims that escalation is an adequate remedy for claimants waiting in interminable lines for a review. HHS Br. 19-21. *Third*, she fights an argument the appellants did not even present, asserting that the appellants are not entitled to an order requiring suspension or modification of the RAC program. HHS Br. 31-33.

Each of these contentions is meritless. The Medicare Act's deadlines are not aspirational. They are statutory mandates. Nor is escalation an adequate remedy—which is why the DAB itself has remanded an escalated case to the ALJ level for lack of a complete adjudicative record. And to be very clear: The appellants are not seeking an order from this Court requiring the Secretary to do anything but abide by the statutory deadlines. *How* she meets that obligation is up to her.

ARGUMENT

I. ABIDING BY STATUTORY DEADLINES IS NOT A "DISCRETIONARY POLICY JUDGMENT."

The Secretary concedes, as she must, that a court may compel action when an agency has "failed to take a *discrete* agency action that it is *required to take*," if that action is "non-discretionary." HHS Br. 18. The first question, then, is whether the Medicare Act's requirement that HHS conduct and conclude each level of the Medicare appeals process within its statutory deadlines is mandatory or

discretionary. *See* 42 U.S.C. §§ 1395ff. The answer is clear: The deadlines are mandatory.

While never quite coming out with it, the Secretary makes a subtle case that the Act's deadlines are actually just suggestions. She maintains, for example, that a MAC's redetermination "*should generally issue* 60 days after the filing of the redetermination request." HHS Br. 4 (emphasis added). The statute itself is less forgiving: "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." 42 U.S.C. § 1395ff(a)(3)(C)(ii) (emphasis added). The only exceptions to this statutory deadline are at the election of a Medicare appellant. *See* 42 C.F.R. § 405.950.

So too with reconsideration. The Secretary says: "Reconsideration decisions *should generally issue* within 60 days of the timely filing of the reconsideration request." HHS Br. 5 (emphasis added). The statute provides that "[e]xcept as provided in clauses (iii) and (iv), the qualified independent contractor shall conduct and conclude a reconsideration . . . *by not later than the end of the* 60-day period beginning on the date a request for reconsideration has been timely filed." 42 U.S.C. § 1395ff(c)(3)(C)(i) (emphasis added). Those excepted clauses provide for alternate deadlines only when a reconsideration is expedited, clause (iii), or when

the deadline is extended at the election of the individual requesting a reconsideration, clause (iv). *Id.* § 1395ff(c)(3)(C)(iii), (iv).

Despite HHS's rampant revisionism of the governing text, the Act's statutory deadlines are just that—deadlines. So when the Secretary accuses the appellant hospitals of seeking an order compelling HHS to adjudicate Medicare appeals "on a particular timetable," HHS Br. 3, she is quite right. That "particular timetable," by its proper name, is a statutory mandate. *See* 42 U.S.C. § 1395ff.

For the first time on appeal, the Secretary claims that holding hearings and rendering decisions on a statutory timetable "implicates discretionary policy judgments of a sort uniquely reserved for the political branches," HHS Br. 2; *see* HHS Br. 21-31, and thus cannot be compelled through the vehicle of mandamus. That argument bakes together two separate concepts—her statutory obligation, which is neither discretionary nor policy-driven, and her *implementation* of that obligation, which *is* subject to her discretion and policy priorities. This mandamus action is (quite properly) directed at only the former issue: forcing the Secretary to answer to the deadlines set by the governing statute. The fact that the Secretary may need to make difficult budgetary choices in order to *comply* with those deadlines does not backhandedly excuse her from compliance with them.

The Secretary attempts to prop up her argument with reliance on this Court's decision in *In re Barr Laboratories*, 930 F.2d 72 (D.C. Cir. 1991). According to

the Secretary, *Barr* stands for the proposition that mandamus never is appropriate to resolve an agency's violation of a statutory mandate where the Secretary would need to exercise "discretionary policy judgments" in allocating her budget resources. HHS Br. 25-26.

The comparison is inapt. Barr Labs sought to force FDA to approve or disapprove *the company's own* generic drug application within the statutory time frame. But as this Court explained, Congress did not intend "super-priority" for Barr; after all, "a judicial order putting Barr at the head of the queue" would not solve the underlying problem of delayed processing of generic drug applications, but would "simply move[] all others back one space and produce[] no net gain." *Id.* at 75. *Barr Laboratories* does not provide an agency with a license to ignore statutory deadlines simply because it also has other competing policy priorities.[2] If that were so, HHS would be utterly immune from the federal courts' mandamus power—and the Department plainly is not. *See Monmouth Medical Ctr. v. Thompson*, 257 F.3d 807 (D.C. Cir. 2001) (granting mandamus relief against HHS); *Ganem*, 746 F.2d 844 (same).

[2] This Court also observed in *Barr Labs* that where an agency has demonstrated "utter indifference to a congressional deadline"—say, by allowing mandatory deadlines to be violated for more than six years, with no end in sight—"the agency will have a hard time claiming legitimacy for its priorities." *Id.* at 76. Indeed.

HHS also reaches for *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094 (D.C. Cir. 2003), for support, but that case is of no help either. Mashpee, a putative American Indian tribe, sought federal recognition from the Bureau of Indian Affairs. *Id.* at 1097. In January 1996, it was placed on the list of applications "waiting for active consideration." *Id.* As of August 2001, there were ten petitions on that list, six of which had been waiting there for at least five years. *Id.* No statute or regulation governed the time in which the BIA had to act, but Mashpee sued the Secretary under the Administrative Procedure Act, claiming that the Secretary had unreasonably delayed resolution of the putative tribe's application. *Id.* at 1099. The district court granted summary judgment for Mashpee because it found that the Secretary "essentially conceded" that competing priorities were entitled to no weight because she failed to appeal an unfavorable result in another case. *Id.* at 1101. Finding that inference was "unwarranted," this Court reversed and remanded for the district court to consider whether the agency's delay was, in fact, unreasonable. Although this Court addressed the importance of "competing priorities," it did so in response to the tribe's *Barr*-like attempt to jump the line: It noted that granting relief to Mashpee, like granting relief to Barr, would force "other equally-deserving petitioners" further back. *Id.* at 1102.

The AHA and the hospital-appellants are not like Barr, and they are not like Mashpee. They do not seek to jump the line. They seek compliance with the statutory deadlines on which they should be able to rely.

The Secretary next claims that a court order requiring her to comply with mandatory statutory deadlines somehow would constitute an impermissible "programmatic attack" on the Secretary's prerogatives. HHS Br. 27 (quoting *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004)). It is nothing of the sort. Again, the AHA and the hospital-appellants seek only an order requiring the Secretary to "take some decision by a statutory deadline," an exercise of mandamus jurisdiction the Supreme Court confirmed in *Southern Utah* was proper. 542 U.S. at 63. They do not seek to *further* compel the agency to exercise its lawful discretion in a manner best suited to their interests, as the *Southern Utah* plaintiff improperly sought to do. The statute in that case required the Bureau of Land Management to manage wilderness study areas to prevent them from being "degraded so far . . . as to significantly constrain" Congress's decision to designate them as wilderness or release them for other uses. *Id.* at 65. However, it left the Bureau "a great deal of discretion" in how to do so. *Id.* at 66. The plaintiff sought mandamus to compel the Bureau of Land Management to maintain public lands in a manner more consistent with that plaintiff's own views. *Id.* The Court declined,

holding that agencies' "lawful discretion" is entitled to protection from "undue judicial interference." *Id.*

Appellants are not seeking to constrain or direct the Secretary's "lawful discretion" here. To the contrary, they come to this Court seeking compliance with HHS's recognized obligation to "take some decision by a statutory deadline." *Id.* at 63. This Court should order the Secretary to conduct and conclude each level of review in accordance with the statutory mandate. The means of doing so are, and remain, within the discretion of the Secretary.

II. ESCALATION IS NOT AN ADEQUATE REMEDY.

As it did before the District Court, HHS attempts to portray escalation—an option subject to the election of Medicare appellants, and which is not without significant procedural and substantive consequences—as an adequate, alternative remedy sufficient to defeat mandamus. HHS Br. 19-21. The District Court made short work of this argument: "[E]scalation does not provide sufficient relief." JA171. And for good reason:

First, escalation merely shuttles an appeal from one unacceptable delay to the next. Escalation from the QIC level to the ALJ level, for example, moves a hospital from the interminable QIC queue to the interminable queue awaiting an ALJ hearing and decision. As of May of this year, the average time from filing to decision of an ALJ appeal was 684.5 days—nearly two years. OMHA, Data,

Current Workload, http://goo.gl/eRtr7D (last visited July 15, 2015). Further escalation is no answer, either: As HHS candidly admits, the DAB is in no better position to handle Medicare appeals than the ALJs are. *See* Judge Constance B. Tobias, Departmental Appeals Board Update, Medicare Appeals Council, at 5, http://goo.gl/yvhTUA (noting that as of June 25, 2015, 9,850 appeals were pending at the DAB level).

Second, escalation forces hospital-appellants to make the unpalatable choice of forgoing the substantive and procedural benefits of pursuing an appeal through all available levels. HHS apparently does not view this as a problem. In maintaining that hospitals may simply escalate to the DAB without first participating in a hearing, for example, HHS invokes the QIC's "on-the-record review of an initial determination" in which an appellant may provide "additional evidence." HHS Br. 20-21 (citing 42 C.F.R. §§ 405.968(a) and 405.966). But as any judge will confirm, there is a world of difference between live testimony and cold paper. ALJ hearings provide a hospital the only opportunity "to present oral testimony, including testimony of clinicians, in support of its claims." JA70, JA75, JA84. And at an ALJ hearing, a hospital has, for the first and only time, "the opportunity to respond to any questions from the ALJ in real-time through the hearing process." JA70, JA75, JA84. The ALJ level of review also affords a hospital "the opportunity to explain and clarify the written arguments it has

submitted to the ALJ prior to hearing." JA75. A hospital forfeits all this when it opts to escalate its claims—which is why HHS itself has previously noted 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." Medicare Program: Changes to the Medicare Claims Appeal Procedures, 67 Fed. Reg. 69,312, 69,329 (Nov. 15, 2002).

Third, and rather absurdly, the lack of a hearing record accompanying an escalated claim has resulted in remands to the very forum that was leapfrogged. *See, e.g.*, *In the case of Pembroke Pines MRI, Inc.*, Docket No. M-12-2514, 2013 WL 7395502, at *1 (DAB Feb. 19, 2013) (citing 42 C.F.R. § 405.1122(b)(2)). The DAB in *Pembroke Pines* remanded an escalated case to the ALJ level, explaining that it was "unable to adjudicate this case without the complete administrative record." The DAB recognized that "the appellant escalated its case *due to the delay in processing time at the [ALJ level]*." *Id.* at *2 (emphasis added). But it denied the *Pembroke Pines* appellant a hearing because "it would be premature to conduct a hearing in this case prior to the administrative record being fully developed." *Id.* at *3. HHS *itself* thus recognizes that the ALJ level of the appeals process adds something of value that cannot be satisfied by skipping to the next level of review—namely, the "complete administrative record," which the DAB says it is unwilling, or unable, to act without.

In light of the evident reluctance of the Department's highest-level adjudicative body to conduct reviews on an incomplete record, perhaps HHS envisions that Medicare claimants will just escalate their claims all the way through to federal district court, arriving there with the Department's bare denial and their bare claim on appeal. But a federal judge presumably would be even less inclined to consider a case escalated through every level of the Medicare appeals process without an adequate administrative record. And when the judge inevitably sends that claim back to HHS for the record to be fully developed in advance of judicial review, the hapless Medicare claimant will return to the end of the same hopeless line from which it came.

III. HHS HAS DEMONSTRATED THAT IT IS UNABLE TO REMEDY THE BACKLOG ABSENT THIS COURT'S INTERVENTION.

The Secretary puts a lot of stock in the ability of Congress and HHS to remedy the backlog without necessitating this Court's intervention. HHS Br. 28-33. Query, then, why more progress has not been made in the *six years* since this backlog emerged. *See* OMHA, Data, Current Workload, http://goo.gl/eRtr7D (last visited July 15, 2015) (noting that, as early as FY 2009, HHS already was transgressing its statutory deadlines at the ALJ level). The Secretary points to three main sources of hope for the future: *first*, the President's proposed fiscal year 2016 Budget; *second*, several Congressional hearings that have been held on

Medicare audit and appeals issues; and *third*, a bill out of the Senate Finance Committee that has not yet been introduced into the full Senate. None of these is actually a solution.

As for the fiscal year 2016 budget, the Senate and House Committees on Appropriations have approved different bills with different levels of funding for the ALJ hearings. The House Committee bill would keep the funding at fiscal year 2015 levels. H.R. Rep. No. 114-195, at 77 (2015). The Senate Committee bill would increase that funding by a modest $10 million. S. Rep. No. 114-74, at 83 (2015). Neither bill comes close to the $270 million appropriation described in the President's Budget and the Secretary's brief (at 11). And additional funding, if any is in store, still is a long way off: These bills have yet to be considered by the full House and the full Senate, respectively, to say nothing of the two chambers negotiating a compromise to meld their respective bills.

And while Congress may have held hearings (HHS Br. 12-15) on the current backlog, those hearings themselves neither carry nor promise any prospect for actually resolving the problem. Notably, moreover, *none* of these hearings or proposals would extend the statutory deadlines for decision in the Medicare appeals process—deadlines the Secretary is missing by a mile.

The Secretary finally points to the Senate Finance Committee's Audit and Appeal Fairness, Integrity, and Reforms in Medicare Act of 2015, HHS Br. 14-15,

which would increase appropriations to OMHA and would make a number of changes to the Medicare appeals process. Sen. Comm. on Finance, *Description of the Chairman's Mark Audit & Appeal Fairness, Integrity, and Reforms in Medicare Act of 2015* (2015).[3] The bill, as drafted, also would require the Secretary to develop a comprehensive strategy and increase transparency for reviews by its auditors. *Id.* But even if it provided the panacea for transgressing the Department's statutory obligation, which it does not, that bill has not even been officially introduced into the full Senate. Such a proposed bill is far too attenuated to affect this Court's analysis. *See, e.g., Student Press Law Center v. Alexander*, 778 F. Supp. 1227, 1231 (D.D.C. 1991) (suit not mooted by Congress's approval of legislation because "[u]ntil the proposed measure actually becomes law, this action remains a live case or controversy"); *cf. United States v. Lawrence*, 662 F.3d 551, 558 (D.C. Cir. 2011) (noting that "[p]ending legislation is generally too removed" to warrant consideration). What is more, the vast majority of the bill's reforms would not take effect until 2017—still two years from now.

The Secretary claims that these hypothetical future arrangements are the best and only hope for solving the current impasse, because "it is currently impossible . . . to adjudicate claims" in accordance with statutory deadlines. HHS Br. 1. But "[n]othing in the statute authorizes the Secretary to adopt a position of

[3] *Available at* http://goo.gl/ZMcyf9.

impossibility." *Ganem*, 746 F.2d at 854. And the Court should question the Department's premise in any event: The AHA and the hospital-appellants have enumerated a partial menu of potential options available to the Secretary simply to demonstrate to the District Court and to this Court that her plea of impossibility should not be taken seriously. *See* AHA Br. 33-38 (noting that the Secretary could, among other things, (1) offer more widespread settlements of claims for hospitals and other Medicare providers and suppliers; (2) change the timeframes for when interest on the dollar amounts of denied claims begins to accumulate and when CMS begins to recoup the funds associated with denied claims; (3) reform the RACs' auditing practices; and (4) transfer funds from other HHS appropriations to OMHA).

HHS critiques these "partial interim solutions," HHS Br. 25-28, but they are concrete steps the Secretary can take *now* to reduce the backlog and to ease the burden that backlog has imposed on hospitals. The Secretary also is simply wrong when she contends that AHA and the hospitals seek to have the Secretary "disregard[] the statutory requirement to operate the recovery audit program." HHS Br. 32. Congress created the RAC program, but it tasked the Secretary with implementing it. *See* Medicare Modernization Act of 2003, Pub. L. No. 108-173 § 306, 117 Stat. 2066, 2256-57 (2003); Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432 § 302, 120 Stat. 2922, 2991-92 (2006) (codified at 42 U.S.C.

§ 1395ddd). Modifying the RACs' wildly aggressive auditing practices—which Congress explicitly gave the Secretary the authority to do—would be just one way in which the Secretary could stem the tide of incoming appeals.

And in any case, it is not for America's hospitals to dictate how HHS should resolve its backlog—as HHS has otherwise made clear, *see* HHS Br. 17-18. The AHA and the hospital-appellants do not purport to dictate *how* the Secretary chooses to remedy her longstanding and egregious statutory violation. They merely ask this Court to require that she do so.

CONCLUSION

For all of the foregoing reasons, and those in appellants' opening brief, the District Court's judgment should be reversed and mandamus should issue.

Respectfully submitted,

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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 3,895 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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