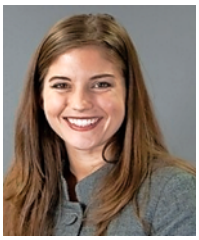
Bloomberg BNA

BNA's
Medicare Report™

A Favorable, New Climate for Challenging Medicare Appeals



BY DAVID TOLLEY AND GREER DONLEY

Over the past decade, health care providers seeking to challenge Medicare claim denials have faced increasing delays in reaching what many consider the most important step in the Medicare appeals process—a hearing before an *impartial* administrative law judge (''ALJ'') (the prior two steps are decided by Medicare contractors who often have a financial interest adverse to that of the provider).[1] Strikingly, providers succeed at overturning denials more than half of the time according to CMS's 2014 data—and even more frequently in previous years[2]—while individual provider data suggests success rates are often much higher than 54%.[3]

Providers currently wait years for an ALJ to hear their appeal even though providers are statutorily entitled to an ALJ hearing *and* determination *within 90 days* of the provider's initial request for ALJ review.[4] Prior to 2010, CMS frequently met this deadline.[5] In 2010, however, the Recovery Audit Contractor program was implemented, and things changed dramatically (and quickly).[6] This program, which incentivized recovery auditors to find overpayments by giving them a financial share in any recoupments they identified, has been credited with kick starting an appeals backlog as the number of appeals quickly and dramatically out-

David Tolley is an associate in the Boston office of Latham & Watkins and a member of the firm's Global Recruiting Committee. He advises health care organizations, including academic medical centers, hospitals, health IT companies, medical device manufacturers and other organizations on a variety of regulatory, compliance and litigation matters. He can be reached at mailto:david.tolley@lw.com.

Greer Donley is an associate in the Washington, D.C., office of Latham & Watkins. She counsels hospital, pharmaceutical, medical device, food and other related industry clients in matters concerning violations of the False Claims Act and regulatory issues involving the Centers for Medicare & Medicaid Services and the Food and Drug Administration. She can be reached at mailto:greer.donley@lw.com.

[1] CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., MEDICARE PARTS A & B APPEALS PROCESS (Feb. 2015), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedicareAppealsprocess.pdf.

[2] U.S. GOV'T ACCOUNTABILITY OFFICE, NO. GAO-16-366, MEDICARE FEE-FOR-SERVICE: OPPORTUNITIES REMAIN TO IMPROVE APPEALS PROCESS 21-22 (2016), http://www.gao.gov/assets/680/677034.pdf.

[3] *See, e.g., Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 188 (D.C. Cir. 2016) (''[T]he American Hospital Association[] reported that they had appealed 52% of RAC denials, and that 66% of these appeals that had been completed were successful.'').

[4] 42 U.S.C. § 1395ff(d)(1)(A).

[5] *Adjudication Timeframes*, Dep't Health & Human Services., Office of Medicare Hearings & Appeals (last updated April 29, 2015), http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html.

[6] AM. HOSP. ASS'N, THE REAL COST OF THE INEFFICIENT MEDICARE RAC PROGRAM 2 (Mar. 1, 2016), http://www.aha.org/content/15/hospsurveyreport.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, SUPRA note 2 at 15.

 ISSN 1049-7986

paced capacity (in particular, at the ALJ level).[7] For instance, ''the number of requests for an ALJ hearing or review increased 1,222%, from fiscal year (FY) 2009 through FY 2014,''[8] while the budget for the office responsible for Medicare's ALJ appeals (OMHA) increased by only 16% from 2010 to 2014.[9] By fiscal year 2014, ALJs issued their decisions after the statutorily mandated 90-day timeline *96% of the time*.[10] The backlog has now become so pervasive that since April 1, 2013, providers requesting an ALJ appeal must wait more than two years just to have their appeal docketed—from there, providers wait even longer for a hearing and then further still for a decision on the merits.[11] Since 2013, the backlog only continues getting worse.[12] According to HHS's own data, OMHA has over 750,000 pending appeals as of April 30, 2016 with capacity to hear only 77,000 appeals per year.[13] This data led the DC Circuit to find that some appeals could take a decade or more to resolve.[14]

In spite of this backlog and the years-long waiting period for a meaningful hearing on claims, the Medicare statute empowers CMS to recoup funds that are the subject of an ongoing appeal well before the provider obtains a hearing before an impartial ALJ. In particular, an ALJ hearing is the third step in the four-step Medicare appeals process, but CMS can recoup funds after the conclusion of the second level in the appeals process, years before the ALJ hearing occurs.[15] When an ALJ hearing occurred within 90 days from the provider's request after the conclusion of phase two, recoupment in the meantime was not of large consequence to providers. With the current backlogs, however, CMS can recoup and hold enormous sums of money from providers while they wait years for an ALJ determination—a determination that will find more often than not that the payment was legitimate and money should have never been recovered or withheld from the provider. For some providers, the recoupments are so large that they are forced to close their doors even while they await the opportunity to present their case to an impartial arbiter. Small health care providers have been hit the hardest and some have already been forced to shut their doors.[16]

It is hard to overstate how much the deck is stacked in the government's favor. Some providers have been willing to litigate—especially those that will close their doors without some kind of relief—and we expect that willingness will only grow as the delays increase. Nevertheless, successful litigation challenging any part of the appeals process prior to completion of the four-step administrative review process has historically been extremely difficult: Plaintiffs face exhaustion requirements,[17] jurisdictional preclusion,[18] and agency deference,[19] which routinely result in dismissal of their claims, often before a court reaches any decision on the merits. Recent case law, however, indicates a more receptive climate that has enabled providers to lodge successful challenges to various aspects of the appeals process.

I. Shifting Tide in Judicial Receptivity to Medicare Challenges

Since late 2015, a series of opinions demonstrate a shifting tide in the judiciary's willingness to consider challenges to Medicare appeals prior to exhaustion as a direct result of the Medicare appeals process drifting further and further away from the process (and timeline) envisioned by the Medicare Act. In particular, plaintiffs have succeeded by:

(i) mounting procedural due process arguments;

(ii) using the Mandamus Act, which allows the judiciary to force an agency to act in compliance with the law;

(iii) attacking CMS as acting ''ultra vires''—i.e., in violation of the law; and

(iv) by challenging Medicare's own interpretation of its regulations.

■ ***Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183 (D.C. Cir. 2016)**: In a unanimous opinion authored by Judge David S. Tatel, the D.C. Circuit reversed and remanded a district court opinion, which denied a writ of Mandamus on jurisdiction grounds to a group of hospitals seeking to compel the Secretary to act within the 90-day timeframe set by statute for an ALJ hearing. The court held that it had jurisdiction. In particular, the D.C. Circuit concluded ''that the statute imposes a clear duty on

[7] U.S. Gov't Accountability Office, supra note 2 at 15.

[8] Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures, 81 Fed. Reg. 43,790, 43,792 (July 5, 2016) (to be codified at 42 C.F.R. § § 401, 405, 422) [hereinafter ''Proposed Rule''].

[9] U.S. Gov't Accountability Office, supra note 2 at 20.

[10] *Id.* at 18.

[11] *Id.*

[12] *Id.* at 41 (''This backlog shows no signs of abating as the number of incoming appeals continue to surpass the adjudication capacity at Levels 3 and 4.''); Office of Medicare Hearings & Appeals, U.S. Dep't of Health & Human Servs., Justification of Estimates for Appropriations Committee –Fiscal Year 2016, at 6 (2015).

[13] Proposed Rule, *supra* note 8.

[14] Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., Medicare Overpayments (Oct. 2015), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/overpaymentbrochure508-09.pdf.

[15] *Am. Health Ass'n v. Burwell*, at 187 (''These figures suggest that at current rates, some already-filed claims could take a decade or more to resolve.'').

[16] Press Release, Am. Orthotic Prosthetic Ass'n, Study: Medicare Audit ''Mess'' Surging At Rate Of 15,000 New Appeals Per Week, Agency Could Avoid Rapidly Mounting Interest Payments, (Mar. 19, 2015), http://www.aopanet.org/2015/03/study-medicare-audit-mess-surging-at-rate-of-15000-new-appeals-per-week-agency-could-avoid-rapidly-mounting-interest-payments/.

[17] *See, e.g., Neurological Assocs.-H. Hooshmand, M.D., P.A. v. Bowen*, 658 F. Supp. 468 (S.D. Fla. 1987); *ABA, Inc. v. District of Columbia*, 40 F. Supp. 3d 153, 173 (D.D.C. 2014).

[18] *See, e.g., Feldman v. Dep't of Health & Human Servs.*, 2012 BL 203232, at *4 (M.D. La. 2012); *Bayou Shores SNF, LLC v. Burwell*, 2014 BL 227305, at *10 (M.D. Fla. 2014); *Triad at Jeffersonville I, LLC v. Leavitt*, 563 F. Supp. 2d 1 (D.D.C. 2008); *Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852 (D.C. Cir. 2007).

[19] *See, e.g., Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S 449 (U.S. 1999).

   ISSN 1049-7986

the Secretary to comply with the statutory deadlines, that the statute gives the Association a corresponding right to demand that compliance, and that escalation—the only proposed alternative remedy[, which allows parties to proceed to the next stage in the appeals process if the current level is untimely]—is inadequate in the circumstances of this case.''[20] Though the Circuit remanded to the district court to determine the merits, it required the district court to consider the worsening situation, which, if not remedied, warranted the use of such an extraordinary remedy:

Taking the above factors into account, the district court—more than a year after its first denial and with the problem only worsening—might find it appropriate to issue a writ of mandamus ordering the Secretary to cure the systemic failure to comply with the deadlines . . . . Given this, and given the unique circumstances of this case, the clarity of the statutory duty likely will require issuance of the writ if the political branches have failed to make meaningful progress within a reasonable period of time—say, the close of the next full appropriations cycle.[21]

■ ***D&G Holdings, LLC v. Burwell*, 2016 BL 7845 (W.D. La. 2016)**: The Western District of Louisiana granted a preliminary injunction barring CMS from recouping overpayments prior to an ALJ hearing under Procedural Due Process and *ultra vires* theories. The court denied the government's motion to dismiss for lack of subject matter jurisdiction and failure to state a claim. In so doing, the *D&G* court made clear that providers can face irreparable harm if their payments are recouped prior to an ALJ hearing:

[P]laintiff states that if it is not granted a timely administrative hearing and recoupment continues in the interim, it will lose the same amount of revenue, will go out of business, could not care for its rural customer base, and must terminate its employees. These are damages not recompensable through retroactive payment. A colorable claim that irreparable harm will result has been made . . . .[22]

■ ***Hospice Savannah, Inc. v. Burwell*, 2015 BL 304404 (S.D. Ga. 2015)**: A hospice provider claimed that CMS violated the statutory and constitutional rights by recouping payments before it could appear before a neutral ALJ. The court entered a TRO to enjoin recoupment; however, the case was later dismissed by settlement before hearing the merits of a preliminary injunction motion.

Hospice Savannah has shown a likelihood of success on the merits. If not enjoined, Hospice Savannah will lose 80% of its total revenues and be irreparably harmed by being forced to close and being unable to provide ongoing care to current hospice patients who by definition are terminally ill and disabled.[23]

■ ***Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 2016 BL 171256 (10th Cir. 2016)**: Caring Hearts challenged CMS under a traditional approach—the ''fifth'' level of review, given to the federal courts, and guaranteed by statute. The court held that CMS must return the funds previously withheld from a home health care provider because the regulations that were used to establish lack of medical necessity were not in effect at the time of the claim, and the health care provider thus acted reasonably in their interpretation of the regulations.

This case has taken us to a strange world where the government itself—the very ''expert'' agency responsible for promulgating the ''law'' no less—seems unable to keep pace with its own frenetic lawmaking. A world Madison worried about long ago, a world in which the laws are ''so voluminous they cannot be read'' and constitutional norms of due process, fair notice, and even the separation of powers seem very much at stake. But whatever else one might say about our visit to this place, one thing seems to us certain: an agency decision that loses track of its own controlling regulations and applies the wrong rules in order to penalize private citizens can never stand.[24]

Taken together, these cases represent a new trend in judicial decision-making with regard to Medicare determinations. They signal a new-found willingness of federal courts to recognize the unfairness in the system, and despite a legal landscape that favors agencies, find exceptions to allow these cases to proceed. We summarize the key developments for providers based on these recent cases. We think that these cases provide fertile ground for new and creative arguments designed to bring fairness back to the Medicare appeals process for providers.

II. Litigation Strategies

A. Jurisdiction

One of the primary victories in *AHA, D&G,* and *Hospice Savanah* was persuading the courts that they had jurisdiction to hear the cases. One of the jurisdictional hurdles has always been 42 U.S.C. § 405(h), which precludes federal jurisdiction prior to administrative exhaustion for claims ''arising under'' federal statutes, including the Medicare Act, where a party has an avenue to a district court review under 42 U.S.C. § 405(g), and that base their jurisdiction on the federal question statute, 28 U.S.C. § 1331, or the Federal Tort Claims Act, 28 U.S.C. § 1346.[25] Mandamus challenges are generally exempt from this § 405(h) because the claims arise under the Mandamus Act; however, such claims face their own jurisdictional challenges.

1. Procedural Due Process/Ultra Vires

Plaintiffs seeking to delay recoupment through Procedural Due Process or *ultra vires* must directly confront § 405(h) by demonstrating that the plaintiff can meet an exception. There are a few potential exceptions to this jurisdictional preclusion. First, litigants challenging the timing of recoupment can argue that their claim is entirely collateral to the underlying substantive appeal (*i.e.*, the procedural challenge has nothing to do

[20] *Am. Hosp. Ass'n*, at 192.
[21] *Id.* at 193.
[22] *See D&G Holdings, LLC v. Burwell*.
[23] *See Hospice Savannah, Inc. v. Burwell*, at *1.
[24] *See Caring Hearts Pers. Home Servs., Inc. v. Burwell*, at *9.
[25] 42 U.S.C. § 405(h); *Wilson v. United States*, 405 F.3d 1002, 1010 n.9 (Fed. Cir. 2005); *Randall D. Wolcott, MD, P.A. v. Sebelius*, 635 F.3d 757 (5th Cir. 2011). The Administrative Procedures Act does not grant jurisdiction.

with whether or not the provider deserves payment for the underlying service).[26] This exception was enumerated in *Mathews v. Eldridge*, which permitted a waiver of exhaustion when a ''challenge is entirely collateral to [the] substantive claim of entitlement.''[27] A claim cannot be collateral if it is ''inextricably intertwined'' with a substantive determination within the purview of the administrative courts.[28] The doctrine is often interpreted to implicate elements of futility and irreparable harm, with some courts requiring plaintiffs to also prove those elements to meet the standard. Others courts, however, have stated that neither factor is required, but all three are relevant to the analysis.[29]

Second, the Supreme Court has stated that the administrative appeals process may be bypassed—and 28 U.S.C. § 1331 invoked—if bringing a claim through the prescribed administrative appeal process would amount to ''no review at all'' of the claim.[30] This exception is rare, and courts differ in the rigor with which they apply the test. For instance, the Fifth Circuit only applies it in instances of ''legal impossibility'' or ''sufficiently widespread'' hardship,[31] but the D.C. Circuit is willing to apply the exception to instances of ''practical impossibility.''[32] All courts agree, however, that it is not enough to show ''potentially isolated instances of the inconveniences sometimes associated with the postponement of judicial review.''[33]

The *D&G* court in particular wrestled with the jurisdictional dilemma and ultimately found that the plaintiffs were able to meet the collateral claim exception.[34] The court held that ''[a] ruling on the merits of Plaintiff's procedural due process claim will involve this Court in no way with a determination of whether Plaintiff was overpaid by Medicare, to what degree any overpayment was made, or the suitability of the statistical extrapolation used to assess Plaintiff's alleged overpayment.''[35] As a result, the court determined that the ''Plaintiff's procedural due process claim is entirely collateral to Plaintiff's substantive claim to Medicare benefits and thus is collateral for purposes of a *Mathews* waiver.''[36] The court reserved its holding regarding applicability of the collateral claim doctrine for the plaintiff's Procedural Due Process and *ultra vires* claims. It is also worth noting that the collateral claim standard applied by the *D&G* court required a showing of irreparable harm.[37]

Though the *D&G* court found jurisdiction under the collateral claim doctrine, it was not persuaded by the ''no review at all'' exception to § 405(h). The court held that this exception is reserved for instances of legal impossibility, and that extreme hardship was not sufficiently widespread[38] to warrant the exception:

> Plaintiff describes a dire situation, one where a government contractor erroneously claims overpayment in an unreasonable amount, binds the provider in a seemingly endless administrative process, withholds 95% of the provider's income, and forces the provider out of business before it can receive its day in court . . . . The risk of plaintiff ''closing its doors'' does not itself satisfy the ''no review at all'' exception to § 405(h) preclusion.[39]

As noted above, other circuits apply this exception more liberally, and practical impossibility might suffice. But even in jurisdictions with harsher standards, we

[26] *Mathews v. Eldridge*, 424 U.S. 319, 330 (U.S. 1976).

[27] *Id*, at 330-31 (''Eldridge's constitutional challenge is entirely collateral to his substantive claim of entitlement. . . . A claim to a predeprivation hearing as a matter of constitutional right rests on the proposition that full relief cannot be obtained at a postdeprivation hearing''); *See V.N.A. of Greater Tift Cty., Inc. v. Heckler*, 711 F.2d 1020, 1032 (11th Cir. 1983) (''Eldridge suggests strongly that there is room for a wholly collateral procedural attack, for example, to compel agency action wrongfully withheld. In other words, to the extent that a provider could show that a delay during PRRB review is contrary to the statute, it might well have a cause of action.'' (internal citation omitted)).

[28] *Heckler v. Ringer*, 466 U.S. 602, 624 (U.S. 1984); *see also Cathedral Rock of N. Coll. Hill, Inc. v. Shalala*, 223 F.3d 354, 363 (6th Cir. 2000).

[29] *Compare Koerpel v. Heckler*, 797 F.2d 858, 862 (10th Cir. 1986) (''One year later, the Mathews court concluded that the exhaustion requirement could also be excused if three requirements were met: if exhaustion would be futile, irreparable harm resulted, and a colorable constitutional claim which was collateral to the substantive claim of entitlement was raised.''), *and D&G Holdings, LLC v. Burwell* at *9-10, *with Bowen v. City of New York*, 76 U.S. 467, 482-86 (U.S. 1986), *City of New York v. Heckler*, 742 F.2d 729, 736 (2d Cir. 1984) (''Although Eldridge and Ringer make clear the circumstances that permit a court to waive exhaustion, they do not establish whether each of the individual factors deemed relevant in those decisions—futility, collaterality, and irreparable harm—must be present before a court may dispense with exhaustion. In the absence of express guidance, we have taken the view that no one factor is critical.''), *and Select Specialty Hosp.-Ann Arbor, Inc. v. Sec'y of HHS*, 2016 BL 34460 at *10 (E.D. Mich. 2016) (''the Supreme court identified three factors to be considered in deciding whether to waive the exhaustion requirement: (1) whether the claims at issue are collateral to the underlying decision as to eligibility for entitlements; (2) whether claimants would be irreparably harmed were the exhaustion requirement enforced against them; and (3) whether exhaustion of administrative remedies would be futile.'').

[30] *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 19 (U.S. 2000) (''[The Medicare Act] does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all.''); *BP Care, Inc. v. Thompson*, 398 F.3d 503, 508 (6th Cir. 2005) (''Put another way, ''parties affected by Medicare administrative determinations may sue in federal court under 28 U.S.C. § 1331, bypassing § 405 preclusion, only where requiring agency review pursuant to § 405(h) would mean no review at all.'').

[31] *Sw. Pharmacy Solutions, Inc. v. Ctrs. for Medicare & Medicaid Servs.*, 718 F.3d 436, 441 (5th Cir. 2013) (''The fact that a plaintiff would suffer great hardship if forced to proceed through administrative channels before obtaining judicial review is insufficient to warrant application of the Illinois Council exception . . . . Instead, a plaintiff must demonstrate ''either a legal impossibility that any claimant would obtain judicial or administrative review, or hardship from administrative channeling that was 'sufficiently widespread' to threaten the loss of any judicial review.'').

[32] A*Am. Chiropractic Ass'n v. Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005) (''this exception 'applies not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court[;] . . . [t]he difficulties must be severe enough to render judicial review unavailable as a practical matter.' '').

[33] *Ill. Council*, 529 U.S. at 23.

[34] *D&G Holdings*, at *9-10.

[35] *Id.* at *11.

[36] *Id.*

[37] *Id.* at *20-21.

[38] *Id.* at *6 (''Sufficiently widespread' means that 'no third party with an interest and a right to seek administrative review' exists.'').

[39] *Id.*

  MCR ISSN 1049-7986

think that plaintiffs should think creatively about the many ways in which they can still plead legal impossibility given the tremendous delays imposed by the current process.

2. Mandamus

Plaintiffs asking for a Writ of Mandamus under the Mandamus Act do not face the § 405(h) hurdle because their actions do not seek to rest jurisdiction in either the Medicare Act or the federal question statute.[40] Actions in Mandamus, however, have their own jurisdictional obstacles, which can be tangled with the merits of a Mandamus action.

In *AHA*, the D.C. Circuit clarified the separate strands of Mandamus jurisdiction and the underlying merits. The fundamental elements of Mandamus jurisdiction are:

- (1) clear duty of the federal agency;
- (2) clear right to relief for the plaintiff; and
- (3) absence of an adequate alternative remedy.[41]

By contrast, the merits determination involves six questions, discussed below. At times, analysis of the jurisdictional and merits-related elements overlaps, but they remain separate inquires.

The plaintiff in *AHA* was able to meet the jurisdictional elements of the Mandamus standard by establishing that:

(i) the Secretary has an obligation to provide an ALJ hearing within 90 days;

(ii) the appealing party has the right to demand that the Secretary fulfill that obligation; and

(iii) there is no alternative remedy for the plaintiff.

.

The Fourth Circuit, however, heard a similar case and denied plaintiff's Mandamus action in *Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48 (4th Cir. 2016). The plaintiff in *Cumberland* was a hospital seeking to compel compliance with the 90-day hearing requirement. The Fourth Circuit held that Congress explicitly chose its remedy for failure to comply with the 90-day statutory time limit when it provided for ''escalation,'' which allows parties to proceed to the next level of the appeals process if the proceeding level has failed to meet the 90-day deadline.[42] Therefore, the Fourth Circuit determined that the plaintiff had an alternative remedy and could not continue with the Mandamus action.[43]

The D.C. Circuit explicitly rejected this argument, finding that escalation was not an adequate alternative remedy because the fourth stage in the Medicare appeals process was also extremely backlogged and escalating further to the federal courts would be insufficient because review at the district court level would be deferential and not an adequate substitute for a de novo ALJ hearing.[44] Fortunately for plaintiffs, jurisdictions outside of DC and the Fourth Circuit will likely place more importance on *AHA* than *Cumberland* as it was published later and from the Circuit most specialized in administrative law.

B. Merits

Beyond procedural hurdles, these cases also face tough standards on the merits. As with the jurisdictional arguments, however, there is reason for optimism given recent case law.

1. Procedural Due Process

A Procedural Due Process claim asks the federal courts to require an ALJ hearing before the government can recoup payments. Unlike Mandamus, a Procedural Due Process claim does not ask the court to force compliance with the 90-day timeline embedded in the Medicare Act. When determining whether some additional process will be required before the government limits a property or liberty interest, courts always weigh three factors: ''[1] the private interest that will be affected by the official action; [2] the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional procedural or substitute procedural safeguards; and [3] the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.''[45]

Recoupment of Medicare payments goes to the heart of a provider's property interests, especially when extrapolation allows the government to recoup millions of dollars from a single provider.[46] Further, the risk of erroneous deprivation in these cases is high—every provider stands to win its ultimate appeal more than half of the time, and some providers will be forced to close their doors after recoupment occurs (before they have a chance for an impartial hearing). However, would the additional procedural safeguards (maintenance of status quo and no recoupment until ALJ hearing) outweigh the additional administrative burden imposed on the government?

At the most basic level, the procedural due process arguments for providers align with fundamental fairness. Why should the government be entitled to collect and hold millions of dollars from providers when:

---

[40] *See, e.g.*, *Belles v. Schweiker*, 720 F.2d 509, 512 (8th Cir. 1983) (''Unless the question sought to be litigated is within the express language of the limiting statute, there is no basis for concluding that Congress sought to limit or preclude judicial review.''); *Randall D. Wolcott, M.D., P.A. v. Sebelius*, at 764 (''We join the near unanimity of all other circuits holding § 405(h) does not preclude mandamus jurisdiction to review otherwise unreviewable procedural issues . . . . § 405(h) is only controlling where a judicial decision favorable to the plaintiff would affect the merits of whether the plaintiff is entitled to the benefits, not when the suit is brought to review otherwise unreviewable procedural issues.'').

[41] *Am. Hosp. Ass'n v. Burwell*, at 190.

[42] *See Cumberland Cty. Hosp. Sys. v. Burwell*.

[43] *Id.*

[44] *Am. Hosp. Ass'n*, 812 F.3d at 190.

[45] *See Mathews v. Eldridge*, at 335.

[46] For additional commentary about a Fourth Circuit case regarding use of extrapolation in FCA cases, *see* Roger S. Goldman et al., Latham & Watkins LLP, Fourth Circuit May Address Use of Statistical Sampling in False Claims Act Actions (July 21, 2015), https://www.lw.com:443/thoughtLeadership/lw-statistical-sampling-false-claims-act.

(i) the providers have had no opportunity to challenge the recoupment before a neutral third party; and

(ii) the government is most likely wrong in its recoupment demands more than half the time?

Moreover, some simple financial analysis actually suggests that CMS could enjoy some financial benefits by waiting to make its recoupments until after the ALJ stage—when Medicare recoups payments for claims that the ALJ later finds valid, the government must pay back the collected money plus a high interest rate (9.625-10.375%).[47] In a recent GAO report, the agency found the following:

CMS officials estimate that from fiscal years 2010 through 2015, the agency paid $17.8 million in interest payments to Part A and B providers that it would not have paid had Level 3 issued appeal decisions within statutory time frames. Moreover, CMS estimates that the agency paid about 75 percent of this interest ($13 million) in fiscal years 2014 and 2015, when delays in issuing decisions have been the longest.[48]

Although *D&G* and *Hospice Savannah* did not have to reach the underlying merits of the procedural due process claims, they found ''likelihood of success on the merits'' as a part of their preliminary injunction/temporary restraining order decisions. Their decisions were perhaps influenced by the increasing potential for success on the merits as delays continue to plague CMS—the private interests at stake are large, the risk of erroneous deprivation is high, and the problem is entirely fixable with little effort required on the part of the government.

2. Mandamus

Courts may issue Writs of Mandamus to compel the government to comply with a statutory obligation. Here, a court could issue a writ to require CMS to comply with the statutory timeframes set forth in the Medicare Act (*i.e.*, ALJ hearing within 90 days). A writ alone, therefore, would not be the proper mechanism to forestall recoupment during the waiting period for an ALJ hearing. Not surprisingly, because mandamus carries with it the power to compel action by the government, courts disfavor it as a remedy: ''The remedy of Mandamus is a drastic one, to be invoked only in extraordinary circumstances.''[49] Courts weigh the merits of any Mandamus action according to six factors enumerated by the Supreme Court in Telecommunications Research & Action Center v. FCC: (1) reasonableness of the timeframe, (2) timeframe established by statutory scheme, (3) whether delays impact human welfare, (4) effect of expediting action on higher priority decisions, (5) nature and extent of the interests prejudiced, (6) agency impropriety is not a concern.[50]

Though these elements may not initially appear to be highly rigorous, they have in practice been applied unfavorably towards plaintiffs. The central question is ''whether the agency's delay is so egregious as to warrant mandamus.''[51] Though the D.C. Circuit remanded to the district court to decide the ultimate merits, it hinted that Mandamus would be appropriate if the agency failed to improve the situation:

In the end, although courts must respect the political branches and hesitate to intrude on their resolution of conflicting priorities, our ultimate obligation is to enforce the law as Congress has written it. Given this, and given the unique circumstances of this case, the clarity of the statutory duty likely will require issuance of the writ if the political branches have failed to make meaningful progress within a reasonable period of time—say, the close of the next full appropriations cycle.[52]

III. INSUFFICIENCY of HHS's Proposed Rule to FIX the Backlog

In an attempt to remedy the severe backlog in the Medicare appeals process, CMS has issued a proposed rule, located at 81 Fed. Reg. 43,790. CMS proposes the use of a three-pronged approach to alleviate the Medicare appeals backlog:

(1) request new resources to invest at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog;

(2) take administrative actions to reduce the number of pending appeals and implement new strategies to alleviate the current backlog; and

(3) propose legislative reforms that provide additional funding and new authorities to address the volume of appeals.[53]

To achieve these goals, the proposed rule suggests that OMHA ''reassign a portion of workload to non-ALJ adjudicators, reduce appeals of low-value claims, and reduce procedural ambiguities that result in unproductive efforts at OMHA and unnecessary appeals to the Medicare Appeals Council.''[54] The proposed rule would also give precedential value to certain ALJ decisions to streamline ALJ decision making.[55]

The proposed rule, by its own estimates, would have a very limited impact in a vacuum. For instance, HHS's proposal to expand the pool of OMHA adjudicators could only redirect from ALJs ''approximately 23,650 appeals per year'' to attorney adjudicators.[56] Similarly, adjusting the calculation methodology to reduce low-

---

[47] U.S. Gov't Accountability Office, supra note 2, at 21.

[48] *Id.*.

[49] *Power v. Barnhart*, 292 F.3d 781, 784 (D.C. Cir. 2002) (internal quotation marks omitted).

[50] *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) (''(1) [T]he 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.'' (internal quotation marks and citations omitted)).

[51] *In re Core Commc'ns., Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008) (citation omitted).

[52] *Am. Hosp. Ass'n v. Burwell*, at 193.

[53] Proposed Rule, *supra* note 8 at 43,792.

[54] *Id.* at 43,856.

[55] *Id.*

[56] *Id.*

  MCR ISSN 1049-7986

value appeals will only reduce 2,600 appeals.[57] The proposed rule provides no estimate for the impact of other proposals, including precedential decisions.[58] With a backlog of 750,000 appeals, eliminating 25,000 per year only scratches the surface of the problem.[59] HHS also proposed significant funding increases and legislative actions, which it estimated would eliminate the backlog by 2021 if implemented in tandem with its proposed rule.[60] However, the agency has little control over Congress, and it is unclear whether these suggestions will ever be incorporated given the current political gridlock. As such, we are left with little hope that meaningful change is imminent.

IV. Moving Forward

The tide is changing for challenges to Medicare appeals—plaintiffs have recently succeeded in sidestepping jurisdictional hurdles that have plagued such lawsuits for decades. Courts have issued strongly worded opinions harshly criticizing a system that is out of control with no end in sight. And given that the agency seems ''unable to keep pace with its own frenetic lawmaking[,]''[61] these appeals are an increasingly important part of ensuring providers are treated fairly. We have yet to see a case ruling against HHS on the merits, but we predict that such a decision is likely absent some fast congressional action. This is a fast-changing area of the law that many will be monitoring closely given the number of providers affected and the scale of the financial and other consequences for the industry.

[57] *Id.*

[58] *Id.*

[59] *See, e.g.*, *Am. Hosp. Ass'n*, *HHS Proposes Changes to Medicare Appeals Procedures*, AHA NEWS NOW (June 28, 2016), http://news.aha.org/article/160628-hhs-proposes-changes-to-medicare-appeals-procedures (''We are skeptical that these proposals will do more than scratch the surface of the severe backlog in ALJ appeals that has led to hospitals facing multi-year waits for hearings . . . .'').

[60] Nancy Griswold & Constance B. Tobias, *Taking Action to Improve the Medicare Appeals Process*, HHS.GOV (June 28, 2016), http://www.hhs.gov/blog/2016/06/28/taking-action-improve-medicare-appeals-process.html.

[61] *Caring Hearts Pers. Home Servs., Inc. v. Burwell*, at *7.