UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUSIANA

ALEXANDRIA DIVISION

MICHAEL DOLE, MD, A PROFESSIONAL MEDICAL CORPORATION
Plaintiff

CIVIL ACTION NO.

JUDGE

MAGISTRATE JUDGE

v.

Alex M. Azar, in his official capacity as Secretary of the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES and Seema Verma, in her official capacity as Administrator for the CENTERS FOR MEDICARE AND MEDICAID SERVICES
Defendants

COMPLAINT FOR INJUNCTIVE RELIEF AND MANDAMUS

Plaintiff, Michael Dole, MD, A Professional Medical Corporation (the "APMC" or the "Practice") brings this action against Alex Azar, Secretary of the United States Department of Health and Human Services ("HHS"), and Seema Verma, Administrator for the Centers for Medicare and Medicaid Services ("CMS"), in their official capacities for: 1) injunctive relief to enjoin the recoupment of earned Medicare reimbursement amounts owed to the APMC for ongoing services following an overpayment audit until such time that the APMC has had a meaningful opportunity to exhaust, and has exhausted, its administrative remedies; and 2) mandamus relief to compel HHS to provide the APMC an administrative hearing within a reasonable time, not to exceed

ninety (90) days after the Court enters an Order, or, alternatively, upon the Court's granting of injunctive relief, within a reasonable time period after Defendants have corrected the deficiencies and backlog that caused a violation of the APMC's rights. HHS's delays are part of an unlawful scheme and are contrary to a clear legal mandate requiring timely administrative review. Lengthy, systemic delays in the Medicare Appeals process, which far exceed required statutory and regulatory timeframes, are causing irreparable injury to the APMC.

INTRODUCTION

1.

In relation to post-payment reviews, Defendants are currently withholding one hundred percent (100%) of the APMC's Medicare receivables until the extrapolated amount of $4,339,672.96 (based on an alleged actual overpayment of only $10,466.84) plus interest, and a second amount of $9,268.48 plus interest, is recouped by the Defendants.

2.

Recoupment means that the APMC's current claims are being approved and "paid" on paper but the APMC receives no money because it is retained by the government.

3.

This is a civil action for: (1) injunctive relief to enjoin the Defendants from withholding all of the APMC's Medicare receivables until such time that Defendants permit the APMC to exercise its right to a hearing before an Administrative Law Judge ("ALJ"); and (2) a mandamus requiring the Defendants to comply with their legal

obligations in administering the Medicare appeals process and schedule the APMC's appeal for hearing before an ALJ.

4.

The APMC is a professional medical practice participating in the Medicare program, providing medically necessary services to Medicare beneficiaries in and around Alexandria, Louisiana and submits claims for payment to HHS, which processes said claims through CMS' contractors.

5.

The underlying billing dispute is premised entirely upon a CMS contractor's incorrect post-payment application of CMS's non-binding, inconsistent guidance and flawed clinical determinations of physician care made by persons who are not physicians.

6.

Defendants, HHS and CMS, have launched a scheme, whereby they have created a system of using outside auditors such as Recovery Audit Contractors ("RACs") and Zone Program Integrity Contractors ("ZPICs") to reopen and deny past paid claims. These auditors are in addition to the Medicare Administrative Contractors ("MACs") who receive and adjudicate claims in the first instance.

7.

The RAC and ZPIC contractors have been awarded contracts worth millions of dollars, to identify as many claims denials as possible on post-payment review. They use methods, including statistical sampling and extrapolation, for CMS to take millions of

dollars in Medicare receivables currently owed to providers based on much smaller base amounts attributed to a small number of past claims.

8.

During these post-payment reviews by the RAC and ZPIC contractors, original payment determinations by the MAC contractor approving claims are overturned based on non-physician reviewers' findings, often based on disputed, subjective and internally inconsistent reviews and finding that, as in this case, certain services were allegedly not medically necessary.

9.

In the APMC's case, the MAC contractor, Novitas Solutions, Inc. ("Novitas"), approved payment of the claims in dispute and the APMC received payment for the medical services rendered.

10.

Later, the APMC was subjected to two post-payment review audits conducted by CMS, through its ZPIC contractor, AdvanceMed, for claims that had been previously approved by Novitas and paid to the APMC.

11.

In one post-payment review, AdvanceMed determined that $10,466.84 in claims were overpaid to the APMC and extrapolated that amount to $4,339,672.96. In the other post-payment review, AdvanceMed determined that $9,268.48 in claims were overpaid to the APMC, but did not extrapolate that amount.

12.

The APMC has timely appealed AdvanceMed's determination in accordance with the appeals process as outlined in the Social Security Act ("SSA").

13.

There are four (4) levels of administrative appeal: a request for redetermination of the initial post-payment review decision (the initial decision is known as the initial determination); a request for reconsideration of the redetermination decision; a request for ALJ hearing; and an appeal of the ALJ decision to the Medicare Appeals Council.

14.

Recoupment can be temporarily suspended once a request for redetermination or a request for reconsideration is made. However, once the reconsideration decision is released, recoupment cannot be further suspended, even if the provider proceeds to the third level of appeal, the ALJ evidentiary hearing.

15.

The APMC is now in the third level of appeal and timely requested an ALJ hearing in the two appeals. The requests were received by the Office of Medicare Hearings and Appeals ("OMHA") on July 28, 2017 and August 18, 2017, respectively, and consolidation of the appeals was requested.

16.

By federal law, the APMC's hearing and a decision from the ALJ following said hearing was required to be issued within ninety (90) days after its requests were received,

which should have been, in all circumstances, no later than November 16, 2017. To date, no ALJ has even been assigned to the case, let alone set a hearing date.

17.

Prior to the filing of the APMC's appeal to the ALJ, the Defendants began recoupment and despite the APMC continuously providing services to Medicare beneficiaries at all pertinent times, the APMC has not been paid any reimbursement amounts for services rendered since July 3, 2017.

18.

Defendants are taking all of the APMC's currently approved Medicare reimbursements, even though the current reimbursements do not relate to the billing dispute at issue.

19.

Recoupment is currently being made at a 10.25% interest rate, and interest is recouped first, before recoupment of the principal amount.

20.

As of early August 2018, CMS has recouped approximately $2.04 million from the APMC.

21.

The recoupment will continue to occur until the entire alleged overpayment amount and calculated interest is recouped, prior to the APMC having a meaningful opportunity to have an administrative hearing before an ALJ.

22.

Under CMS's present backlogged appeal system resulting from the RAC and ZPIC audits, the APMC will wait many years for the first opportunity at a fair, impartial and unbiased review at a hearing before an ALJ.

23.

On information and belief, on its current course, the backlog of appeals at the ALJ level is projected to grow to 950,520 by the end of FY 2021, and some already-filed claims could take a decade or more to resolve.

24.

These extraordinary delays are in violation of federal statutes and regulations (42 U.S.C. ¶ 1395ff; 42 C.F.R. ¶ 405.1016), which require the ALJ to hold a hearing and render a decision within ninety (90) days after a request for ALJ hearing is filed.

25.

It is inconceivable—and a clear denial of the APMC's statutory, regulatory and procedural due process rights—that CMS may recoup more than $4.3 million and $9,268.48, plus interest (the current rate is 10.25%), from it *years* before the Practice would even have its first opportunity to be heard by an independent adjudicator and complete the appeals process.

26.

The extraordinary amount that CMS is currently recouping, combined with the excessive and ever growing backlog of claims before the ALJs, effectively strips the APMC

of the procedural due process to which it is entitled by law. Without intervention by this Court, this mandated appeals process is rendered moot.

27.

Deprived of the value of the services already provided, the APMC is unable to use Medicare funds to furnish patient care in the community, or to invest in the improvement of the medical practice and facilities.

28.

Without injunctive relief, the APMC, Medicare beneficiaries, and the community in which it provides services is situated are being, and will continue to be, irreparably harmed before the APMC is allowed the meaningful opportunity for the administrative and judicial review to which it is entitled.

29.

The APMC does not ask this Court to usurp the power of the ALJ to decide any issue with respect to the underlying billing dispute nor of the Medicare Appeals Council's (the "Council") power to review the ALJ's decision. The APMC is not asking this Court to look at the merits of the pending administrative appeal. The APMC simply requests that this Court maintain the status quo pending completion of the administrative appeals process.

30.

The APMC seeks a Preliminary and Permanent Injunction preventing the Defendants from recouping any more of the $4,339,672.96 and $9,268.48 in alleged

overpayment amounts, plus interest, until it has been afforded a meaningful opportunity to exhaust all administrative remedies.

31.

Defendants' recoupment of the amounts at issue without allowing the APMC the opportunity to complete the appeals process within the timeframes required by applicable law, is *ultra vires* and violates procedural due process rights.

32.

HHS's delays violate the clear timetables set forth by Congress in the Medicare Act, 42 U.S.C. §§ 1395, *et seq*., and implementing regulations, are egregious and unreasonable, and should be remedied.

33.

As such, the APMC also brings a mandamus action to have the Court remedy these unlawful actions and order Defendants to provide the APMC an ALJ hearing with full reservation of any further rights to appeal and judicial review.

PARTIES

34.

Michael Dole, MD, A Professional Medical Corporation, is a Louisiana corporation, with its principal place of business in Alexandria, Louisiana. Its president and sole shareholder is Michael Dole, M.D. ("Dr. Dole").

35.

Defendant Alex M. Azar is the Secretary of HHS, the federal agency of the United States charged with overseeing the operation of the Medicare program. The Secretary is responsible for implementing the Medicare program. Title XVIII of the Social Security Act, as amended, 42 U.S.C. § 1395 *et seq.* The Secretary administers the Medicare program through CMS, an agency of HHS.

36.

CMS directs the contractors who are responsible for the first two levels of administrative review of Medicare denials. OMHA and the Departmental Appeals Board ("DAB") within HHS provide the third and fourth levels of administrative review, respectively.

37.

Defendant Secretary Azar is sued in his official capacity.

38.

Defendant Seema Verma is the Administrator for CMS and is sued in her official capacity.

JURISDICTION AND VENUE

39.

This action arises under the Social Security Act, 42 U.S.C. § 301 et seq., implicating both the Medicare Act, 42 U.S.C. § 1395 et seq., as well as the Fifth and Fourteenth Amendments to the United States Constitution.

40.

This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1361, 5 U.S.C. § 705, 42 U.S.C. § 405(g), 42 U.S.C. § 1395ii, and 28 U.S.C. § 1331.

41.

The APMC is currently challenging the billing dispute at issue through the appropriate administrative process; however, the ALJs do not have the authority to issue a mandamus order or an injunction to stay recoupment until the APMC has had the opportunity to appear before a fair and impartial ALJ.

42.

Since recoupment began, Defendants have taken some $2.04 million of the APMC's Medicare receivables.

43.

Accordingly, the APMC lacks an adequate administrative remedy through which it can pursue the relief it seeks in this suit.

44.

Moreover, there is no formal administrative mechanism to request deferral of recoupment before CMS.

45.

Due to the amounts that Defendants are recouping and the lengthy delay before a hearing can be held before an impartial ALJ, which could be five (5) or more years, the APMC is facing the equivalent of a total denial of administrative and judicial review.

46.

If this Court does not issue injunctive relief, the APMC will have no review at all and will suffer irreparable harm, making the theoretically available administrative remedies too late and of no value.

47.

Accordingly, this matter is ripe and falls under this Court's jurisdiction.

48.

Further, this Court has jurisdiction over this action under 28 U.S.C. § 405 pursuant to the "waiver" exception to the usual requirement of exhaustion of administrative remedies.

49.

The APMC has requested a hearing before an ALJ in an attempt to exhaust all administrative remedies. The APMC cannot get a hearing. Exhaustion of administrative remedies under the Medicare Act is not required where, as here, the plaintiff's interest in having a particular issue resolved promptly is so great that the requirement is considered waived.

50.

In addition, the APMC's request for injunctive relief and mandamus is collateral to the APMC's substantive claims in the billing dispute and administrative appeal.

51.

The APMC does not ask this Court to resolve the merits of the underlying billing dispute. Rather, the APMC requests the Court preclude Defendants from continuing to

engage in recoupment based on the disputed determinations of its own contractors until after the APMC has been afforded its legally mandated opportunity to appeal through all levels of the appeals process, including the opportunity for a hearing to obtain a ruling from an impartial and unbiased ALJ.

52.

Further, pursuant to 28 U.S.C. § 1361, district courts have original jurisdiction of any mandamus action to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff. This action is also brought to compel the Secretary, an officer of the United States, to perform duties owed to the APMC, namely to provide a timely hearing before a fair, unbiased, and impartial ALJ, and thus provides a basis for mandamus jurisdiction.

53.

Because the current appeals process cannot provide adequate redress, the APMC has no option but to bring this mandamus lawsuit to require the Secretary's compliance with the deadlines established by law.

54.

Venue is proper in this District under 28 U.S.C. § 1391(b) and (e) and 5 U.S.C. § 703.

FACTUAL BACKGROUND

I. The Medicare Payment Process and Post-Payment Review

55.

The Medicare program was enacted in 1965 under Title XVIII of the Social Security Act to provide health insurance to individuals sixty-fix years of age and older. Social Security Amendments of 1965, Pub. L. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395, *et seq*. The program's main objective is to ensure that its beneficiaries have access to health care services. *Id.* The APMC qualifies as a provider of physician services, including in-office clinical diagnostic laboratory services, under Title XVIII, also known as Medicare.

56.

Medicare Part B generally covers medically necessary services and supplies for the diagnosis and treatment of a beneficiary's health condition, including doctor's visits and services ancillary thereto. All of the services at issue were provided by the APMC and are covered by Medicare Part B.

57.

Under the Medicare statute, an eligible Medicare beneficiary is entitled to have payment made by Medicare on his or her behalf for services provided by a medical provider participating in the Medicare program.

58.

The Secretary has delegated much of the responsibility for administering the Medicare program to CMS, which is a component of HHS.

59.

The Secretary, through CMS, has contracted with MACs to perform many of the audit, processing, and payment functions that arise under the Medicare program. 42 U.S.C. § 1395kk-1(a)(3).

60.

When medical providers furnish services to a Medicare beneficiary, the providers thereafter submit a claim for reimbursement to a designated MAC. 42 U.S.C. § 1395ff(a)(2)(A).

61.

CMS reimburses providers for covered claims through the MACs. The MAC responsible for processing and paying the APMC's claims during the relevant time period was Novitas Solutions, Inc. ("Novitas").

62.

MACs are to pay the participating health care providers for approved services rendered within 30 days of receiving a Medicare claim. 42 U.S.C. § 1395h(c)(2). A MAC's decision to either pay or deny payment of a claim upon submission is known as an "initial determination." 42 U.S.C. § 1395ff(a); 42 C.F.R. § 405.920.

63.

Nevertheless, the Secretary is permitted to "reopen or revise any initial determination …under guidelines established by the Secretary in regulations." 42 U.S.C. § 1395ff(b)(1)(G).

64.

The Medicare statute and implementing regulations also permit a number of contractors to reopen and audit claims that have been approved and paid by the MAC, such as RACs and ZPICs. See 42 U.S.C. § 1395ddd(h); 42 C.F.R. § 405.370.

65.

A Medicare contractor may reopen and revise a claim that was initially approved and paid by a MAC within one year after payment "for any reason." 42 C.F.R. § 405.980(b)(1). A Medicare contractor may also reopen and revise a claim within four years of the date paid, but only if it can show "good cause" for doing so. *Id.* § 405.980(b)(2). Good cause reopenings are not appealable; therefore, a provider may be subjected to a reopening that goes back in time indefinitely and cannot be challenged.

66.

This process by which these claims are reopened and, therefore, made subject to the appeal process is known as "post-payment review."

67.

During post-payment review, RACs and ZPICs re-open claims and audit MAC payment decisions, meaning claims initially paid may subsequently be denied by a RAC or ZPIC. MACs then adopt these findings verbatim and assert an overpayment has occurred. This MAC action is also called an "initial determination" of reopened claims.

68.

The APMC was audited in post-payment review by AdvanceMed, a ZPIC contractor.

69.

ZPICs are paid on a contractual basis by the Centers for Medicare & Medicaid Services (CMS). ZPICs are incentivized and driven by financial interests – if the ZPIC does not produce positive results, it stands to lose its lucrative ZPIC contract. In 2012, a ZPIC's average government contract was valued at $81.9 million.

70.

AdvanceMed is the largest ZPIC under contract with CMS, holding **three** CMS ZPIC contracts at the time of the APMC's audits and covering more than half the country.

71.

The primary role of ZPICs is to identify cases of suspected fraud or abuse, investigate them, and take action to ensure any allegedly inappropriate Medicare payments are recouped. However, ZPICs have engaged in wide spread and overzealous audits, with little oversight from CMS, identifying allegedly improper payments and forwarding this information to the MAC to adopt and seek recoupment.

72.

ZPICs typically use statistical sampling to calculate and project the amount of overpayments made on claims. This process, called extrapolation, results in an extraordinarily large overpayment amount derived from the findings of a narrow review performed on a very small number of claims.

73.

In the APMC's case, the base amount from which the extrapolation to $4,339,672.96 occurred is only $10,466.84.

74.

The majority of ZPIC claim denials are overturned on appeal.

75.

According to data provided to the American Hospital Association ("AHA"), through the first quarter of 2013, hospitals reported that when they appealed a post-payment auditor's denials, including through an ALJ hearing, the denials were overturned seventy-two percent (72%) of the time. *See* AHA, Exploring the Impact of the RAC Program on Hospitals Nationwide, at 55 (Jun. 1, 2013), *available at* http://www .aha.org/content/13/13q1ractracresults.pdf.

76.

At an April 2015 United States Senate hearing before the Committee on Finance, the Honorable Orrin Hatch testified that over 60 percent of the appeals that are heard by an administrative law judge were favorable or partially favorable to appealing providers. *See* Opening Statement of the Honorable Orrin Hatch at April 28, 2015 Hearing before the Finance Committee of the United States Senate, Creating A More Efficient and Level Playing Field: Audit and Appeal Issues in Medicare, *available at* https://www .finance.senate.gov/imo/media/doc/20035.pdf.

II. The Medicare Appeals Process

77.

Pursuant to the SSA, appeals of all post-payment review denials are subject to a multi-level administrative appeals process, ultimately leading to judicial review. *See* 42 U.S.C. § 1395ff.

78.

The first two levels of the administrative appeals process (requests for redetermination and reconsideration) are overseen by CMS; the third level, the ALJ hearing, is overseen by the OMHA; and the fourth (a review of an ALJ decision by the Council) is overseen by the Departmental Appeals Board ("DAB").

79.

In cases of ZPIC denials followed by the MAC adoption of the denials, the appealing provider appeals the denied claims to the MAC that originally approved and paid the claim. This appeal is called a request for redetermination.

80.

The MAC is required to issue its decision on a provider's redetermination request within sixty (60) days from its receipt of the request for redetermination. *42* U.S.C. § 1395ff(a)(3)(C)(ii).

81.

At the second level of appeal, a provider dissatisfied with the redetermination result may appeal the MAC's redetermination to a Qualified Independent Contractor ("QIC") within one hundred eighty (180) days after the date the party received the

redetermination decision. The QIC is required to issue its decision on a reconsideration request within sixty (60) days of its receipt of the reconsideration request. 42 U.S.C. § 1395ff(c).

82.

A party dissatisfied with the QIC's decision may appeal within sixty (60) days of receipt of the QIC's decision and request a hearing before an ALJ at the OMHA, provided that the amount in controversy is greater than $160 (for calendar year 2017). 42 U.S.C. §§ 1395ff(b)(1)(E),(d)(1)(A).

83.

Review by an ALJ is the first opportunity for independent review of a claim.

84.

The ALJ is required to hold a hearing on the denied claims and render its decision within ninety (90) days after OMHA has received the request for ALJ hearing. 42 U.S.C. § 1395ff(b).

85.

At the ALJ level, appellants are granted an evidentiary hearing before an independent trier of fact.

86.

At an ALJ hearing, appellants are allowed to make legal and factual arguments, and to brief the matters at issue in the appeal. Most importantly, the providers are able to offer testimony of witnesses. The ALJ has the opportunity to hear testimony directly from the treating provider as to the treatment and medical decision making at issue.

Appealing providers also have the opportunity to offer experts to testify at the ALJ hearing. Expert testimony is particularly important in cases of denials based on medical necessity and improper coding levels, which are at the heart of the APMC's case.

87.

The ALJ level of appeal is the **only** level of appeal where an evidentiary hearing with testimony is allowed and will become part of the record.

88.

It is at the ALJ level of appeal where providers historically have been able to obtain the most relief from adverse ZPIC determinations.

89.

If a party is dissatisfied after the ALJ issues its decision, it may appeal the ALJ decision within sixty (60) days to the Council within the DAB. The Council conducts a *de novo* review of the ALJ's decision and either renders its own decision or remands to the ALJ for further proceedings.

90.

The DAB is independent of both CMS and OMHA. The Council must render a decision or remand the case to the ALJ within ninety (90) days from the date of the request for review.

91.

Finally, a party may request judicial review in a federal district court within sixty (60) days from the date of receipt of the Council's decision.

92.

Although it would not afford the APMC adequate process in this case, there is also a separate "escalation" process applicable to skipping the ALJ hearing and moving to the DAB level of review. The process permits a decision to be made only on the paper record from the first two levels of appeal. 45 C.F.R. § 405.1122. The process would not provide the APMC a fair and adequate opportunity to exercise due process rights, including offering the live testimony of Dr. Dole and expert witnesses.

93.

If an ALJ has not held a hearing and rendered a decision within ninety (90) days after the provider has filed a request for ALJ hearing, an appealing provider may bypass the ALJ level by escalating its claim to the DAB. 42 U.S.C. § 1395ff(d)(3). In such situations, the QIC's decision becomes the decision subject to Council review.

94.

An escalation from the ALJ level would mean that there would be **no** testimony of any kind available to the Council, whether from the treating provider or, importantly, from the experts who are necessary to counter the medical necessity denials and code level denials asserted by non-physician reviewers of the ZPIC.

95.

The Council may conduct additional proceedings, but is not required to do so. In fact, OMHA has explained that, in escalation situations, the DAB will "NOT hold a hearing or conduct oral argument unless there is an extraordinary question of

law/policy/fact." Office of Medicare Hearings and Appeals, *Medicare Appellant Forum*, February 12, 2014, at 117 ("OMHA Forum Presentation").

96.

Even in the event a hearing were permitted by DAB, it would not be a full evidentiary hearing that is afforded a health care provider at the ALJ level of appeal. Accordingly, in the APMC's case, which is one of medical necessity and coding levels, both subject to expert testimony, escalation offers him no remedy whatsoever.

III. Limitation on Recoupment

97.

Appealing providers may avoid recoupment during the first two levels of appeals by filing appeals within specified time frames. This is referred to as a Limitation on Recoupments.

98.

The specified time frame to prevent recoupment is shorter than the actual time frame allowed to appeal the first and second levels of the administrative appeals process.

99.

A provider has one hundred twenty (120) days to timely file a request for redetermination of a MAC's adoption of a ZPIC's determination. However, the provider must file a request for redetermination within forty-one (41) days from the date of the notice of the initial determination in order to avoid some recoupment taking place. 42 C.F.R. § 379.

100.

This means that if an appealing provider wishes to prevent CMS from recouping at all, the provider must submit an appeal months earlier than the permitted appeal deadline.

101.

Similarly, a provider has one hundred eighty (180) days to timely file a request for reconsideration of the redetermination decision. However, a provider must file a request for reconsideration within sixty (60) days from the date of the notice of the redetermination results in order to avoid some recoupment taking place, reducing the time an appealing provider has to prepare its appeal by half if it wishes to avoid recoupment. 42 C.F.R. § 379.

102.

The Limitation on Recoupments is not available following issuance of the reconsideration decision. While the appeal is pending at the ALJ level or any subsequent stage, CMS can and will begin recouping from the entirety of an appealing provider's current Medicare reimbursements earned for services rendered, although they are wholly unrelated to the disputed claims, until CMS has recouped the total amount of the alleged overpayments plus interest. 42 C.F.R. § 405.379.

IV. Medicare Appeals Backlog and Resulting Delays in Adjudication Times

103.

The mandated time periods governing the appeals process provide for all levels of administrative review to be completed within approximately one year. In practice,

however, the amount of time it takes for a provider to pursue a claim appeal through the appeals process greatly exceeds the timeframes established by the SSA.

104.

Aggressive and widespread auditing activity by ZPICs have predictably increased the number of appeals being brought by providers, creating a significant strain on the statutory appeals process and an ever-growing backlog of pending Medicare appeals.

105.

An exponential increase in claim appeals has caused this growing delay in the Medicare appeals process, fueled in large part by the Medicare Fee-For-Service Recovery Audit Contractor Program ("RAC Program"), a demonstration program that was established in 2009 and fully implemented by September 2010. Under the RAC Program, aggressive RACs have issued numerous inappropriate claim denials, forcing a disproportionate number of providers into the Medicare appeals system to challenge these denials.

106.

Inappropriate denials by over-zealous ZPICs have also flooded the appeals system.

107.

Subsequently, OMHA has received an increasingly large percentage of the cases resulting from RAC and ZPIC appeals. *See* OMHA Medicare Appellant Forum Presentation at 108 (February 12, 2014).

108.

For example, in FY 2009, the last full fiscal year before the permanent RAC program was instituted, there were 35,831 appeals filed with OMHA for ALJ review. *Important Notice Regarding Adjudication Timeframes,* Office of Medicare Hearings and Appeals, U.S. Department of Health & Human Services, available at http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html (last visited May 7, 2018) ("*Important Notice").*

109.

In comparison, in FY 2013, well after the implementation of the RACs, 384,651 appeals were filed—more than ten times as many as only four years earlier, and a 300% increase from FY 2012 to FY 2013. *Id.; see also* OMHA Forum Presentation at 16.

110.

The value of appealed, RAC-denied claims alone is well over $1 billion. *See* AHA, Exploring the Impact of the RAC Program on Hospitals Nationwide, at 47 (June 1, 2013), *available at* http://www.aha.org/content/13/13q1ractracresults.pdf.

111.

In just two years (2012 and 2013), the backlog of ALJ-level appeals *quintupled,* growing from 92,000 to 460,000 pending claims. Memorandum from Nancy J. Griswold, Office of Medicare Hearings & Appeals, Chief Admin. Law Judge, to OMHA Medicare Appellants (Dec. 24, 2013) ("2013 Griswold Memorandum").

112.

Indeed, the number of filed Medicare appeals continued to grow to over 594,000 in FY 2017—an almost twentyfold increase in claims. *American Hospital Assoc. v. Sylvia Burwell*, Case No. 1:14-cv-00851 (D.C. App. Feb. 9, 2016), at Doc 58-1, Decl. of Jennifer Moughalian, ¶ 7.

113.

Based on current data, OMHA predicts that the number of pending appeals will rise to 972,591—almost one million—by the end of FY 2021 (September 30, 2021).

114.

Currently there are only 66 ALJs within OMHA.

115.

In FY 2013, of the 384,651 appeals that were filed, only 79,303 were decided – a meager twenty-one percent. OMHA Forum Presentation at 12 (reflecting decision figures); *Important Notice* (reflecting adjusted appeals receipts figures).

116.

Even in the best case scenario, wherein the FY 2018 President's Budget includes legislative and budget proposals aimed at improving the efficiency of the Medicare appeals process, OMHA still predicts that the number of pending appeals will be over 500,000 through FY 2019, and under the best of circumstances, the number of pending appeals will have only dropped to 375,674 by the end of FY 2021. Decl. of Jennifer Moughalian, at ¶¶ 12, 13.

117.

By OMHA's own admission, the ALJs have simply been unable to keep up with the increasing volume of Medicare appeals. As of OMHA's September 1, 2017 status report, OMHA has received 167,899 new claims for adjudication in 2017, but has only been able to adjudicate 76,000 of its total 595,000 outstanding claims. The rate at which the ALJs can adjudicate these appeals is far below the rate at which new appeals are being filed, resulting in a long and ever-growing backlog.

118.

As of February 2014, the average wait time for a provider's case to even be *assigned* to an ALJ docket was twenty-eight (28) months. *See* OMHA Forum Presentation, at 20.

119.

On February 14, 2014, Judge Griswold conceded that the wait times for a hearing before an ALJ are unacceptable. Michelle M. Stein, *ALJs Lay Out Path Forward For Stakeholders As Appeals Backlog Continues*, INSIDE HEALTH POLICY, Feb. 14, 2014, *available at* http://insidehealthpolicy.com/201402142461310/Health-Daily-News/Daily-News/aljs-lay-out-path-forward-for-stakeholders-as-appeals-backlog continues/menu-id-212.html.

120.

This ever-growing delay in appeals has continued to benefit Defendants. The federal government has, by its own making, created programs such as MAC and ZPIC, to greatly increase the number of post-payment reviews, while doing little to nothing to

increase the ALJ pool for cases to be heard within time frames required by law. The Defendants know, or in the exercise of common sense and reasonableness should know, the RAC and ZIC programs would create, and have created, this vast increase in delayed appeals through the ALJ level. This scheme takes 100% of providers' Medicare reimbursements, allowing CMS to continue to recoup all of their earned reimbursements from newly provided services without affording them due process for years.

121.

As of March of 2018, OMHA had only begun assigning third level appeal requests that had been filed in December of 2014, meaning that appeals currently being assigned to an ALJ have been sitting unassigned for until more than forty (40) months after the requests were timely filed.

122.

This delay does not take into account the time it will take to actually receive a hearing date.

123.

Once assigned to an ALJ, the average processing time for appeals decided thus far in FY 2015 had grown to 588.9 days, or approximately nineteen (19) months. (2015 OMHA Forum Presentation by Nancy J. Griswold, Office of Medicare Hearings & Appeals, Chief Administrative Law Judge) ("2015 Griswold Presentation").

124.

The increase in appeals, growing backlog, concomitant delay in adjudication, and the previous moratorium on assignment to ALJs has reached a crisis point that is

continuing to deteriorate. The predicted wait times to obtain a hearing once a case is assigned to an ALJ means providers who lodge new appeals from the QIC to the ALJ, such as the APMC, can realistically expect to wait five (5) to seven (7) years—and likely longer—to even obtain an ALJ hearing date, much less a decision.

125.

The backlog at the ALJ level likely will increase as appeals continue to be filed without being assigned or decided.

126.

The DAB – the last level of administrative review – is similarly inundated. At the end of FY year 2013, the DAB had 4,888 pending appeals, 112% more than it had at the end of FY 2012. OMHA Forum Presentation at 106. In FY 2015 the DAB received 8,162 appeals, and was only able to process 2,323, leaving 14,874 pending appeals on file with the DAB. HHS Primer: The Medicare Appeals Process, available at https://www.hhs.gov/sites/default/files/dab/medicare-appeals-backlog.pdf (last visited May 7, 2018).

127.

As with the ALJ appeals, the DAB is experiencing an increased caseload due to the behavior of the RACs, ZPICs and other Medicare contractors.

128.

OMHA itself recognizes that, like the ALJs, the DAB cannot keep up with the dramatic increase in appeals. It has conceded that the DAB is "unlikely to meet the 90-day deadline for issuing decisions in most appeals." OMHA Forum Presentation at 110.

129.

This concession does not account for the increase in escalated cases the DAB will receive, where an ALJ has failed to render any decision and the DAB is forced to remand the case or begin and conclude adjudication from scratch, with only the record from the QIC (or potentially even from the MAC) as a basis for review.

130.

Even if the DAB could find a way to adjudicate all of the appeals pending before it, it is not equipped to conduct the full evidentiary hearing that would otherwise occur at the ALJ level. There are just *four* Appeals Officers within the DAB responsible for final administrative review of Medicare managed care, and prescription drug claims in addition to the hundreds of thousands of claims such as the APMC's, challenging fee-for-service payment denials. OMHA Forum Presentation at 103-104.

131.

Publicly available information about the DAB's actions in escalated cases reveals that it has not conducted a hearing in any of them. Instead, the DAB can take one of only four actions, all of which are inadequate. First, it may render a summary decision on the basis of only the record established before the QIC, which would not provide the APMC due process of an ALJ hearing contemplated under law. Second, it may remand the appeal to the ALJ, which would place appealing providers in the same position in which they started, waiting years for a relatively small number of ALJs to wade through an enormous and increasing backlog of ALJ appeals. Third, the DAB may issue a notice that it, too, is unable to fulfill its statutory duty within the required timelines, thereby

allow appealing providers to escalate their claims to federal court. At the federal court level, the review of the case is solely on the record created below, thereby still not permitting an evidentiary hearing. Or fourth, it may do nothing at all.

132.

Given the immense backlog at the ALJ level and the increase in escalations to the DAB, itself already backlogged, appealing providers are put to the difficult position of deciding whether to escalate their claims from the DAB to federal court, which cannot provide an adequate remedy in any event.

133.

Under the regulations, an appealing provider may file an action in federal district court if the DAB notifies it that no decision will be issued and if its claim meets an amount-in-controversy requirement (currently $1,600). 42 C.F.R. § 405.1132(b); 42 C.F.R. § 405.1006(c); Notice of Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014, 82 Fed. Reg. 45592 (September 29, 2017).

134.

Providers who meet the amount-in-controversy requirement must decide whether to undertake an attempt at escalation. As an initial matter, escalation may be thwarted by the DAB: The DAB may prevent escalation to federal court by remanding the claim to the ALJ level, 42 C.F.R. § 405.1108(d)(3), where the claim will languish in a futile loop of escalation and remand. Under that scenario, appealing providers that attempt to escalate may instead merely forfeit their position in the ALJ queue.

135.

Alternatively, if the DAB permits escalation to federal court by providing notice that it will not issue a decision, an appealing provider must face the dilemma of whether to wait out the lengthy administrative review delays or incur the cost of a federal court lawsuit, which is neither an adequate remedy nor a viable alternative.

136.

Federal court escalation is not an adequate remedy for the APMC because (a) the APMC would not be offered an evidentiary hearing; and (b) the court will have before it only the paper record and determination made by the QIC without the hearing and will lack the benefit of an independent ALJ's findings of fact and conclusions of law.

137.

In view of the undeveloped record before the federal court, the court might remand the matter to the agency for fact-finding. This result would send the APMC back to the endless loop of escalation and remand with no meaningful opportunity to be heard and no decision on the merits.

V. Impact of the Backlog

138.

Providers such as the Practice are suffering nationwide under HHS's refusal to render decisions on appeals in a timely manner. While ongoing delays continue to grow, providers must repay the amount initially reimbursed before they get to the third and fourth levels of appeal. In this case, Dr. Dole and his staff continue to provide medically

necessary services to Medicare beneficiaries, while receiving no reimbursement and having to pay all costs of providing the services out of pocket.

139.

The deprivation of funds tied up in the appeals process is a profound problem. In the APMC's case, the funds are needed for patient care or to sustain the Practice, its facilities, and staff necessary to provide the care. The delays in the system strain cash flow and have a direct impact on patient care. HHS's delay in meeting the statutory Medicare claim appeal deadlines thus presents a serious threat to the APMC's ability to continue to provide quality patient care while maintaining financial viability.

THE UNDERLYING BILLING DISPUTE

140.

The APMC is currently in the process of appealing two alleged overpayments following post-payment reviews performed by AdvanceMed. Neither appeal has been assigned to an ALJ.

141.

On November 2, 2015, AdvanceMed requested medical records from the APMC to initiate a post-payment review of Medicare reimbursements for Evaluation and Management (E&M) services, Nerve Conduction Studies (NCS) and Electromyography (EMG), Quantitative (Definitive) Urine Drug Testing (UDS), and Smoking Cessation Counseling.

142.

Subsequently, on April 4, 2016, AdvanceMed again requested medical records from the APMC to initiate another post-payment review of Medicare reimbursements for Evaluation and Management (E&M) services, Nerve Conduction Studies (NCS) and Electromyography (EMG), Quantitative (Definitive) Urine Drug Testing (UDS), and Smoking Cessation Counseling.

143.

The APMC produced records to AdvanceMed at considerable time and expense to the Practice.

144.

By letter dated September 29, 2016, AdvanceMed provided results from both post-payment reviews and alleged that the APMC had received two alleged overpayments: one post-payment review involved a set of fifty-eight (58) claims that resulted in an alleged 85% error rate (82% denial rate and a 3% change rate). The amount of alleged overpayment related to these claims was $9,268.48; the other post-payment review involved a set of ninety (90) claims that resulted in an alleged seventy-five percent (75%) error rate on a base amount of $10,466.84. This $10,466.84 amount was subjected to an extrapolated calculation, whereby AdvanceMed alleged that the APMC had been overpaid a total of $4,339,672.96.

145.

AdvanceMed denied the claims in the two post-payment reviews on several alleged grounds: (i) the billed services were not considered reasonable and necessary; (ii)

some of the services were statutorily excluded; (iii) there was lack of documentation; and (iv) diagnostic testing provided was not used in the management of the beneficiaries care. Notably, AdvanceMed's review was based exclusively on a retroactive record review performed by non-physician reviewers, without any communications with or input from the physician who had actually interacted with and treated the patient.

146.

On October 5, 2016, Novitas adopted these findings and issued an overpayment demand letter demanding that $4,339,672.96 be paid by November 3, 2016 to avoid interest charges.

147.

On December 20, 2016 the APMC timely requested a redetermination of this initial determination. Novitas issued its redetermination decision on February 9, 2017, not surprisingly granting no relief.

148.

On October 18, 2016, Novitas, after adopting AdvanceMed's allegation of an overpayment of $9,268.48, issued an overpayment demand letter, demanding $9,268.48.

149.

On January 12, 2017 the APMC timely requested a redetermination of this initial determination. Novitas issued its redetermination decision on March 3, 2017, not surprisingly granting no relief.

150.

On April 6, 2017, the APMC submitted a request for the reconsideration of Novitas's decision on the $4,339,672.96 appeal to C2C Innovative Solutions, Inc. ("C2C"), a Medicare Part B East QIC Contractor. C2C issued its Reconsideration Decision on June 16, 2017.

151.

On April 27, 2017, the APMC submitted a reconsideration request to C2C on the $9,268.48 appeal. C2C issued its final Reconsideration Decision in the first post-payment review on July 7, 2017.

152.

The Novitas overpayment demand letters informed the APMC that it would begin recoupment in both cases, plus interest, after thirty (30) days had passed from the APMC's receipt of the letters.

153.

On July 28, 2017, and August 18, 2017, respectively, the APMC's timely submitted requests for ALJ hearings were received. By law, the APMC was entitled to have an ALJ determination by November 16, 2017. As of this date, the APMC had not even been assigned to an ALJ for a hearing. The OMHA website currently shows that the APMC has appealed but due to "delay" an ALJ has not been assigned to the appeals.

IRREPARABLE HARM

154.

CMS is and has been recouping 100% of the APMC's Medicare reimbursements since it received the QIC's decision.

155.

As of early August 2018, CMS has recouped approximately $2.04 million.

156.

The APMC has not received any funds from Medicare since July 3, 2017.

157.

Prior to the institution of recoupment, the APMC's Medicare reimbursements represented more than 40% of the total Practice revenue.

158.

Since recoupment began, the APMC has been treating every Medicare beneficiary on its patient census at a cost to the APMC.

159.

The delay in the appeals process and continued recoupment at 100% plus interest also has irreparably harmed the APMC by interfering with the APMC's business.

160.

The APMC has had difficulty meeting its financial obligations as a result of the recoupment. The APMC has had to borrow money in 2018 to cover expenses.

161.

Because of financial strain on the APMC, it has been unable to bring a new physician into the APMC. Additionally, the APMC has had to reduce its staff by one-fourth, including the loss of one of its two nurse practitioners.

162.

As a Board certified sole pain management practitioner who takes care of many Medicare patients, Dr. Dole must practice medication management while also having to consider other, sometimes multiple, comorbidities. This type of patient management can be very time-consuming. The addition of another physician to the APMC at this time would be at an expense not offset by any additional Medicare revenue.

163.

The current recoupment also prevents Dr. Dole from joining another practice because of the pending recoupments. Linking his provider number to another practice could taint the other practice, and might put the other provider at risk of a decrease in Medicare reimbursement.

164.

If Dr. Dole were to attempt to sell an ownership interest in the Practice, in whole or in part, any purchasing physician would be at risk for the remaining recoupment.

165.

The delay in the appeals process and continued recoupment has also irreparably harmed the APMC by interfering with patient relationships.

166.

While Dr. Dole is one of only two pain management physicians in the Alexandria area who provide medication management to Medicare beneficiaries suffering from chronic pain, the other physician is severely limiting the number of new Medicare patients he will take.

167.

The APMC also has had to severely limit acceptance of new Medicare patients because the Practice is not being paid and will not be paid by Medicare until the entire $4,339,672.96 and $9,268.48, plus interest, has been collected.

168.

As a result of the recoupment, these Medicare beneficiaries in the Alexandria area are either forced to travel extreme distances to be seen by a physician elsewhere who will treat their chronic pain with medication management, or they may go without necessary and appropriate care.

169.

If the APMC will not be granted an ALJ hearing for the next five (5) or more years, it is being denied the opportunity to offer evidence to a neutral arbiter, in a timely fashion, that all or part of the recoupment was in error. For the Defendants to be permitted to hold funds, particularly this amount of funds, indefinitely and under circumstances the government created in violation of its own rules constitutes irreparable injury on its face.

170.

It is unknown how much longer the APMC can withstand the financial strain of Defendants' recoupment, and the future existence of the APMC is becoming a consideration.

171.

In addition to not being paid for treating the APMC's current Medicare patients, the APMC loses money on every Medicare beneficiary treated. The APMC receives no reimbursement to cover the cost of related services and supplies. Despite this loss, the Practice cannot (and would not) discharge the entire Medicare population in one fail swoop, and must continue treating these beneficiaries at a loss.

172.

The APMC anticipates that if Defendants are to continue recouping without any opportunity for an attempt at relief in sight, the APMC could be forced either to close the practice or, alternatively, to reduce staff and services. It is doubtful that the APMC's employees could find equivalent work in the Alexandria area.

173.

The harm to the APMC, its employees, its patients, and the community is therefore irreparable.

LIKELIHOOD OF SUCCESS ON THE MERITS

174.

The facts are not in dispute. The APMC has identified the applicable laws and regulations, the chronology of events, the status of the recoupment, the status and failure

to receive an ALJ hearing within the time frames mandated by law, and the APMC's right to recovery in this lawsuit.

COUNT ONE

INJUNCTIVE RELIEF

175.

The allegations contained in paragraphs 1 through 174 are incorporated by reference as if fully set out herein.

176.

The APMC has no other avenue to stay the continued recoupment of payments. Therefore, without intervention from this Court, the APMC, its patients and the community the APMC serves will continue to suffer irreparable harm.

177.

If recoupment is allowed to proceed indefinitely, the APMC will have suffered irreparable harm and 100% recoupment will have occurred long before it receives an opportunity to have a meaningful review by an impartial and unbiased ALJ. The APMC's patients will suffer immediate and irreparable harm, including, but not limited to, the loss of Dr. Dole's specialized treatment, and his ability to provide medication management services to Medicare patients with chronic intractable pain in the Alexandria area. The APMC will suffer a loss of good will and business reputation, and, ultimately, the loss of economic viability.

178.

Under these circumstances, with the extraordinary backlog of claims at the ALJ and DAB levels, the administrative appeal process mandated by law does not afford an adequate remedy at law because recoupment of over $4.3 million and $9,268.48, plus interest, on both amounts, and the complete withhold of all Medicare reimbursement threatens the APMC's ability to stay open and continue treating Medicare beneficiaries, and detrimentally affects the Medicare population.

179.

The APMC's legitimate expectation of receipt of Medicare payments for services provided to patients and Dr. Dole's interest in engaging in the practice of medicine, specifically the narrow practice of pain management in Alexandria, Louisiana, and maintaining the goodwill associated therewith, constitute valuable property and liberty rights and interests protected by the United States Constitution.

180.

The requested relief will not adversely affect any public interest and will instead, further it. There is no harm to the government resulting from a provider being permitted to enforce rights granted under federal law and regulation, rights the Defendants themselves granted. The harm here is to the APMC, patients, and the Medicare community in Alexandria and the surrounding areas if the requested relief is not granted. The balance of the harms clearly favors the APMC, its employees, its patients, and the surrounding community, while CMS cannot demonstrate any harm to the United States if

an injunction is issued. HHS and CMS cannot be harmed by being required to follow rules they created.

181.

The APMC seeks only to return to the status quo pending the outcome of a hearing before an ALJ. The APMC seeks an injunction preventing the Defendants from continuing to recoup the APMC's Medicare payments prior to a decision from an unbiased and impartial ALJ on the merits of the billing dispute.

COUNT TWO

PROCEDURAL DUE PROCESS

182.

The allegations contained in paragraphs 1 through 174 of this Complaint are incorporated by reference as if fully set out herein.

183.

The contractors and procedures created by CMS greatly increase the number of post-payment reviews without any increase in the ALJ pool. They permit recoupment of substantial, extrapolated, alleged overpayments based on the determinations of entities that have an established track record of overstating overpayments are constitutionally inadequate.

184.

To satisfy the requirements of due process, the Secretary is required by law to provide an appealing provider with a timely ALJ hearing. The Secretary is required to afford an opportunity to challenge the overpayment determinations before a fair and

impartial decision maker prior to imposing a self-help recoupment remedy that would cause irreparable harm, such as in this case.

185.

Defendants are depriving the APMC of its property interests in or associated with its Medicare payments and medical practice and goodwill without due process of law, in violation of the United States Constitution and other applicable law. Such action is causing irreparable harm to the APMC and the patients Dr. Dole treats. The issuance of injunctive relief prohibiting such recoupment until such due process has been had will not harm the Defendants and is in the public interest.

COUNT THREE

ULTRA VIRES

186.

The allegations contained in paragraphs 1 through 174 of this Complaint are incorporated by reference as if fully set out herein.

187.

Defendants are required to provide the APMC with an ALJ hearing and decision within ninety (90) days of its request. 42 U.S.C. § 1395ff(d)(1)(A); 42 C.F.R. § 405.1016. ALJ hearing requests were made on July 28, 2017 and August 18, 2017. Accordingly, the APMC was entitled to a hearing and decision at least by November 16, 2017.

188.

Defendants are recouping all of the APMC's Medicare payments even though they cannot, have not and will not provide the ALJ hearing in the legally required time frame.

189.

Such actions are contrary to the limitations on the Defendants' authority as set forth in the Medicare Act, and are in essence ultra vires.

190.

The Court should enjoin Defendants from engaging in such ultra vires actions against the APMC.

191.

Defendants will have taken the entire amount of alleged overpayments from the APMC's Medicare receivables in years prior to the ALJ hearing, and during these years the APMC, patients, and the surrounding community will be harmed irreparably by Defendants' ultra vires actions.

192.

The Court should enjoin Defendants from engaging in such ultra vires actions against the APMC, which actions are contrary to the limitations on the Defendants' authority as set forth in the Medicare Act.

COUNT FIVE

RELIEF UNTER THE MANDAMUS ACT (28 U.S.C. 1361)

193.

The allegations contained in paragraphs 1 through 174 of this Complaint are incorporated by reference as if fully set out herein.

194.

The Mandamus Act, 28 U.S.C. § 1361, vests district courts with original jurisdiction over 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 Plaintiff.

195.

Mandamus may issue when (1) the plaintiff has a clear right to relief, (2) the defendant a clear duty to act, and (3) no other adequate remedy exists.

196.

According to the SSA, the APMC has a clear right to a decision on a hearing before an ALJ.

197.

Under federal law, HHS has a clear, indisputable, and non-discretionary duty to "conduct and conclude a hearing on a decision of a qualified independent contractor . . . 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).

198.

Accordingly, the Secretary should have afforded the APMC an ALJ hearing and decision by November 16, 2017 and should be ordered to grant the APMC a hearing within a reasonable period of time following the Court's decision.

199.

HHS has breached this duty by acting in derogation of law by, *inter alia*, permitting its delegee, OMHA, to fail to hold hearings and render decisions within ninety days at the ALJ level.

200.

HHS's delays throughout the appeals process, and most notably at the ALJ level, plainly violate the timetables set forth by Congress in the Medicare Act.

201.

HHS's delays in resolving Medicare appeals affect human health and welfare by compromising the economic well-being of providers such as the APMC and the health and wellbeing of Medicare beneficiaries.

202.

Absent mandamus, the APMC has no adequate remedy. Neither the DAB nor the federal district courts can provide an adequate remedy. The escalation process does not provide a meaningful option for the reasons alleged above. It deprives the APMC of it right to an evidentiary hearing and the presentation of testimony of Dr. Dole and expert witnesses, while imposing costs that threaten the very value of the remedy the APMC seeks.

203.

Accordingly, the Defendants should be ordered to provide the APMC a timely ALJ hearing, no later than 90 days after the Court renders its decision and Order; or, alternatively, upon the Court's granting of injunctive relief, within a reasonable time

period after Defendants have corrected the deficiencies and backlog that caused a violation of the APMC's rights.

PRAYER

WHEREFORE, the APMC respectfully requests the following relief:

1. That the Court grant a preliminary and permanent injunction, preventing the Defendants from further recouping from the APMC's Medicare receivables prior to the completion of the ALJ hearing;

2. That the Court grant a preliminary and permanent injunction, preventing the Defendants from applying interest to any future alleged outstanding overpayment amounts prior to the completion of the ALJ hearing;

3. That the Court enter an order requiring Defendants to provide the APMC a hearing before an ALJ, as required by law, within 90 days, or, alternatively, upon the Court's granting of injunctive relief, within a reasonable time period after Defendants have corrected the deficiencies and backlog that caused a violation of the APMC's rights;

4. That the Court enter an Order requiring Defendants to otherwise comply with their statutory and regulatory obligations in administering the appeals process, including honoring deadlines; and

5. That the Court enter a judgment in favor of the APMC for costs and reasonable attorney's fees pursuant to 28 U.S.C. § 2412, 28 U.S.C. § 1920.

Respectfully submitted:

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UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUSIANA

ALEXANDRIA DIVISION

MICHAEL DOLE, MD, A PROFESSIONAL MEDICAL CORPORATION **Plaintiff**	**CIVIL ACTION NO.** **JUDGE**
v.	**MAGISTRATE JUDGE**
Alex M. Azar, in his official capacity as Secretary of the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES and Seema Verma, in her official capacity as Administrator for the CENTERS FOR MEDICARE AND MEDICAID SERVICES **Defendants**	

VERIFICATION AND DECLARATION OF MICHAEL DOLE, M.D.

I, Michael Dole, M.D., am of full age and swear the following to be true:

1. I am the sole shareholder and president of Michael Dole, MD, A Professional Medical Corporation.

2. I have read the foregoing Complaint for Injunctive Relief and Mandamus and know the contents thereof and that the factual statements contained therein are true and correct to the best of my knowledge, information and belief and upon review of the business records of Michael Dole, MD, A Professional Medical Corporation.

Pursuant to 28 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and information.

Executed on this 10 day of September, 2018.

Michael Dole, M.D.