UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

JOANNE BARROWS, SUSAN HAGOOD, SHARON MERKLEY, LORRAINE KOHL, and DOLLY BALANI, individually and on behalf of all other similarly situated, Plaintiffs, vs. HUMANA, INC., Defendant.	Case No. 3:23-cv-00654-RGJ

PLAINTIFFS' MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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I. INTRODUCTION

This putative class action arises from Humana's unlawful and undisclosed use of artificial intelligence to wrongfully make coverage determinations for elderly patients' post-acute care without sufficient individualized review by doctors. Humana uses an AI Model known as nH Predict to make claims determinations and override real treating physicians' determinations as to medically necessary care patients require. Humana knows that nH Predict's results are highly inaccurate and are not based on patients' individual medical needs but continues to use nH Predict to make coverage determinations to the detriment of its insureds. Plaintiffs and Class members are enrollees of Humana's Medicare Advantage plans who have had post-acute care coverage determinations processed, and ultimately denied, by Humana via nH Predict. Plaintiffs, on behalf of themselves and the Class, assert claims for breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, unfair claims settlement practices, unfair methods of competition, insurance bad faith, unfair and deceptive insurance practices, and common law fraud.

Now, Humana brings their Motion to Dismiss ("MTD") arguing that Plaintiffs' claims should be dismissed because: (1) this Court lacks jurisdiction because Plaintiffs were required to exhaust administrative remedies and failed to do so; and (2) that Plaintiffs' claims are preempted by the Medicare Act. MTD at 2. Both arguments fail.

This Court has jurisdiction because Plaintiffs' claims do not "arise under" the Medicare Act. Even if this Court finds Plaintiffs' claims do arise under the Medicare Act and exhaustion applies, only the presentment requirement is a true jurisdictional inquiry, which Plaintiffs have clearly satisfied here. Further, the circumstances here warrant judicial waiver of the exhaustion prong because (1) Plaintiffs' claims are wholly collateral to claims for benefits; (2) Humana's

conduct puts Plaintiffs at risk of irreparable harm if they were required to exhaust administrative remedies; and (3) exhaustion would be futile because Humana abuses the appeals process and the Secretary lacks the authority to grant the relief sought by Plaintiffs via administrative appeal.

Additionally, Plaintiffs' common-law claims are not preempted because the Medicare Act's express preemption provision is inapplicable to state common law and Plaintiffs' statutory claims are not preempted because those claims do not "arise under" the Medicare Act.

For these reasons, Humana's Motion to Dismiss should be denied in its entirety.

II. BACKGROUND

Humana covertly uses nH Predict, an artificial intelligence algorithm developed by a contractor called naviHealth, in its Medicare Advantage plans to make coverage determinations for elderly patients' post-acute care claims. First Am. Compl. ("FAC") ¶¶ 1 ,7. Despite a 90% error rate and a factual finding by the Senate that 80% of prior authorization claims alone are reversed on appeal, Humana continues to systemically use this flawed AI algorithm to make coverage determinations because they know only a tiny minority of policyholders (roughly 0.2%) will appeal denied claims. FAC ¶¶ 41, XX. The vast majority of policyholders will either pay out-of-pocket costs or forgo the remainder of their medically necessary post-acute care—a grand savings for Humana. FAC ¶¶ 4, 9. Humana banks on patients' impaired physical and mental conditions, lack of knowledge, and lack of resources to appeal the wrongful AI-driven coverage determinations. FAC ¶ 3.

This scheme affords Humana a clear financial windfall in the form of policy premiums and savings on review staff, all while also saving on care they would have otherwise been required to cover but-for these sham algorithmic coverage determinations. FAC ¶ 4, 9. Humana's practice leaves patients without means to have their claims determined based on their medical necessity,

instead resulting in elderly patients being prematurely kicked out of care facilities nationwide, forced to deplete their life savings to continue receiving necessary medical care, or being forced to forgo care altogether risking serious injury or death—all because the nH Predict algorithm "disagrees" with their real live doctors' determinations. *Id.*

A. NH PREDICT IS UNREGULATED, UNDISCLOSED, AND UNLAWFULLY USED BY HUMANA TO UNJUSTLY INCREASE PROFITS AT THE EXPENSE OF VULNERABLE ELDERLY PATIENTS

Using nH Predict, Humana purports to predict how much care a patient "should" require by comparing demographic and surface-level data points with a database of other patients. FAC ¶¶ 7, 34. nH Predict takes this data and issues a discharge date based on the amount of time it took *other patients* to recover, without considering patients' individualized circumstances or doctor's recommendations. *Id.* Humana uses nH Predict to terminate coverage of patients' claims as soon as possible. FAC ¶¶ 6–7. Humana and the naviHealth contractor it employs intentionally limit employees' discretion to deviate from the nH Predict predicted discharge dates by setting targets to keep lengths of stay within 1% of the days projected by nH Predict. FAC ¶¶ 8, 37. Employees who deviate from the nH Predict prediction are disciplined or terminated, regardless of whether a patient requires more care. *Id.* This "length-of-stay" budget factors into Humana's employees' bonus determinations—if employees come in under budget by ensuring patients receive less care, they receive higher bonuses. FAC ¶ 44. Humana's delegation of coverage determinations to nH Predict is contrary to the requirements of state laws Humana is required to abide by, beyond the reach of the Secretary to remedy, and otherwise unregulated. FAC ¶¶ 33, 42.

Humana's use of nH Predict is undisclosed, and is even actively concealed, from patients. FAC ¶ 39. When patients or their doctors request to see the bases for the denials, Humana or their agents deny their requests and tell them the information is proprietary. FAC ¶ 39. Humana actively

deceives its insureds by stating in its written policies that it does not provide financial incentives to employees for denying coverage, and that in the event of a denial, an accurate written statement will be provided explaining the basis for the denial. FAC ¶¶ 139, 144. When Humana issues denials based on nH Predict, they do not explain that the basis for the denial was nH Predict's determination—instead, they fabricate pretextual reasons, often claiming that the care was not medically necessary. These medical necessity determinations are being made by a flawed algorithm, not by actual doctors. FAC ¶¶ 7, 33.

B. EXHAUSTION/PLAINTIFFS

When Humana decides to end coverage before doctors' recommended discharge date, patients are left with an impossible choice—to either forgo medically necessary care despite not being well enough to function without it, or to pay out-of-pocket to continue receiving care that they were wrongfully denied—if they can afford it. FAC ¶ 31. Humana also uses nH Predict to review and deny some claims before treatment has even begun, by issuing prior authorization denials. FAC ¶ 32. Because of Humana's use of nH Predict to make coverage determinations, patients rarely receive post-acute care for more than 14 of the 100 days they are eligible for before they start receiving denials. FAC ¶ 38.

Upon receiving denials, patients have the option to appeal the denials. The appeals process provides for four levels of administrative review: (1) an appeal before an independent third-party reviewer called a Quality Improvement Organization ("QIO"); (2) a reconsideration by the QIO; (3) a hearing before an administrative law judge; and (4) review by the Medicare Appeals Council. FAC ¶¶ 40, XX. These administrative reviewers have the limited authority to overturn denials and reinstate benefits in individual cases. FAC ¶ 40.

However, Humana's abuse of the appeals system coupled with the limited authority of administrative reviewers make exhaustion of administrative appeals futile. FAC ¶¶ 40–43. If

Plaintiffs' denials are reversed on appeal, Humana immediately issues another denial despite having no factual basis for doing so, forcing patients to restart the appeals process from the beginning. FAC ¶ 43. For example, Plaintiff Sharon Merkley received *seven* denials for the same care within 30 days, each after a successful appeal and without a factual basis for doing so. FAC ¶¶ 78–86. After a subsequent hospital stay a month later, Humana issued *five* more denials for post-acute care—also after successful appeals, and also without factual bases. FAC ¶¶ 90–94.

Further, in the rare case a patient's appeal makes it to the third level before an ALJ, Humana frequently pays the claim or defaults at the hearing. FAC ¶ 46. Thus, patients are unable to exhaust administrative remedies, rendering any benefits challenges unreviewable in court—while only requiring Humana to pay the tiny fraction of claims that make it to the ALJ to receive such strong protection. FAC ¶¶ 46–47.

Even if Humana did not stand in the way of exhaustion administrative remedies, exhaustion often takes years. FAC ¶ 45. While waiting for a decision on appeal, patients are left with two options: (1) stay in the post-acute care facility and risk being responsible for months or years of medical bills if their appeals are denied; or (2) forgo care while they await a decision. *Id.* Plaintiffs are elderly and/or ill patients who have suffered serious medical traumas—if they opt to forgo care while awaiting a decision on appeal, they risk further serious injury. *Id.*

For example, when Humana terminated Plaintiff JoAnne Barrows' coverage, she was bedridden and using a catheter. FAC ¶ 56. Because Mrs. Barrows could not afford the facility her doctor recommended, she was transferred to a more affordable facility where she received substandard care, jeopardizing her health. FAC ¶¶ 58–59. Fearing for her health and safety, Mrs. Barrows opted to return home despite not being unable to use her leg, use the restroom without assistance, and while she still used a catheter. FAC ¶ 60. When Humana refused to pay for Plaintiff

Susan Hagood's care she had just been readmitted to the hospital for her serious and worsening condition, including a multi-level disc edema with discitis osteomyelitis, consolidative phlegmon within her epidural spaces, a large staghorn calculus in each kidney, and pneumonia. FAC ¶ 68. Humana terminated Plaintiff Lorraine Kohl's rehab care just three weeks after she fractured her hip, claiming that she needed "little" help to move around, when she was completely unable to walk. FAC ¶ 98. Humana denied prior authorization for Plaintiff Dolly Balani's post-acute care, despite her recently fractured hip and her doctor deeming her at risk of falling. FAC ¶¶ 110–11.

III. ARGUMENT

A. PLAINTIFFS ARE NOT REQUIRED TO EXHAUST ADMINISTRATIVE REMEDIES, AND THIS COURT THEREFORE HAS JURISDICTION

Section 405(h) of the Social Security Act precludes judicial review in any action challenging the denial of claimed benefits, except as provided for by Section 405(g). See 42 U.S.C. § 405(h); *Mathews v. Eldridge*, 424 U.S. 319, 327 (1976); *Weinberger v. Salfi*, 422 U.S. 749, 757–58 (1975).

Conversely, actions that do not challenge the denial of benefits (and thus do not "arise under" the Medicare Act) are not restricted by Sections 405(h) and 405(g) and may be freely reviewed by this Court. *See Salfi*, 422 U.S. at 760–61 (construing 405(g) only to require exhaustion for claims of entitlement to benefits); *Heckler v. Ringer*, 466 U.S. 602, 605, 614–15 (1984) (applying Section 405(g) only to claims "arising under the Medicare Act").

Humana argues this Court lacks jurisdiction over Plaintiffs' claims, asserting that Plaintiffs' claims arise under the Medicare Act, which requires them to exhaust administrative remedies. MTD at 12. Humana is wrong and overstates the jurisdictional nature of the exhaustion analysis. Even if this Court finds Plaintiffs' claims arise under the Medicare Act and exhaustion applies, only the presentment requirement is a true "jurisdictional" inquiry, and Plaintiffs have

clearly satisfied that threshold inquiry by alleging sufficient presentment of their claims. *See infra* Section I.B.1; *see also Eldridge*, 424 U.S. at 328; *A1 Diabetes & Med. Supply v. Azar*, 937 F.3d 613, 617 (6th Cir. 2019) (recognizing *Eldridge* as holding "that § 405(g)'s exhaustion requirement is not a jurisdictional prerequisite for review in federal court."); *Accident, Inj. & Rehab., PC v. Azar*, 943 F.3d 195, 200 (4th Cir. 2019) (stating that in *Eldridge*, "the Supreme Court specifically held that the § 405(g) exhaustion requirement is not jurisdictional because its mandate can be waived, whereas a defect in the subject-matter jurisdiction of a court cannot be waived").

This Court has jurisdiction over Plaintiffs' claims because (A) Plaintiffs' claims do not arise under the Medicare Act, and thus are not subject to the exhaustion requirement; and (B) even if Plaintiffs' claims are subject to the exhaustion requirement, Plaintiffs have adequately presented their claims and the circumstances warrant judicial waiver of the exhaustion prong.

1. Exhaustion is Not Required Because Plaintiffs' Claims Do Not Arise Under the Medicare Act

A claim "arises under" the Medicare Act when (1) the "standing and substantive basis for the presentation of the claims" is the Medicare Act; or (2) it is "inextricably intertwined" with a Medicare benefits determination. *Salfi*, 422 U.S. at 760–61. Humana makes no arguments that the "standing and substantive basis" for Plaintiffs' claims is the Medicare Act, and instead only argues that Plaintiffs' claims are "inextricably intertwined" with a claim for benefits. MTD at 13–14.

To determine whether a claim is "inextricably intertwined" with a Medicare benefits determination, courts examine whether the claim is, "at bottom," a claim for benefits. *See Ringer*, 466 U.S. at 614. To reiterate, Plaintiffs do not seek benefits—they instead only challenge

Humana's use of the nH Predict AI Model to make coverage determinations.[1]

Humana mistakenly argues that Plaintiffs' claims are "inextricably intertwined" with a claim for benefits, partly because they misunderstand Plaintiffs' claims as challenging "the denial of benefits." MTD at 14–15 (citing *Harwood* and *Hepstall*, in which the courts found the plaintiffs challenged the denial of Medicare benefits or sought Medicare benefits as a remedy). Humana, and the cases it cites, rely chiefly upon *Ringer*.

The Supreme Court found the claims at issue in *Ringer* were "inextricably intertwined" with claims for benefits because plaintiffs sought an injunction compelling the Secretary to declare a certain procedure reimbursable under the Medicare Act, such that "only essentially ministerial details will remain before [plaintiffs] would receive reimbursement." 466 U.S. at 615–16. Unlike here, the claims in *Ringer* were claims for benefits merely disguised as a procedural challenge. *See id.*

Humana also argues that "[e]ven claims challenging the *process* by which a Medicare coverage determination is made are inextricably intertwined with claims for Medicare Benefits." MTD at 15. However, the cases cited by Humana involve, like *Ringer*, claims for benefits *disguised* as procedural challenges—not true procedural challenges like those brought by Plaintiffs here. *See Ex Parte Blue Cross & Blue Shield of Ala.*, 90 So.3d 158, 164 (Ala. 2012) ("Although framed as a contractual dispute . . . [plaintiff's] claim is, 'at bottom,' a claim that [plaintiffs] are

[1] FAC ¶ 2 ("By this action, Plaintiffs challenge the process employed by Humana to make claim determinations—i.e., its use of the nH Predict AI Model—and not the denial of any individual claim."); *see, e.g.,* FAC ¶ 145 ("By using the nH Predict AI Model to resolve Plaintiffs' and Class members' claims without an adequate individualized investigation, Humana breached the insurance agreement"); FAC ¶ 150 ("Humana has breached its duty of good faith and fair dealing by . . . Improperly delegating its claims review function to the nH Predict AI Model system"); see also FAC ¶ 157 (Unjust Enrichment); FAC ¶ 166 (Unfair Claims Settlement Practices); FAC ¶ 177 (Unfair Methods of Competition); FAC ¶ 187 (Insurance Bad Faith); FAC ¶ 209 (Unfair and Deceptive Insurance Practices); FAC ¶ 212 (Common Law Fraud).

being denied coverage and/or benefits to which they are entitled"); *DiCrescenzo v. UnitedHealth Group, Inc.*, 2015 U.S. Dist. LEXIS 123852, at *9 (D. Haw. Sept. 16, 2015) (finding plaintiff's claims "inextricably intertwined" with a claim for benefits because it "inevitably turn[ed] upon a determination that [plaintiff] was entitled to a Medicare benefit"); *Moses v. United Healthcare Corp.*, 2020 U.S. Dist. LEXIS 74260, at *8 (D. Ariz. Apr. 28, 2020) (holding plaintiff's claims arose under the Medicare Act because they "directly concern[ed] the denial of Medicare benefits"); *Zhang v. UnitedHealthcare*, 2021 U.S. Dist. LEXIS 143138, at *3 (D. Ariz. July 30, 2021) (finding plaintiff's claims for consequential damages arose under the Medicare Act because he sought "pain and suffering" damages caused by the denied benefits, which the court found was "inextricably intertwined" with his claim for benefits).

Here Plaintiffs' claims are not based on the denials of benefits, disguised or otherwise, but instead the use of nH Predict to make coverage determinations (regardless of the outcome) without sufficient individualized review of the merits of their claims. *See supra* note 1. Thus, Plaintiffs' claims are distinguishable from the claims in *Ringer* (and the cases that relied on *Ringer*), because Plaintiffs' claims are not, "at bottom," claims for benefits.

Therefore, Plaintiffs' claims do not arise under the Medicare Act, and they were not required to exhaust administrative remedies before seeking relief in federal court.

2. Even if it Applied, Plaintiffs Satisfy the Exhaustion Requirement Because They Meet the Requirements for Judicial Waiver of the Exhaustion Prong and Have Presented Their Claims.

Section 405(g) allows for judicial review when two requirements are met: (1) the plaintiff must present the claim for benefits to the Secretary; and (2) the administrative remedies prescribed by the Secretary must be exhausted or waived. *See* 42 U.S.C. § 405(g); *Eldridge*, 424 U.S. at 328. To the extent that the "presentment" requirement remains a nonwaivable jurisdictional inquiry, Plaintiffs have satisfied it here. *See Ringer*, 466 U.S. at 617; *Eldridge*, 424 U.S. at 328. The second

requirement is waivable and not a bar to jurisdiction. *See A1 Diabetes & Med. Supply v. Azar*, 937 F.3d 613, 617 (6th Cir. 2019) (recognizing *Eldridge* as holding "that § 405(g)'s exhaustion requirement is not a jurisdictional prerequisite for review in federal court.").

a) Plaintiffs Have Satisfied the Presentment Requirement

The presentment requirement to exhaustion is satisfied by presenting "an application for benefits; or, in the case of someone who had been receiving benefits and was terminated, it requires notification to the agency that the claimant still asserts disability." *Mental Health Ass'n v. Heckler*, 720 F.2d 965, 969 (8th Cir. 1983) (citing *Eldridge*, 424 U.S. at 329); *Ringer*, 466 U.S. at 617 (finding requirement satisfied when claims were submitted for reimbursement); *A1 Diabetes*, 937 F.3d at 617 (finding claims presented when first and second level appeals were processed); *Global Rescue Jets, LLC v. Kaiser Found. Health Plan, Inc.*, 30 F.4th 905, 915 (9th Cir. 2022) (finding presentment satisfied when the claims were submitted to the MAO in the first instance).

Humana mistakenly conflates the presentment and exhaustion prongs, arguing that this Court lacks jurisdiction because Plaintiffs did not receive final determinations from the fourth-level appeal before the Medicare Appeals Council. MTD at 18–19. However, presentment never requires complete exhaustion—it is a threshold inquiry that requires only that the claim be presented to the Secretary in the first instance, by submitting a claim for payment or a first-level appeal. *See Ringer*, 466 U.S. at 617; *A1 Diabetes*, 937 F.3d at 617; *Global Rescue Jets*, 30 F.4th at 915.

Plaintiff Dolly Balani was issued a prior authorization denial for inpatient rehab care. FAC ¶ 111. By seeking a determination from Humana in the first instance, she presented her claims. *See Global Rescue Jets*, 30 F.4th at 915.

Many Plaintiffs had benefits prematurely terminated by Humana. Plaintiff JoAnne Barrows presented her claims by appealing the denial—her appeal was denied. FAC ¶ 56. Plaintiff Sharon

Merkley was denied coverage seven times in thirty days and appealed every denial. FAC ¶¶ 79–86. Mrs. Merkley was admitted to another SNF a month later after a subsequent hospitalization. FAC ¶ 89. Humana denied coverage for her second stay another five times, and Mrs. Merkley appealed each denial. FAC ¶¶ 89–94. Plaintiff Lorraine Kohl appealed her multiple denials both to the independent reviewer and to Humana directly. FAC ¶¶ 99–106. Mrs. Balani also had skilled nursing benefits prematurely terminated by Humana—she has pursued that appeal to the Medicare Appeals Council but has not yet received a hearing. FAC ¶¶ 114–19.

Humana denied Plaintiff Susan Hagood's coverage for skilled nursing care after she had received treatment, leaving her with the bill—Mrs. Hagood adequately presented this claim by submitting her application for benefits in the first instance. FAC ¶ 69.

Thus, Plaintiffs have all satisfied the presentment requirement.

b) Plaintiffs Satisfy the Requirements for Judicial Waiver of the Exhaustion Prong

The exhaustion prong may be waived either by the Secretary or by a court. *Eldridge*, 424 U.S. at 330; *Bowen v. City of New York*, 476 U.S. 467, 484 (1986). The Supreme Court established judicial waiver in *Eldridge*, noting that "cases may arise where a claimant's interest in having a particular issue resolved promptly is so great that deference to the agency's judgment is inappropriate." *Eldridge*, 424 U.S. at 330; *Bowen*, 476 U.S. at 483. Particularly where the policy giving rise to the claims is a policy that claimants did not know existed, such as Humana's use of nH Predict to make claims determinations, exhaustion should not be required because "it would be unfair to penalize these claimants for not exhausting under these circumstances." *Bowen*, 476 U.S. at 483.

Judicial waiver is appropriate where (1) the claim is entirely collateral to claims for benefits; (2) irreparable harm would result from exhaustion; and (3) that exhaustion would

otherwise be futile. *See Bowen*, 476 U.S. at 483; *Eldridge*, 424 U.S. at 330–31; *Day v. Shalala*, 23 F.3d 1052, 1059 (6th Cir. 1994). Examining the prongs of this test, Plaintiffs have clearly satisfied its application here.

i. Plaintiffs' Claims are Collateral to Any Claim for Medicare Benefits

Plaintiffs' claims here are "wholly collateral" to a claim for benefits. In *Day*, the Sixth Circuit found that the plaintiffs' claims were wholly collateral to their claims for benefits because if the plaintiffs were to succeed, they "would not automatically be entitled to receive benefits if they prevail, but only to receive 'the procedure they should have been accorded in the first place.'" 23 F.3d at 1059 (citing *Bowen*, 476 U.S. at 484). The *Day* court went on to recognize that several other circuits have reached the same conclusion—challenges to procedure are wholly collateral to claims for benefits. *Id.* (citing *Schoolcraft v. Sullivan*, 971 F.2d 81, 86 (8th Cir. 1992); *Marcus v. Sullivan*, 926 F.2d 604, 614 (7th Cir. 1991); *State of New York v. Sullivan*, 906 F.2d 910, 918 (2d Cir. 1990); *Hyatt v. Heckler*, 807 F.2d 376, 379–80 (4th Cir. 1986)).

In *Bowen*, the Supreme Court held that plaintiffs' claims were collateral to claims for benefits because plaintiffs had challenged the very procedure by which claims were processed, rather than seeking benefits. 476 U.S. at 483. The Court stated that whether claimants received the "procedure they should have been afforded in the first place" was entirely collateral to the merits of their claims for benefits. *Id.*

The present case falls squarely within *Day* and *Bowen*—Plaintiffs do not seek benefits, but instead challenge the procedure by which their claims were processed. Plaintiffs' claims are therefore "wholly collateral" to their substantive claims of entitlement to benefits.

ii. Plaintiffs Would Suffer Irreparable Harm if the Exhaustion Prong Was Not Waived

To demonstrate irreparable harm, Plaintiffs must demonstrate that "deferment of judicial

review until exhaustion of administrative remedies would cause them injury that cannot be remedied by later payment of the benefits requested." *Martin v. Shalala*, 63 F.3d 497, 505 (7th Cir. 1995). Courts should "be especially sensitive to irreparable injury where the Government seeks to require claimants to exhaust administrative remedies merely to enable them to receive the rights that they should have been afforded in the first place." *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 504 (5th Cir. 2018) (citing *Bowen*, 476 U.S. at 484).

In *Bowen*, the Court noted that, like in *Eldridge*, the claimants would be irreparably injured if they were required to exhaust administrative remedies, because the "ordeal of having to go through the administrative appeal process" could trigger medical setbacks which could not be remedied by interim benefits or ultimate success on appeal. 476 U.S. at 484. Here, Plaintiffs suffered many such setbacks. For example, Mrs. Merkley was hospitalized again shortly after Humana's final denial because of forgoing care she should have received. FAC ¶¶ 88–89. These kinds of irreparable harms cannot be remedied by interim benefits, exhaustion of administrative process, or "ultimate success if they manage to pursue their appeals." *Bowen*, 476 U.S. at 485.

In *Schoolcraft*, the Eighth Circuit found irreparable harm when the claimants produced affidavits which "clearly demonstrate[d] the harms caused by administrative exhaustion." 971 F.2d at 86–87. The *Schoolcraft* court also recognized that the "overwhelming body of case law" states that retroactive benefits are not an adequate remedy. *Id.*; *see, e.g., Eldridge*, 424 U.S. at 331 ("an erroneous termination [of benefits] would damage [claimant] in a way not recompensable through retroactive payments"). In *Schoolcraft*, the court found that "eventual correction" of the "systemic errors at the initial and reconsideration stages of the administrative process" would not cure the harm the claimants suffered. 971 F.2d at 87.

In addition to the irreparable harm administrative exhaustion poses to elderly Class

members dealing with serious, often chronic injuries, the Eighth Circuit has also held that the high reversal rate for their claims denials augers in favor of waiver as a result of "irreparable harm." In *Mental Health Association*, the Eighth Circuit found that the irreparable harm resulting from exhaustion of administrative remedies was exacerbated by a high reversal rate on appeal of 80%. 720 F.2d at 970. Here, Plaintiffs allege that nH Predict's error rate is 90% and the United States Senate has made a factual finding that 80% of prior authorization requests denied by nH Predict are reversed on appeal. FAC ¶¶ 41.

Thus, Plaintiffs' allegations sufficiently allege that would suffer irreparable harm if they were required to exhaust administrative remedies before seeking relief in federal court.

iii. Pursuit of Further Administrative Proceedings Would be Futile

When "any efforts before the agency would be pointless, the courts do not insist that litigants go through the motions of exhausting the claim anyway." *Merit Leasing Co., LLC v. Becerra*, 2023 U.S. Dist. LEXIS 213713, at *19 (N.D. Ohio Dec. 1, 2023) (quoting *Herr v. U.S. Forest Serv.*, 803 F.3d 809, 822 (6th Cir. 2015)). In *Salfi*, the Court explained that the purposes of exhaustion are so "[that] the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." 422 U.S. at 765. The decision whether to waive exhaustion should be guided by these policies, not "solely by mechanical application of the *Eldridge* factors." *Bowen*, 476 U.S. at 484.

In *Bowen*, the Supreme Court found that exhaustion was futile and should be waived because the plaintiff's alleged a "systemwide, unrevealed policy that was inconsistent in critically important ways with established regulations." 476 U.S. at 485. Under these circumstances, the Court determined that "there was nothing to be gained from permitting the compilation of a

detailed factual record, or from agency expertise," rendering exhaustion futile. *Id.*

Here, exhaustion is futile for three reasons: (1) even if Plaintiffs succeed in any individual administrative appeal, Humana subjects them to immediate renewed denials that do not address the successful appeal with any new information, causing Plaintiffs to have to re-start the appeals process anew; (2) the Secretary lacks the authority to grant the relief necessary to systemically address Humana's improper denials based on the reliance on nH Predict; and (3) Humana abuses and undermines the administrative review process such that its conduct is capable of repetition while evading judicial review.

(1) Humana's Continuous Subsequent Denials Make It Impossible for Plaintiffs to Prevail on Appeal

In *Salfi*, the Court held that pursuing administrative remedies was futile when there was no chance that the claimant could prevail on appeal, stating that "further exhaustion would not merely be futile for the applicant, but would also be a commitment of administrative resources unsupported by and administrative or judicial interest." 422 U.S. at 765–66.

Here, it is impossible for Plaintiffs to truly prevail on appeal, because even if they receive a favorable determination on appeal, they will be faced with another denial within mere days. Humana's naviHealth reviewers are instructed to issue a new denial immediately following a successful appeal, without any change in circumstances to justify the new denial. FAC ¶ 43. By doing so, Humana can lock Plaintiffs and Class members into a perpetual loop of administrative appeals, until either the patient gives up and decides not to appeal further, fails to submit an appeal on time, or the patient dies. FAC ¶¶ 43, 45. Though Plaintiffs may obtain a favorable result in a single appeal, he or she is unable to obtain any relief that results in them receiving a meaningful amount of further required care, because they will only receive a few days of additional care before another denial is issued. FAC ¶ 43.

(2) Administrative Reviewers Lacks the Authority to Grant the Relief Sought by Plaintiffs

The authority of administrative reviewers is "circumscribed by the appointing agency's enabling statutes and its regulations." *Matthews v. Leavitt*, 452 F.3d 145, 152 (2d Cir. 2006). CMS has circumscribed the bounds of administrative review authority, in 42 U.S.C. § 1395w-22(g)(5), which allows review of challenges to payments of benefits. *Id.* In *Leavitt*, the Second Circuit was confronted squarely with the question of whether administrative reviewers had the authority to review state common law causes of action, and it ruled that they did not because Section 1395w-22(g)(5) did not grant them that authority. *Id.* (holding that an ALJ was "not vested with authority to hear an ordinary breach of contract suit for damages independent of his determination of entitlement to benefits").

Here, Plaintiffs seek nationwide injunctive relief and damages resulting from Humana's illegal conduct, not including damages for denied benefits. This relief is beyond the scope of the administrative remedies prescribed by the Secretary, making appeal before him futile. FAC ¶¶ 40, 42.

(3) Humana's Conduct is Capable of Repetition While Evading Review

Lastly, if exhaustion were required, Humana's conduct would be capable of repetition while evading review. Humana knows that if patients are required to exhaust administrative remedies, they need only pay the relatively small number of claims appealed before they reach the highest level of appeal, and its systemic misconduct would never be reviewable in court. FAC ¶ 47. Only 0.2% of people appeal their denials, and far fewer pursue their appeal to the third-level appeal before an ALJ. FAC ¶ 47. If an appeal reaches the ALJ, Humana frequently defaults or agrees to pay the claims. *Id.* In this way, Humana can ensure that virtually nobody is able to exhaust administrative remedies, making its conduct never reviewable in court unless exhaustion is

waived. *Id.*

The Eighth Circuit addressed a similar issue in *Schoolcraft*, stating, "We think the most telling and forceful argument plaintiffs make is that unless exhaustion is waived, if the *ALJ* implements the correct procedures and applies the correct standards and, where appropriate, awards benefits, there will never be judicial review to challenge the actions the DDS takes at the initial and reconsideration stages. Exhaustion would be futile if the challenged policy could never be judicially reviewed." 971 F.2d at 87. Similarly, here, so long as the ALJ continues to reverse nH Predict determinations on appeal, Humana's conduct will not be reviewable in court, as its unlawful denials will be overturned before patients are able to exhaust administrative remedies. *See* FAC ¶ 41 (alleging a 90% total appeal reversal rate, and 80% reversal of prior authorization claims).

Thus, it would be futile for Plaintiffs to exhaust their administrative remedies, and this Court should waive the exhaustion requirement as to Plaintiffs' claims, to the extent any are found to arise under the Medicare Act.

3. Humana is the Proper Defendant for Plaintiffs' Claims, Not the Secretary

Humana argues that, even if exhaustion were not required, Plaintiffs' claims fail because the Secretary, not Humana, is the proper party to answer for Humana's fraudulent and illegal conduct. MTD at 19–20.

Humana relies on two district court cases, *Madsen v. Kaiser Found. Health Plan, Inc.*, 2009 U.S. Dist. LEXIS 46122 (S.D. Cal. June 2, 2009) and *Ebert v. Anthem Health Plans of Ky., Inc.*, 2022 U.S. Dist. LEXIS 29553 (W.D. Ky. Feb. 18, 2022). However, the relevant statute and authority state that the Secretary is the proper defendant only for claims seeking review of final determinations from the Medicare Appeals Council. *See* 42 U.S.C. § 405(g); 42 C.F.R. §§

405.1136(a)(1), (d)(1); *Madsen*, 2009 U.S. Dist. LEXIS 46122, at *9 ("In any civil action seeking judicial review **of a decision of the Medicare Appeals Council**, 'the Secretary of HHS, in his or her official capacity, is the proper defendant.'") (emphasis added).

As Humana emphasizes, Plaintiffs have not exhausted their administrative remedies and have not been issued a final decision by the Medicare Appeals Council. Plaintiffs' claims do not arise under the Medicare Act, or alternatively Plaintiffs' claims are exempt from the exhaustion requirement—either way, Plaintiffs have not received a final determination from the Medicare Appeals Council, and thus Plaintiffs are not restricted by § 405.1136(d)(1), making Humana the proper party.

B. PLAINTIFFS' STATE LAW CLAIMS ARE NOT PREEMPTED BY THE MEDICARE ACT

1. The Text of the Preemption Provision Reaches Only Positive Statutory Enactments and Regulations, Not State Common Law

Plaintiffs' state common-law claims can go forward because they do not fall within the scope of Medicare preemption. The Medicare Act's express preemption provision provides:

> The standards established under [Part C] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under [Part C].

42 U.S.C. § 1395w-26(b)(3). The plain language of the statute and United States Supreme Court precedent both indicate this preemption language does not include state common-law claims.

In *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63 (2002), the Supreme Court explained that the phrase "law or regulation" was "most naturally read as *not* encompassing common-law claims." *Id.* at 63 (emphasis added). The Court based its reasoning on the idea that "a word is known by the company it keeps." *Id.* The terms "'law' and 'regulation' used together in the pre-emption clause indicate that Congress pre-empted only positive enactments." *Id.* The Court noted that if it read "law" to include the common law, then "law" would also include "regulations," and

would "render the express reference to 'regulation' in the preemption clause superfluous." *Id.*

Dictionary definitions are consistent with the Supreme Court's conclusion in *Sprietsma*. "Law" refers to "the aggregate of legislation, judicial precedents, and accepted legal principles," including "the body of authoritative grounds of judicial *and administrative action*." *Webster's Third International Dictionary* 1279 (2002) (emphasis added); *see also* Bryan A. Garner, *A Dictionary of Modern Legal Usage* 503 (2d ed.1995) (differentiating between "*a* law," which refers to "a particular and concrete instance of a legal precept," with "*the* law," which describes "something much broader and more general" (emphasis added)). Assigning a meaning to "law" in the Medicare Act's preemption provision that includes the broader and general concept of "the law" would sweep in not only common law but also regulations (i.e., authoritative administrative action). *See Sprietsma*, 537 U.S. at 63.

That interpretation, however, makes the term "regulation" superfluous, and therefore is not the proper interpretation that should be applied by this Court. *See, e.g., Advocate Health Care Network v. Stapleton*, 581 U.S. 468, 477 (2017) (rejecting a proposed reading of an ERISA provision that would read two words out of the statute because "the presumption [is] that each word Congress uses is there for a reason"). *See also* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 174 (2012) (canons of statutory interpretation require that, "[i]f possible, every word . . . is to be given effect" rather than considering words to be mere surplusage). The proximity of "law" to "regulation" indicates the term refers only to positive legislative enactments, just like the term "regulation" refers to positive administrative rules. *Sprietsma*, 537 U.S. at 63.

Reading "law" to encompass only positive enactments is consistent with the preemption provision's broader context. Congress knew how to refer to "State law" and thus more broadly

include both state common laws and regulations. Indeed, Congress did so repeatedly throughout the Medicare Part C statute. *See* 42 U.S.C. §§ 1395w-21(h)(7)(A), 1395w-22(b)(2), §1395w-28(f)(8)(D)(i). Congress could have done the same in 42 U.S.C. § 1395w-26(b)(3) but chose not to do so. By saying "any State law or regulation" instead of "State law," Congress meant something different. 42 U.S.C. § 1395w-26(b)(3); *see* Scalia & Garner, *supra*, at 170 ("A material variation in terms suggests a variation in meaning."). Specifically, Congress meant to implicate positive legislative enactments—state statutes or regulations—not common law. *See Rodriguez v. United States*, 480 U.S. 522, 525 (1987) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (brackets and citation omitted)); *see also Sprietsma*, 537 U.S. at 63.

Ignoring this Supreme Court precedent and the statute's text, Humana cites non-binding, out-of-circuit cases for the proposition that common law claims are included in the Medicare Act's preemption provision. MTD at 20-23. Humana also claims that the preemption at issue is both express (from the language of the statute itself) and implied (in the form of "field preemption"). *Id.* But as the Sixth Circuit recently recognized, those two forms of preemption are distinct. In *In re Ford Motor Company F-150 and Ranger Truck Fuel Economy Mktg. and Sales Pract. Litig.*, 65 F. 4th 851 (6th Cir. 2023), state law claims can be preempted *either expressly* or *impliedly*. *Id.* at 859. There is a difference between the two. "Through an express preemption clause, Congress may make clear 'that it is displacing or prohibiting the enactment of *state legislation* in a particular area.'" *Id.* (quoting *Matthews v. Centrus Energy Corp.*, 15 F. 4th 714, 720 (6th Cir. 2021) (emphasis added)). Field preemption, on the other hand, is a form of implied preemption that "occurs where a scheme of federal regulation is so pervasive as to make reasonable the inference that Congress

left no room for the States to supplement it." *Id.* (citations omitted).

The Sixth Circuit has never held that the Medicare Act preempts state common law claims, nor applied field preemption in the way Humana encourages this Court to do. Notably, Humana cites no Sixth Circuit cases at all, instead citing cases from the Ninth and Tenth Circuits.

The Eighth Circuit's reasoning in *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 971 (8th Cir. 2021) provides the better, narrower approach. In *Wehbi*, the Eighth Circuit took a limited view of Medicare preemption and held that 42 U.S.C. § 1395w-26(b)(3) "does not preempt *all* state laws as applied to Medicare Part [C]," just "those that occupy the same 'place'—that is, that regulate the same subject matter as—federal Medicare Part [C] standards." *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 971 (8th Cir. 2021).[2] A "standard . . . is a [Medicare Part C] statutory provision or a regulation promulgated under [Medicare Part C] and published in the Code of Federal Regulations." *Id.* In other words, express preemption of a state law occurs when "(1) Congress or [CMS] has established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to' those standards." *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018), *rev'd on other grounds*, 592 U.S. 80 (2020) (quoting 42 U.S.C. § 1395w-26(b)(3)); *see Wehbi*, 28 F.4th at 971. Additionally, the Eighth Circuit has recognized implied preemption where a state law would "otherwise frustrate the purpose of a federal Medicare Part [C] standard." *Wehbi*. at 972.

The Eighth Circuit recognized the preemption provision as containing limitations—including only applying when federal standards "supersede" state law. *Id.* at 971 (noting that the

[2] Although *Wehbi* dealt with Medicare Part D, not Part C, it still controls this Court's analysis because Medicare Part D's preemption provision is identical. *See Wehbi*¸18 F.4th at 971 (noting that Congress extended the express preemption provision applicable to Medicare Part C in 42 U.S.C. § 1395w-26(b)(3) to Medicare Part D in 42 U.S.C. § 1395w-112(g)).

amendment revising preemption is titled "Avoiding *duplicative* State regulation"). Though the classifies the preemption provision as applying field preemption, Eighth Circuit takes a narrow approach in determining what the relevant "field" is. *Id.* The *Wehbi* court drew narrow distinctions between the scope of Medicare standards and state statutory standards. 18 F.4th at 972–76 (holding that a state law controlling which conditions a PBM *must* place on pharmacies' participation in its network was not preempted by a Medicare standard governing which conditions a PBM *may not* place on pharmacies' participation in its network because the statute did not "claim this area for federal control"). The *Wehbi* court also held that when Medicare standards use "highly general language," it indicates "an intent to leave to the states the specifics of what plans . . . may or may not" do. *Id.* at 973.

The most recent CMS Medicare Manual supports this conclusion. There, the agency writes that "generally applicable standards[] that are not specific to health plans are not preempted" by the Medicare Act. *Medicare Managed Care Manual: Chapter 10 - MA Organization Compliance with State Law and Preemption by Federal Law*, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c10.pdf (emphasis added). And the few cases that have been decided in the Sixth Circuit have similarly concluded that the Medicare Act does not preempt state law where that state law is not inconsistent with Medicare. *See, e.g., Downhour v. Somani*, 85 F.3d 261, 265–66 (6th Cir. 1996)) ("Medicare does not completely preempt state law where billing for medical services is concerned."); *Greenbaum v. Clarksville Health Sys., G.P.*, No. 3:21-CV-00030, 2021 WL 1816901, at *5–6 (M.D. Tenn. May 6, 2021) (holding "the Medicare program does not completely preempt state tort law claims.").

2. Plaintiffs' Statutory Claims Are Not Preempted Because They Do Not Arise Under the Medicare Act

Plaintiffs' common-law claims are not preempted because the Medicare Act's express

preemption provision is inapplicable to state common law. In addition, Plaintiffs' statutory claims are not preempted because, as set forth above, those claims do not "arise under" the Medicare Act. *See Day*, 23 F.3d at 1059; *see also Harvey v. Colvin*, No. 1:13-CV-01957, 2015 WL 4078223, at *7 (D.D.C. July 1, 2015) (federal lawsuit requesting new determination of whether an award of benefits is warranted is "collateral to a substantive claim for benefits").

Nor do Plaintiffs' state statutory claims regulate the same subject matter as the Medicare standards cited by Defendant. Those statutes do not, for example, regulate "basic pre-admission and post-admission requirements" (42 C.F.R. § 409.30) or "examples of what qualifies as skilled nursing services" (42 C.F.R. § 409.33). MTD at 24. Again, Plaintiffs' claims are *not* that "Humana wrongly denied Medicare Benefits for post-acute care." *Id.*; *see supra* note 1. Plaintiffs' statutory claims also are not based on Defendants' failure to establish written policies and procedures that allow for individual medical necessity determinations. Contrary to Defendants' characterization (MTD at 24), section § 422.122(a)(6)(ii) has nothing to do with regulating "how MAOs can make coverage determinations using utilization management policies and procedures." Instead, it provides:

> (a) Rules for Coordinated Care Plans. An MA Organization that offers and MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:
>
> ***
>
> (6) Written standards. Establish written standards for the following:
>
> ***
>
> (ii) Policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations.

42 C.F.R. § 422(a)(6)(ii). Similarly, 42 C.F.R. § 422.137 requires an MAO that "uses utilization management (UM) policies and procedures, including prior authorization (PA), must establish a UM committee that is led by a plan's medical director (described in §422.562(a)(4))." Plaintiffs do not allege Defendants failed to establish a UM committee, and the state statutes do not set forth standards relating to the establishment of an MAO's UM committee. In short, the state statutes in question do not regulate or even address the Medicare standards with which Defendants claim they "interfere" and the Court need not "second guess" Humana's administration of these standards which are irrelevant to Plaintiffs' actual claims.

The cases cited by Defendants are once again distinguishable. *Hepstall* and *Alston* involved common law claims, which for the reasons set forth above are not preempted. The plaintiff in *Snyder v. Prompt Medical Transportation, Inc.*, 131 N.E.3d 640 (Ind. Ct. App. 2019) alleged the decedent's injuries and death "were a direct and proximate result of the carelessness and negligence of Humana." *Id.* at 653. In short, the case involved a coverage determination itself, not the process for making the coverage determination. As set forth at length above, and unlike *Snyder*, Plaintiffs here challenge Defendants' process for making coverage determinations and, contrary to Defendants' contention, *do not* allege "that the MAO wrongfully denied Medicare Benefits." MTD at 25. Thus, Plaintiffs' statutory claims are not preempted.

IV. CONCLUSION

For the reasons stated above, Plaintiffs request that this Court deny Humana's motion in its entirety.

Dated: June 27, 2024

Respectfully Submitted

/s/ John C. Whitfield, Esq.

John C Whitfield, Esq.
Whitfield Crosby & Flynn PLLC
19 North Main Street
Madisonville, KY 42431
Tel: (270) 821-0656
JWhitfield@wcfjustice.com

Glenn A. Danas
Ryan J. Clarkson
Zarrina Ozari
Clarkson Law Firm, P.C.
22525 Pacific Coast Highway
Malibu, CA 90265
Tel: (213) 788-4050
rclarkson@clarksonlawfirm.com
gdanas@clarksonlawfirm.com
zozari@clarksonlawfirm.com

Gary M. Klinger
Milberg Coleman Phillips Grossman PLLC
227 W. Monroe Street, Suite 2100
Chicago IL 60606
Tel: (866) 252-0878
gklinger@milberg.com

James Guilfoyle
Guilfoyle Law Office
229 West Spring Street
New Albany, IN 47150
Tel: (812) 208-9704
jfg@inkylegal.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that, on June 27, 2024, the foregoing was electronically filed with Court of Clerk using the CM/ECF system, which will automatically serve all parties through their counsel of record in accordance with Fed. R. Civ. P. 5(b)(2)(E).

/s/ John C. Whitfield, Esq.
John C Whitfield, Esq.

Attorney for Plaintiffs