THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

ELECTRONICALLY FILED

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

DEFENDANT'S REPLY IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED CLASS ACTION COMPLAINT

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Federal law dictates what benefits MAOs[1] like Humana must cover, the process by which they must make Medicare coverage determinations, and who must make those determinations. CMS has even issued guidance as to whether MAOs can use artificial intelligence in the coverage determination process. Federal law also sets forth the exclusive process by which Medicare enrollees may challenge matters that are "inextricably intertwined" with a claim for Medicare Benefits—such as coverage determinations. Plaintiffs ask this Court to jettison the mandatory Medicare administrative appeal process and superintend the Medicare Program itself by applying 23 separate states' standards to Humana's administration of Medicare Part C benefits. This is exactly what Congress sought to avoid by enacting the Medicare Act's preemption and exhaustion provisions. The Court should decline Plaintiffs' invitation and dismiss their Amended Complaint.

I. PLAINTIFFS CONCEDE THAT THEY FAILED TO EXHAUST THE MEDICARE ACT'S MANDATORY ADMINISTRATIVE APPEAL PROCESS, AND NO BASIS FOR JUDICIAL WAIVER EXISTS HERE.

Plaintiffs concede that they did not exhaust the Medicare Act's mandatory administrative appeal process. *See* Opp., R.43 ("Opp"), PageID# 544–45, 552; Am. Compl., R.37 ("Am. Compl."), PageID# 218–29 (¶¶ 51–118). And Plaintiffs candidly acknowledge that "Section 405(h) . . . precludes judicial review in any action challenging the denial of claimed benefits, except as provided for by Section 405(g)." Opp. at 540. Yet they ask this Court to let them sidestep Congress' directive and take the "extraordinary" step of waiving the Medicare Act's administrative exhaustion requirement. But the Sixth Circuit's clear direction and the public policy rationale for the exhaustion requirement cut against Plaintiffs' arguments.

[1] Defined terms carry the same meaning as described in Humana's Motion to Dismiss (R. 40).

A. Plaintiffs' Challenges To The Processes For Determining Whether To Grant Medicare Benefits Are "Inextricably Intertwined" With Claims For Benefits.

Plaintiffs try to fight the self-evident conclusion that their claims are "inextricably intertwined" with claims for Medicare Benefits, *Heckler v. Ringer*, 466 U.S. 602, 614–15 (1984), by characterizing their causes of action as "true procedural challenges" based solely on "the use of nH Predict to make coverage determinations (regardless of the outcome)," Opp. at 542–43 & n.1, and by arguing that the relief they seek is "beyond the scope" of the Medicare Act's prescribed remedies. *Id.* at 550. Neither argument holds water.

As the Supreme Court explained in *Ringer*, the inquiry in determining whether § 405(h) bars federal-question jurisdiction is "not whether it lends itself to a 'substantive' rather than a 'procedural' label." 466 U.S. at 615; *see also* Mot., R.40 ("Mot."), PageID# 274–76 (collecting cases finding purported "procedural" challenges were inextricably intertwined with claims for Medicare Benefits). And the Sixth Circuit rejected Plaintiffs' proffered logic in *Giesse v. Secretary of the Department. of Health and Human Services,* 522 F.3d 697 (6th Cir. 2008), holding that an enrollee's causes of action, which sought various consequential damages, "indeed 'ar[o]se under' the Medicare Act," *id.* at 702, even though the "award of damages" that the enrollee sought was "not available" under the Medicare Act. *Id.* at 704 (citing 42 C.F.R. § 422.618). There, as here, a Medicare Part C enrollee brought multiple common law causes of action (tort, breach of contract, fraud, and respondeat superior) seeking damages for the denial of SNF benefits. *Id.* at 701.

Here, Plaintiffs' causes of action are inextricably intertwined with Humana's allegedly "unreasonabl[e] and premature[] refusal to cover" their post-acute care, Am. Compl. at 239 (¶ 166), in at least two ways. *First*, Plaintiffs' statutory claims challenge the "reasonableness" of the process Humana used to make Medicare coverage determinations, Am. Compl. at 235–36, 243–44 (¶¶ 150, 145, 192), necessarily implicating the Medicare Program's process

requirements and criteria for making coverage decisions. *See infra* Section II.C.1. *Second*, the alleged injuries Plaintiffs pursue—out-of-pocket costs, discontinuation of medical care, and associated emotional distress—are tied directly to Humana's Medicare coverage determinations. Opp. at 538 ("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[.]"); Opp. at 539–40 (describing alleged emotional distress associated with denials of Plaintiffs' coverage requests).[2] These alleged losses would not have occurred had Humana approved Plaintiffs' request for benefits. "At bottom," then, Plaintiffs' alleged injuries are "inextricably intertwined" with claims for Medicare Benefits that must be exhausted. *See Ringer*, 466 U.S.at 615; *Giesse*, 522 F.3d at 702–03.

B. The Sixth Circuit Has Made Clear: Exhaustion Of The Medicare Administrative Appeal Process Is Not Optional.

Plaintiffs describe administrative exhaustion as a mere formality that can easily be dispensed with. Not so. The Sixth Circuit has been clear: § 405(h) "channels most, if not all, Medicare claims through the special review system" and "purports to make exclusive the judicial review method set forth in § 405(g)." *Cathedral Rock of N. Coll. Hill, Inc. v. Shalala*, 223 F.3d 354, 359 (6th Cir. 2000) (internal citation omitted; cleaned up). The Sixth Circuit reaffirmed that Medicare Part C enrollees cannot circumvent the administrative appeal process in *Giesse*, where it warned that such an upside-down view of exhaustion—of the type Plaintiffs advance here—threatens to "nullify" Congress' direction in § 405(h). 522 F.3d at 704–05.

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[2] The Amended Complaint similarly alleges that each named Plaintiff paid out-of-pocket after their denial of Medicare coverage. *See* ¶¶ 61 (Ms. Barrows), 70 (Ms. Hagood), 95 (Ms. Merkley), 107 (Ms. Kohl), 112 (Ms. Balani). It also ties their "severe emotional distress" to the denial of benefits, which caused stress as to who would pay for those benefits. *See id.* ¶¶ 196–97.

C. These Are Not "Extraordinary" Circumstances Warranting Judicial Waiver.

Plaintiffs seek refuge in the judicial waiver doctrine—an "extraordinary" "exception to the general rule" that "may be admitted only under special circumstances." *See Schoolcraft v. Sullivan*, 971 F.2d 81, 85 (8th Cir. 1992) (citing *Bowen v. City of New York*, 476 U.S. 467 (1986)). Courts must weigh three factors when determining whether there are "extraordinary" "special circumstances" justifying waiver: (1) the claimant's claim must be "entirely collateral" to a claim for Medicare Benefits; (2) the administrative review process must be futile; and (3) plaintiffs must show that they would be irreparably harmed by going through the administrative review process. *See*, *e.g., Ringer*, 466 U.S. at 617–18. None of these special circumstances are present here.[3]

1. Plaintiffs' Claims Stem Directly From Their Benefits Determinations.

First, Plaintiffs' causes of action cannot be "entirely collateral" to their claims for Medicare Benefits because they arise from the denial of those same Medicare Benefits. The Sixth Circuit's inquiry for determining whether a claim is "entirely collateral" to a claim for Medicare Benefits is "whether the allegedly collateral claim involves *completely* separate issues from the party's claim that it is entitled to benefits . . . or whether it is inextricably intertwined with its substantive claim to benefits or participation." *Cathedral Rock*, 223 F.3d at 363.

The cases Plaintiffs cite illustrate this test. *See supra* at Section I.A. For example, *Bowen* concerned an agency-wide policy that instituted a presumption against mentally disabled claimants at the initial determination stage, which was "subsequently given 'great weight' by ALJs in the administrative appeals process." 476 U.S. at 475. And *Day v. Shalala* considered a due process

[3] Humana disagrees that Plaintiffs satisfied the threshold "presentment" requirement by presenting a claim to Humana, *see* Opp. at 544–45. Humana is plainly not "the Secretary," 42 USC § 405(g); *id.* § 1395ii. Only a Level 4 appeal decision counts as a final decision of the Secretary. 42 U.S.C. § 405(g)-(h); *id.* § 1395w-22(g)(5); 42 C.F.R. §422.612. Humana, however, need not address the presentment requirement further because Plaintiffs admit that they have not satisfied the separate exhaustion requirement under Section 405(h).

challenge that a state agency's benefits denial notices lacked proper notice of appeal rights, which caused some claimants to reapply for benefits, rather than seek administrative review. 23 F.3d 1052, 1065–66 (6th Cir. 1994). The causes of action in these cases stemmed from a structural flaw in the administrative review process—independent from the claimants' actual benefits determinations—that made administrative review of the underlying determinations unfair. *See also Califano v. Sanders*, 430 U.S. 99, 109 (1977) (commenting that waiver in *Eldridge* and *Salfi* involved constitutional challenges). Unlike the "great weight" that ALJs accorded the erroneous presumption in *Bowen*, the alleged use of the nH Predict AI model here had no bearing on the subsequent appeals of Plaintiffs' claims. *See infra* at Section I.D.3. And Plaintiffs do not allege that the independent administrative review process is fundamentally misleading or unfair.

Furthermore, in *Bowen* and *Day*, "the class members neither sought nor were awarded" damages. *Bowen*, 476 U.S. at 483 (relief sought was reopening decisions and redetermining eligibility); *Day*, 23 F.3d at 1059.[4] Here, despite contending otherwise, Plaintiffs *do* seek damages that stem from the allegedly wrongful denial of Medicare benefits. *See supra* at Section I.A. And their alleged injuries—out-of-pocket costs, discontinuation of care, and associated emotional distress—*would not exist* if their benefits had been covered. *See supra* at Section I. A. Thus, Plaintiffs' causes of action are not "completely separate" from a claim of entitlement to benefits.

[4] Plaintiffs assert that if they 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." Opp. at 546. However, Plaintiffs' contention that they are entitled to a procedural remedy absent showing of actual injury (entitlement to further coverage) is dubious in light of the Supreme Court's recent pronouncements that plaintiffs lack standing to challenge a private defendant's process without demonstrating actual injury. *See Thole v. U.S. Bank N.A.*, 590 U.S. 538, 541 (2020); *Transunion LLC v. Ramirez*, 594 U.S. 413 (2021).

2. The Medicare Act's Administrative Review Process Is Not Futile.

Second, Plaintiffs fail to show that administrative review is futile. As in *Ringer*, "[a]lthough respondents would clearly prefer an immediate appeal to the District Court rather than the often-lengthy administrative review process, exhaustion of administrative remedies is by no means futile for these [plaintiffs]," 466 U.S. at 619. Far from futile, Plaintiffs' own administrative appeal records show the process works as Congress and CMS intended. Indeed, more than one of Plaintiffs' own appeals led to overturned coverage determinations. *See* Am. Compl. at 222–25 (¶¶ 79, 81, 83–85, 90–93); Ex. 8, R.40-7 (filed under seal at R.41) ("Ex. 8"). The contention that further appeals would be futile and also "a commitment of administrative resources unsupported by an[] administrative or judicial interest," Opp. at 549, is not just wrong, but belied by their actual records. *See* Exs. 1, 3 (ALJ decisions); Exs. 2, 4–6 (QIO decisions).[5]

Further, Plaintiffs' capable-of-repetition-but-evading-review argument (*see* Opp. at 549–50) rests on a fundamental misunderstanding of how Medicare's post-acute care coverage works. The Medicare Act creates a right for Medicare Beneficiaries to receive *up to* 100 days of SNF care per year. *See* 42 U.S.C. § 1395d(a)(2)(A); *Giesse*, 522 F.3d at 706. Once a patient is admitted to a SNF, the medical necessity determination is an ongoing factual inquiry that can change day-to-day. High-intensity post-acute care may be medically necessary for a beneficiary on one day, but

[5] Humana acknowledges that the Court must take the facts in the Amended Complaint as true for purposes of the Motion to Dismiss; however, Plaintiffs' Opposition raises new allegations not pled in the Amended Complaint and grossly mischaracterizes statements by one Senator in doing so. Specifically, Plaintiffs claim that the entire "United States Senate has made a factual finding that 80% of prior authorization requests denied by nH Predict are reversed on appeal." Opp. at 548, citing Am. Compl. at 215 (¶ 41) (citing *Examining Health Care Denials and Delays in Medicare Advantage Before the Permanent Subcommittee on Investigations*, 118th Cong. (2023) (statement of Sen. Richard Blumenthal, Chairman, Permanent Subcomm. on Investigations)). In reality, Plaintiffs' source is not a "factual finding" by the "United States Senate." Rather, the source is an individual Senator's opening remarks, which *never* mentions the 80% figure Plaintiffs cite, let alone specifically refers to nH Predict at all.

no longer warranted the next day. *See, e.g.*, 42 U.S.C. § 1395i-3(b)(2) & (3) (Medicare Part A requiring ongoing determinations of medical necessity of SNF care); 42 C.F.R. § 409.30 ("SNF care. . . is covered only if the beneficiary meets the requirements of this section and only for days when he or she needs and receives care of the level described in § 409.31"); 88 Fed. Reg. 22120 (Apr. 12, 2023) (MAOs may conduct ongoing review of medical necessity). Thus, what Plaintiffs call repetitions of the same continuous injury are actually distinct and independently reviewable coverage determinations required by the Medicare coverage criteria.

Plaintiffs' futility arguments similarly mischaracterize the administrative review process and misunderstand CMS's central role in administering the Medicare program. Contrary to Plaintiffs' implication through the cases they cite that an allegedly flawed policy would infect subsequent appeals, *see* Opp. at 548–49,[6] administrative appeals under the Medicare Act are *wholly independent* from Humana's determination. *See* Exs. 1–5 (appeal determinations referencing Medicare coverage criteria, not the "nH Predict AI Model," as the basis of the decision that Plaintiffs' requested care was not covered by Medicare). Further, Level 3 of the administrative appeal process requires ALJs to conduct a *de novo* review of the MAO's coverage determination, which includes making independent findings of fact. *E.g.* Ex. 1, R.28-1, PageID# 149 (filed under seal at R.29) ("Ex. 1").

Plaintiffs ask this Court to casually waive the exhaustion requirement and instead determine for itself whether Humana's process for making coverage determinations was "reasonable." But under *Cathedral Rock*, waiver is inappropriate where, as here, the agency's opportunity to review coverage determinations amidst "hundreds of pages of statutes and

[6] The claimants in *Bowen* challenged a Social Security policy that not only impacted the initial determination of whether Social Security benefits should be granted, but also infected all subsequent administrative appeals of that eligibility determination. *Bowen*, 476 U.S. at 467.

thousands of pages of often interrelated regulations" could provide guidance and lead to more efficient outcomes across the entire federal benefits program. 223 F.3d at 359 (quoting *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000)). Indeed, ALJ decisions that upheld Humana's Medicare coverage determinations as to two of the named Plaintiffs illustrate the administrative appeal process's utility. *See* Exs. 1, 3. The ALJs parsed extensive Medicare Coverage Guidelines, examined voluminous medical records, and considered testimony and evidence used to evaluate whether the additional days of SNF or IRF care were warranted under Medicare coverage criteria. *Id.*

3. Plaintiffs Have Not Demonstrated Irreparable Harm.

Third, Plaintiffs have not shown any irreparable harm that would justify an "extraordinary" judicial waiver. Plaintiffs contend that they would be irreparably harmed because "[w]hile waiting for a decision on appeal, patients are left with two options: (1) to stay in the post-acute care facility and risk being responsible for months or years' worth of medical bills if their appeals are denied; or (2) forgo care while they await a decision." Am. Compl. at 216 (¶ 45); Opp. at 546–48 (same). But Plaintiffs' own appeal records undercut their contention of irreparable harm.

As an initial matter, Plaintiffs presume that they were actually entitled to additional Medicare coverage at the heightened level of care they demanded. But for each named Plaintiff, an ALJ or an Independent Review Entity has already made a finding that additional care at the requested level was not medically necessary, and thus not covered, under Medicare's coverage criteria. *See* Mot. at 266–68; Exs. 1–5. For example, an ALJ issued a lengthy decision based on extensive medical records, documentation, and testimony, which concluded that Humana properly determined that Ms. Hagood did not require daily care at the skilled nursing level and could instead be properly cared for in a custodial setting. Ex. 1 at 149. The ALJ found that Ms. Hagood had refused to participate in daily skilled therapy, which is an indispensable feature of requiring

continued daily SNF care. Ex. 1, at 150. Prior to ALJ review, independent reviewers at a QIO had already reached that same conclusion—twice. Ex. 1 at 138. Under these circumstances, it is difficult to say that Plaintiffs were actually injured because they have not plausibly alleged any of these independent administrative appeal decisions were erroneous.

Likewise, contrary to Plaintiffs' contention that getting redress through the Medicare administrative appeal process "often takes years," Opp. at 539, the process provides for *near-immediate* Level 1 review—within hours or days—of a termination of SNF or IRF coverage. *See*, *e.g.,* 42 C.F.R. § 422.626. Indeed, Plaintiffs' appeal records confirm the availability of this quick and cost-free avenue to have an independent entity review coverage determinations. *See, e.g.*, Ex. 1, (appeal decision issued the day after Ms. Hagood's appeal); Ex. 4, R.40-3 (filed under seal at R.41) (QIO Level 1 appeal decision issued the day after Ms. Kohl's appeal).

D. Plaintiffs Should Have Sued The Secretary, Not Humana.

Plaintiffs unconvincingly end their exhaustion section with a circular argument: Plaintiffs contend that "the Secretary is the proper defendant *only* for claims seeking review of final determinations from the Medicare Appeals Council," and because Plaintiffs have admittedly *not* exhausted the administrative appeal process, they are "not restricted by [42 U.S.C. § 405]," and thus free to name Humana—rather than the Secretary—as the proper Defendant. Opp. at 551–52. But Section 405(g) only permits a Medicare enrollee to sue *the Secretary*—not Humana—after exhausting the administrative appeal process. *See* 42 U.S.C. § 405(g); 42 C.F.R. § 405.1136(d)(1). It does not authorize Medicare enrollees to *both* sidestep the administrative appeal process and sue an MAO instead—something the Sixth Circuit has warned against. *See Giesse*, 522 F.3d at 700–01. Plaintiffs further critique Humana's reliance on two district court decisions. *See* Opp. at 551–52. But Plaintiffs cite no cases at all holding that an MAO like Humana, rather than the Secretary,

is the proper defendant, simply because Plaintiffs admittedly have not completed the administrative appeal process. *See* Opp. at 551–52.

II. THE MEDICARE ACT EXPRESSLY PREEMPTS ALL OF PLAINTIFFS' CLAIMS WHICH ENCROACH ON THE FIELD WHERE AN MAO'S CONDUCT IS ALREADY GOVERNED BY FEDERAL LAW.

A. State Common Law Causes Of Action Fall Within The Medicare Act's Express Preemption Provision.

Plaintiffs argue that the Medicare Act's preemption provision "does not include state common-law claims." Opp. at 552. Plaintiffs are wrong, and their contention contradicts the statute's plain text, congressional intent, and the approach adopted by courts across the country.

First, Plaintiffs cherry-pick parts of the Supreme Court's analysis in *Sprietsma v. Mercury Marine,* 537 U.S. 51 (2002), to urge this Court to go against the multitude of courts that have held the Medicare Act's preemption provision applies to state common law claims. Opp. at 552–54. These courts reviewed the preemption provision at issue in *Sprietsma* (from the Federal Boating Safety Act ("FBSA")) and rejected the same argument that Plaintiffs recycle here. *See Uhm v. Humana, Inc.*, 620 F.3d 1134, 1154 (9th Cir. 2010); *Estate of Ethridge v. Recovery Mgm't Syst., Inc.*, 326 P.3d 297, 304–05 (Ariz. Ct. App. 2014); *Roberts v. United Healthcare Servs., Inc.*, 2 Cal. App.5th 132, 147 (Cal. Ct. App. 2016); *Quishenberry v. UnitedHealthcare, Inc.*, 532 P.3d 239, 1068–69 (Cal. 2023). Tellingly, Plaintiffs do not point to *any* court that has agreed with their *Sprietsma*-based argument as applied to Medicare Part C's express preemption provision.

Plaintiffs avoid key differences between the two preemption provisions and hide the bottom line—the text of the Medicare Act's provision is broader than the FBSA's. *See*, *e.g., Ethridge*, 326 P.3d at 305. Rather than preempting "*a* law or regulation" (the phrase at issue in *Sprietsma*), the Medicare Act "supersede[s] *any* State law or regulation." 42 U.S.C. § 1395w-26(b)(3)

(emphasis added).[7] In the FBSA, "the article 'a' before 'law or regulation' implies a discreteness . . . that is not present in the common law." *Sprietsma*, 537 U.S. at 63. Here, Congress's use of the word "any" in the Medicare Act indicates that the preemptive effect is "much broader in scope" than the FBSA's provision. *See Uhm*, 620 F.3d at 1153 ("use of 'any' negates the 'discreteness' that the Court identified in *Sprietsma*"); *accord Erie R. Co. v. Tompkins*, 304 U.S. 64, 73 (1938), (recognizing the phrase "state law" includes common law as well as statutes and regulations); *see also Norfolk & W. Ry. Co. v. Am. Train Dispatchers Ass'n*, 499 U.S. 117, 128 (1991) (the phrase "'all other law, including State and municipal law'" "does not admit …[a] distinction…between positive enactments and common-law rules of liability"). Similarly, Plaintiffs omit *Sprietsma*'s reliance on the FBSA's savings clause, which specifies that compliance "does not relieve a person from liability at common law or under State law." 537 U.S. at 63–64. This is presumably because the Medicare Act's savings clause, in contrast, only exempts "state licensing laws or State laws relating to plan solvency." 42 U.S.C. § 1395w-26(b)(3); *see also Uhm,* 620 F.3d at 1153.

Second, Plaintiffs' interpretation of the preemption provision's clear text ignores the Act's legislative history and would frustrate Congress's purpose in creating a uniform, nationwide Medicare program. In 2003, Congress amended the preemption provision and "removed the requirement that a state law be 'inconsistent' with federal standards to be preempted." *Medicaid & Medicare Advantage Prod. Ass'n of Puerto Rico v. Emanuelli Hernandez*, 58 F.4th 5, 12 (1st Cir. 2023). The accompanying Conference Report emphasized: "[T]he MA program is a federal program operated under Federal rules. *State laws, do not, and should not apply*."

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[7] The full Medicare Part C preemption provision reads: "The standards established under this part 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 this part." 42 U.S.C. § 1395w-26(b)(3) (emphasis added).

H.R. Rep. No. 108-391, at 557 (2003) (Conf. Rep.) (emphasis added). This legislative history "indicates that Congress intended to expand the preemption provision beyond those state laws and regulations inconsistent with the enumerated standards." *Uhm*, 620 F.3d at 1149–50; *see also Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 971 (8th Cir. 2021) (the amendment "expand[ed] the scope of express Medicare preemption from conflict preemption to field preemption.").

Third, courts across the country have routinely concluded that common law causes of action are preempted by the Medicare Act. *See, e.g.*, *Alston v. United Healthcare Servs., Inc.*, 291 F. Supp. 3d 1170, 1173 (D. Mont. 2018); *Hepstall v. Humana Health Plan, Inc.*, 2018 WL 6588555 (S.D. Ala. Nov. 26, 2018), *R. & R. adopted by* 2018 WL 6588552 (S.D. Ala. Dec. 6, 2018); *Uhm*, 620 F.3d 1134 (9th Cir. 2010); *Williams v. Allegheny Cnty*, 2023 WL 4238892 (W.D. Pa. June 28, 2023); *Rudek v. Presence Our Lady of Resurrection Med. Ctr.,* 2014 WL 5441845 (N.D. Ill. Oct. 27, 2014). And, while *Giesse* does not directly address preemption, it strongly suggests that the Sixth Circuit believes allowing such common law actions would frustrate the exclusive processes and forms of relief available under the Medicare Act. *Cf.* 522 F.3d at 700–02, 704–05. Besides this faulty attempt at statutory interpretation, Plaintiffs offer no other basis to avoid preemption of their common law claims. *See* Opp. at 556–58.

B. Plaintiffs' Causes of Action Implicate The Process And Basis For Medicare Coverage Determinations, Which Are Exclusively Governed By Federal Law.

Plaintiffs argue that their state statutory causes of action cannot be preempted because they "do not arise under the Medicare Act" and do not "regulate the same subject matter" as the standards cited in Humana's Motion to Dismiss. Opp. at 556–57. Plaintiffs are wrong. *First*, as explained above, Plaintiffs' claims "arise under the Medicare Act" because their theory of harm is inextricably intertwined with Humana's allegedly "unreasonabl[e] and premature[] refus[al] to cover" their post-acute care, Am. Compl. at 239 (¶ 166). Plaintiffs' statutory claims, which

challenge the "reasonableness" of the process Humana used to make Medicare coverage determinations, necessarily implicate the Medicare Program's criteria for such decisions. *See supra* Section I.A. Thus, as the Supreme Court and Sixth Circuit have determined in similar circumstances, Plaintiffs' claims are "inextricably intertwined" with claims for Medicare Benefits.

Second, Plaintiffs' proposed preemption test is wrong. Plaintiffs urge this Court to use something akin to *conflict preemption*, rather than *field preemption*, based on their reading of Eighth Circuit caselaw. *See* Opp. at 555–56. But the text and legislative history of Part C's preemption provision contradict Plaintiffs' test for preemption. *See supra* at Section II A. And at least three other circuits[8] have disagreed with Plaintiffs' approach, instead concluding that Part C's preemption provision "sweeps more broadly than conflict preemption." *Emanuelli*, 58 F.4th at 14; *Uhm*, 620 F.3d at 1150; *Pharm. Care Mgmt Ass'n v. Mulready*, 78 F.4th 1183 (10th Cir. 2023), *petition for cert. docketed*, No. 23-1213 (U.S. May 15, 2024). The proper standard for evaluating Part C preemption is whether "the conduct underlying the plaintiffs' allegations and state law claims was governed by federal regulatory standards." *Hepstall*, 2018 WL 6588555 at *6 (surveying caselaw to describe preemption's touchstone as "whether the applicable federal regulations provide standards governing the alleged action or inaction of Defendant.").

Third, even under Plaintiffs' incorrect test for conflict preemption, their causes of action are clearly preempted. Crucially, Plaintiffs gloss over the *nature* of their state statutory causes of action: Plaintiffs rely on state *insurance laws* that govern health insurers' coverage determinations.

[8] Plaintiffs' Opposition cites one Sixth Circuit case, *Downhour v. Somani*¸ 85 F.3d 261, 265–66 (6th Cir. 1996), in support of their proposition that "the Medicare Act does not preempt state law where that state law is not inconsistent with Medicare." Opp. at 556. But *Downhour* interpreted a now-outdated version of the Medicare Act—one "contain[ing] no express preemption of state law." *Id.* at 266. Seven years later, when Congress amended the Medicare Act to include the current preemption provision, it abrogated the part of *Downhour*'s holding on which Plaintiffs rely.

See Am. Compl. at 242–45 (¶¶ 182–202) (insurance bad faith), 239–41 (¶¶ 165–202) (unfair claims settlement practices), 246 (¶¶ 205–210) (unfair and deceptive insurance practices). Only by omitting this detail can Plaintiffs argue with a straight face that their "state statutory claims [do not] regulate the same subject matter as the Medicare standards cited by Defendant." Opp. at 557.

Plaintiffs' claims *do* regulate the same subject matters as Medicare standards and would require the Court to evaluate whether Humana's process for determining Plaintiffs were not entitled to their requested Medicare Benefits was reasonable, Am. Compl. at 242–43, 246 (¶¶ 179, 187–88, 207), which necessarily requires deciding whether the process was adequate, Am. Compl. at 241, 244, 246 (¶¶ 177, 191–92, 208–09). But the Medicare Act already dictates what MAOs must do to make reasonable benefits determinations and have adequate processes: 42 C.F.R. § 422.101(b) requires MAOs to comply with "CMS's national coverage determinations," "[g]eneral coverage guidelines included in original Medicare manuals and instructions,"[9] and "written coverage decisions of local Medicare contractors." And CMS has spoken to what benefits MAOs must cover, *id.* § 422.100, who at the MAO must make coverage determinations, *id.* §§ 422.101(c)(1)(i)(D), 422.562(4), considerations when MAOs adopt new procedures for making coverage determinations, *e.g. id.* § 422.137, the criteria MAOs must use to make post-acute care coverage determinations, *e.g. id.* § 409.30, and use of Artificial Intelligence, *see* CMS, Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F) at 2 (Feb. 6, 2024).

While Plaintiffs argue that their state statutory causes of action do not conflict with the minutiae of CMS regulations, challenges to the reasonableness and adequacy of the "procedure by

[9] This part of the provision was amended in 2024 and now states "[g]eneral coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. . .".

which their claims were processed" implicate the Medicare requirements that Humana must follow, including when Medicare covers post-acute care, *see e.g.*, 42 C.F.R. § 409.30 *et seq.* (coverage of SNF care); *id.* § 412.622(a)(3) (coverage criteria for IRF). In particular, 42 C.F.R. Section 422.101(c), which specifies the criteria MAOs may use to make medical-necessity determinations, directly conflicts with the reasonableness analysis this Court would have to apply under state law.[10]

Plaintiffs' preemption argument becomes even more specious when compared against the preemption provision itself. Plaintiffs' state law actions are nakedly *not* "State licensing laws or State laws relating to plan solvency," 42 U.S.C. § 1395w-26(b)(3), and thus are not among the *only* state laws that Congress expressly saved from preemption. Federal standards dictate every step of the process for how MAOs operate and evaluate claims for Medicare Benefits. Indeed, this Court—or a jury under its supervision—will be unable to adjudicate this case without considering evidence of whether and how Humana complied with each of these federal standards. This puts the Court, and Humana, on a fatal collision course of the type Congress sought to avoid by enacting Medicare Part C's preemption provision: forcing MAOs to juggle federal and state standards when they make Medicare coverage determinations.

CONCLUSION

For these reasons, the Court should dismiss Plaintiffs' Amended Complaint with prejudice.

Dated: July 18, 2024

Respectfully Submitted,

/s/ Michael P. Abate

[10] Further, Plaintiffs attempt to brush aside 42 C.F.R. § 422.137 by mischaracterizing the regulation as merely requiring establishment of "a [Utilization Management] committee." Opp. at 558. That is just the *first* requirement of this regulation. Section 422.137 also outlines duties that CMS places on the MAO through the UM committee, including restrictions on the utilization management procedures an MAO can use. *See id.* § 422.137(d)(2).

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CERTIFICATE OF SERVICE

I hereby certify that, on July 18, 2024, a copy of the foregoing was electronically filed with the Court of Clerk using the CM/ECF system, which will automatically send email notification of such filing to all counsel of record.

/s/ Michael P. Abate
Counsel for Defendant