UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

ELECTRONICALLY FILED

JOANNE BARROWS, 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 POST-ARGUMENT SUPPLEMENTAL BRIEF IN SUPPORT OF MOTION TO DISMISS

Preemption: Plaintiffs concede that Counts Four, Six, and Seven are preempted, so each must be dismissed. Tr. at 27:7–9. Plaintiffs' remaining Counts assert that, by allegedly using an AI model to make coverage determinations, Humana: breached a "promise" to "work with [Plaintiffs'] doctors and other providers to help [them] get the most appropriate care"[1] (Counts One and Two[2]), was unjustly enriched (Count Three), engaged in unfair competition with other MAOs (Count Five), and committed fraud-by-omission (Count Eight). Humana denies these allegations.

[1] Am. Compl. ¶¶ 142–43. Although Plaintiffs quote other EOC language indicating that "Humana does not reward or provide financial incentives" to doctors or Humana employees for denying coverage, Count I and Count II do *not* actually allege a breach of contract or a breach of implied covenant of good faith and fair dealing based on the payment of "financial incentives" to doctors or Humana employees. Notably, the *Lokken* court also did not analyze that allegation, which was not pled in plaintiffs' Minnesota complaint against UnitedHealthcare. *See Estate of Lokken v. UnitedHealth Grp., Inc.,* --- F. Supp. 3d ---, 2025 WL 491148 at *8 (D. Minn. Feb. 13, 2025).

[2] In re-characterizing its claims in this way, Plaintiffs ask the Court to ignore Plaintiffs' actual allegations—for example, Plaintiffs' Count One allegation that Humana failed to "abide by applicable state laws." Am. Compl. ¶ 142.

But even assuming their truth, they are squarely preempted.

First, Counts One through Three attempt to "'regulate the same subject matter as federal Medicare [standards],'" *Lokken*, 2025 WL 491148 at *7, because the "process" Plaintiffs challenge is *for making Medicare coverage determinations*—which is, of course, already regulated by CMS. *See, e.g.*, MTD at PageID# 283 (citing 42 C.F.R. §§ 409.30, 409.31, 409.32, 409.33, 424.20); Reply at PageID# 590 (citing 42 C.F.R. §§ 422.100; 422.101; 422.562, 422.137, 409.30).

Second, the document from which the alleged "promise" in Counts One and Two arises is unquestionably regulated by CMS. The Medicare Evidence of Coverage ("EOC") document that Plaintiffs rely upon is not a "contract." *See, e.g.*, *Honey v. Bayhealth Med. Ctr., Inc.*, 2015 WL 4594163, at *5 (Del. Super. Ct. July 28, 2015) ("[T]here is no such thing as a [M]edicare Advantage insurance policy. Medicare Advantage is, instead, a federal program." (cleaned up)); 2013 Health Law Handbook § 12.5 (Because MAOs have no "insurance contracts" with their enrollees, they "do not pay benefits pursuant to a 'policy' but rather under a statutory framework."). The EOC is a layman's attempt to explain Medicare's regulatory requirements to Medicare Part C enrollees, which fulfills CMS's minimum disclosure requirement that MAOs provide "a general description of procedural rights". *See Humana Med. Plan, Inc. v. Reale*, 180 So.3d 195, 202 (Fla. Dist. Ct. App. 2015).

And even if the EOC were a contract, these claims are still preempted because CMS already regulates the truthfulness and accuracy of the EOCs' statements, and whether MAOs have lived up to the EOCs' "promises." *See*, *e.g.*, 42 C.F.R. §§ 422.2267, 422.111. To start, Humana must submit its EOC to CMS for review to ensure "[c]ompliance with all applicable requirements under §§422.2260 through 422.2267," and "CMS may determine, upon review of such materials, that the materials must be modified or may no longer be used." 42 C.F.R. § 422.2261. Thus, even if

Humana made promises beyond the Medicare Act's requirements,[3] the EOCs say what they say only because CMS approved them as consistent with CMS regulations. Indeed, one case that Plaintiffs cited for the first time at oral argument, *Pacificare of Nevada, Inc. v. Rogers*, 266 P.3d 596 (Nev. 2011), adopts this very reasoning.[4] Tr. at 18:1–7. Nonetheless, if an MAO does make misleading statements to Part C enrollees in an EOC, CMS can take enforcement action against the MAO. *See, e.g.*, 42 C.F.R. § 422.2262 ("[MAOs] may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees"); 42 C.F.R. § 422.750 (CMS's powers to take enforcement action against MAOs). Thus, CMS already regulates adherence to "promises" made by MAOs in an EOC—the very issue Plaintiffs attempt to litigate here.

Third, Plaintiffs' thinly-pled common law fraud-by-omission count is preempted. Fraud by omission requires a duty to disclose. *See Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 248 (6th Cir. 2012). But the unidentified duty here comes from the Medicare Act. As explained above, CMS already regulates Humana's disclosures to enrollees. Here, as in *Uhm v. Humana, Inc.*, Plaintiffs' fraud claim is preempted because it "would necessarily [require this Court] to determine whether the [EOCs] were misleading"—and thus risks "directly undermin[ing] CMS's prior determination that those materials were not misleading and in turn [further]

[3] Tellingly, an MAO's use of technology in claims review processes is not among the enumerated items that CMS requires MAOs to disclose to enrollees. *See* 42 C.F.R. § 422.111.

[4] There, CMS's EOC approval process preempted an unconscionability challenge to an EOC's arbitration provision. *Id.* at 600 (citing *Clay v. Permanente Med. Grp., Inc.*, 540 F. Supp. 2d 1101, 1109 (N.D. Cal. 2007) (preemption proper because "the EOC is considered 'marketing material' and must be approved by the CMS."")). The other cases Plaintiffs raised for the first time at oral argument are not helpful, either. Tr. at 17:6–18:11. *Muth v. Sebelius*, 856 F. Supp. 2d 1127, 1134 (C.D. Cal. 2012) found that the MAO *had not* agreed to covering benefits beyond what was already required by the Medicare Act—it did not discuss recourse if the MAO had promised more. And *Insurance Trust for Delta Retirees v. UnitedHealth Group, Inc.,* 2015 WL 13754318 at *7 (N.D. Ga. Aug. 24, 2015), merely acknowledged the parties' dispute over whether the EOC was a contract but concluded the answer was irrelevant to the motion to dismiss.

undermin[ing] CMS's ability to create its own standards for what constitutes 'misleading' information about Medicare Part [C]." 620 F.3d 1134, 1157 (9th Cir. 2010).

Fourth, Plaintiffs' theories of liability under Count Five—pled and unpled—are preempted. At oral argument, Plaintiffs floated a new theory of anti-competitive injury not pled in Count Five: injury to *competing Medicare Advantage plans*. Tr. at 27:22–25. Setting aside that Plaintiffs lack standing to assert the rights of Humana's competitors, the theory is also preempted. CMS extensively regulates both the bid process for competing Part C plans, 42 C.F.R. § 422.250 *et seq.*, and whether AI may be used by MAOs in the coverage determination process.[5] The theory *actually pled* in Count Five fares no better, as it alleges the same conduct as Count Four,[6] which Plaintiffs now concede is preempted. And, because they concede Count Four, the part of Count Five that is expressly predicated on the Count Four statutory violation automatically falls away.[7]

Presentment and Exhaustion of the Medicare Administrative Appeal Process: The Court need not wade into these preemption issues, though, because presentment and exhaustion provide independent—and mandatory—bases for dismissal.

Here, Plaintiffs failed to "present" either their concerns about Humana's alleged use of AI or any of the Amended Complaint's claims to the Secretary of HHS—running afoul of the Sixth Circuit's "mandate[] that 'virtually all legal attacks' be presented to the agency." *S. Rehab. Grp., P.L.L.C. v. Sec'y of Health & Hum. Servs*., 732 F.3d 670, 679–80 (6th Cir. 2013) (holding that presentment requirement is "nonwaivable and nonexcusable") (quoting *Shalala v. Ill. Council on*

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[5] *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).
[6] *Compare* Count Five, Am. Compl. ¶ 177 and ¶ 179 *with* Count Four, *id.* ¶166 (similar to ¶ 177), and *id.* ¶ 167 (similar to ¶ 179).
[7] *See* Am. Compl. ¶ 178 ("As alleged in the immediately preceding cause of action, Humana has violated N.C. Gen. Stat. § 58-63-15(11), resulting in a *per se* violation of N.C. Gen. Stat. § 75-1.1").

Long Term Care, Inc., 529 U.S. 1, 15 (2000))); *see also New Vision Home Health Care, Inc. v. Anthem, Inc.,* 752 F. App'x 228, 236–37 (6th Cir. 2018).

Plaintiffs also failed to exhaust the Medicare mandatory administrative appeal process. At least five times in the last thirty years, the Sixth Circuit has underscored that the Medicare administrative appeal process is compulsory and refused to allow judicial waiver. *See Giesse v. Dept. of Health & Human Servs.*, 522 F.3d 697, 707 (6th Cir. 2008) (dismissing Medicare Part C enrollee's breach of contract and fraud claims for lack of exhaustion); *Cathedral Rock of N. Coll. Hill, Inc. v. Shalala*, 223 F.3d 354, 357 (6th Cir. 2000); *S. Rehab Grp.*, 732 F.3d 670; *Manakee Pro. Med. Transfer Serv., Inc. v. Shalala*, 71 F.3d 574, 580–81 (6th Cir. 1995); *New Vision*, 752 F. App'x at 235.[8] And, for the reasons explained in Humana's Response to Plaintiffs' Notice of Supplemental Authority, the judicial waiver doctrine identified in *Bowen v. City of New York*, 476 U.S. 467, 482–86 (1986) is unavailable here in the Sixth Circuit. *See* R.68 at PageID# 646–48.

The Avenues of Redress Authorized by Congress: Plaintiffs have avenues to redress perceived misconduct. Plaintiffs had access to the Medicare administrative appeal process, which includes an option for "fast track," next-calendar-day review by physician medical directors at an independent, external review organization. *See* 42 C.F.R. 422.626. Notably, two named Plaintiffs had successful appeals, undercutting Plaintiffs' futility arguments. *See* MTD Exs. 7 and 8.

Part C enrollees can also file grievances with their Medicare Advantage plan, 42 C.F.R. § 422.564, or lodge complaints directly with CMS, which CMS tracks. *See* 42 C.F.R. § 422.125; MEDICARE.GOV, *Medicare Complaint Form*, https://www.medicare.gov/my/medicare-

[8] Plaintiffs cite no Medicare cases where the Sixth Circuit has allowed waiver—*Day v. Shalala*, 23 F.3d 1052, 1065–66 (6th Cir. 1994), involved disability denial notices with improper notice of appeal rights, which infected the appeal process by preventing some plaintiffs from appealing at all. And the Supreme Court rejected the "procedural" dichotomy that Plaintiffs contend exempts them from the exhaustion requirement. *See Heckler v. Ringer*, 466 U.S. 602, 614–15 (1984).

complaint/step2b. And Congress empowered CMS to bring enforcement actions, including intermediate sanctions or suspension, against MAOs that violate the Medicare Act, 42 U.S.C. § 1395w-27(g). This includes situations where an MAO "[m]isrepresents or falsifies information that it furnishes," whether the recipient is CMS itself or "an individual or . . . any other entity," 42 C.F.R. § 422.752, as well as cases where an MAO does not provide "medically necessary" services to enrollees, *id.* § 422.750(a)(1).

These are the exclusive pathways set by Congress for Medicare Part C enrollees to seek redress. As the Sixth Circuit held in *Giesse*, Congress chose not to allow Part C enrollees to sue for money damages, as Plaintiffs attempt to do here. 522 F.3d at 702–05, 707. Plaintiffs' current legal theory that Medicare Part C enrollees can sue for treble damages in federal court to complain about the "process" through which their Medicare coverage determinations were made—even if their claims for Medicare Benefits were paid in full or even if they never sought Medicare Benefits for post-acute care at all[9]—would open the floodgates for nearly every Medicare enrollee to sue for money damages under state law. That would sabotage Congressional intent, and runs contrary to clear Sixth Circuit caselaw. *See supra* at 5. The Motion to Dismiss should be granted.

Dated: April 28, 2025

Respectfully Submitted,

/s/ Michael P. Abate

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[9] *See* Tr. at 5:6–10; Opp. at PageID# 542.

Certificate of Service

I hereby certify that on April 28, 2025, I filed the foregoing with the Court's CM/ECF system, which will deliver notice to all counsel of record.

s/ Michael P. Abate
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