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VIA ELECTRONIC FILING

The Honorable John R. Tunheim
U.S. District Court for the District of Minnesota
300 South Fourth Street, Courtroom 14E
Minneapolis, MN 55415

Re: Lokken, et al. v. UnitedHealth Group, Inc., et al., No. 23-CV-03514 (JRT/SGE)

Dear Judge Tunheim:

Pursuant to Local Rule 7.1(j), Defendants respectfully request leave of Court to file a motion for reconsideration or clarification of the Court's Order on Defendants' Motion to Dismiss. ECF 91. In the Order, the Court narrowed the case to two claims: Count 1 (Breach of Contract) and Count 2 (Implied Covenant) (collectively the "Contract Claims") because, "in analyzing these claims the Court would only be required to investigate whether UHC complied with its own written documents" and that it "need only review insurance documents to resolve these claims." *Id*. at 19, 2. By contrast, the Court dismissed Counts 3-7 reasoning that these claims "regulate the same subject matter" as the Medicare Act. *Id.* at 20-21. Specifically, the Court held that Count 3 (Unjust Enrichment) and Count 4 (Bad Faith) would require "evaluation of the medical payments Plaintiffs allegedly should have received" or "to evaluate whether the denial of coverage was reasonable and whether the use of nH Predict to make that denial decision was reasonable," and the statutory claims in Counts 5-7 "require insurers to use reasonable standards for prompt, individualized evaluation of insurance claims." *Id.* at 20-21.

A party seeking leave to file a motion for reconsideration "must show compelling circumstances to obtain such permission," L.R. 7.1(j), which may include "a decision which is clearly erroneous or would work a manifest injustice," *In re Potash Antitrust Litig.*, No. 3-93-197, 1994 U.S. Dist. LEXIS 21920, at *10 (D. Minn. Jan. 4, 1994), or a need to "correct manifest errors of law or fact." *Dixon v. Fresh Seasons Mkt., LLC*, No. 15-cv-3099-JNE/TNL, 2015 U.S. Dist. LEXIS 151652, at *3 (D. Minn. Nov. 9, 2015). Defendants respectfully submit that they meet this standard because the state laws underlying the Contract Claims "regulate the same subject matter as the Medicare Act." Four independent grounds support that conclusion.

First, in holding the Contract Claims not preempted, the Court focused on language in the Evidence of Coverage ("EOC") stating that clinical services staff and physicians make claim decisions. ECF 91 at 19 (citing Am. Compl. ¶ 187). But this EOC language tracks a Medicare regulation, which the Court cited in its analysis of Counts 3-7 as requiring preemption. ECF 91 at 20 & 21 (citing 42 C.F.R. § 422.566(d)). Section 422.566(d) states that "[i]f the MA organization expects to issue a partially or fully adverse medical necessity…decision based on the initial review of the request, the organization determination must be reviewed by *a physician or other appropriate health care professional*…." 42 C.F.R. § 422.566(d) (emphasis added). *See also* ECF 43 at 17. Thus, a determination whether Defendants complied with the EOC language and the consequence of any non-compliance would necessarily require the Court to evaluate a matter specifically covered by a Medicare regulation and which the Centers for Medicare and Medicare Services ("CMS") regulates.

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CMS has made clear that its regulation of Medicare Advantage Organizations ("MAO") extends to oversight of the tools and criteria that MAOs use to carry out utilization management processes. Indeed, CMS has issued guidance addressing use of artificial intelligence and algorithms in the coverage determination process, specifying: (1) the benefits MAO's must cover, (2) the criteria applicable to MAO coverage determinations, and (3) who must make those determinations. ECF 43 at 17-18 (citing CMS, FAQs Related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F) at 2 (Feb. 6, 2024) ("An algorithm or software tool may be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made.")).[1] Because resolution of the Contract Claims would require the Court to assess Defendants' use of nH Predict and their compliance with CMS regulations and guidance, they are preempted.

Second, damages are an essential element of a breach of contract claim. *Jensen v. Duluth Area YMCA*, 688 N.W.2d 574, 578-79 (Minn. Ct. App. 2004). But to assess damages for the Contract Claims, the Court would need to determine whether Defendants' applications of CMS coverage criteria were appropriate in individual cases, whether and the extent to which Plaintiffs were entitled to additional coverage to remain in the facility longer. As the Court recognized in holding Counts 3-7 preempted, "evaluation of the medical payments Plaintiffs allegedly should have received would regulate the covered serv[ice]s already regulated by the Medicare Act." ECF 91 at 20. Because a damage award would regulate the same subject matter as the Medicare Act, the Contract Claims also must be preempted.

Third, the state law underlying the Contract Claims and the Medicare Act regulate the same subject matter because CMS comprehensively regulates all aspects of Medicare Advantage EOCs. The Medicare Act and its regulations impose a remedial scheme for correcting non-compliance with the EOC's terms. ECF 43 at 3-5 (appeal process and enforcement). CMS also regulates extensively the form, content and accuracy of the EOC. *See* 42 C.F.R. § 422.111 (necessary disclosures), § 422.2261(d) (CMS review of MAO materials for compliance), § 422.2267 (requirements for standardized MAO materials). Varying state law damages claims and remedies based on non-compliance with the EOC would undermine the national uniform scheme Congress intended in enacting the Medicare Act. As the Court recognized, the Medicare Act supersedes any state law or regulation "with respect to MA plans which are offered by MA organizations," 42 U.S.C. § 1395w-26(b)(3), and courts in similar cases have held that claims for breach of the EOC are preempted. ECF 43 at 14-15.

Finally, the Court read the Contract Claims as limited to the allegation that Defendants breached the insurance contract terms requiring clinical staff to make decisions on health care services (Am. Compl. ¶ 187), but these claims also reference the fairness and individualized nature of the claim investigation and whether the reasons for claim denial were accurately disclosed (*id.* at ¶ 189), the appropriateness of care (*id.* at ¶ 190), whether Defendants conducted a thorough, fair, and objective investigation of each claim (*id.* at ¶ 196), and the reasonableness of the denial (*id.* at ¶¶ 198-199). If the Court intended the Contract Claims to survive as pled, these claims should be preempted just as the Court ruled with regard to Counts 3-7.

If the Court finds the Contract Claims are not preempted, Defendants request clarification that the Contract Claims are limited to breach of the EOC terms and that any damages cannot be based upon the extent of coverage or defendants' compliance with CMS coverage criteria in making coverage determinations. Absent clarification, we anticipate discovery disputes regarding how the Court's Order affects the scope of discovery.

[1] As stated in Defendants' briefing and on the record at the hearing, Defendants do not use nH Predict to make coverage determinations – physician reviewers make coverage determinations -- but nH Predict is used by Defendants for other purposes as permitted by CMS.

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Respectfully submitted,

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