IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CEDAR RAPIDS DIVISION

STATE OF KANSAS, et al., Plaintiffs, vs. ROBERT F. KENNEDY, JR.,[1] in his official capacity as Secretary of the United States Department of Health and Human Services, et al., Defendants.	No. C24-110-LTS-KEM **MEMORANDUM OPINION AND ORDER**

I. INTRODUCTION

This case, brought pursuant to the Administrative Procedure Act (APA), is before me on two motions. The first is the plaintiffs'[2] motion (Doc. 118) for summary judgment. The defendants[3] filed a resistance (Doc. 148)[4] and the plaintiffs filed a reply (Doc. 154). The second is the defendants' motion (Doc. 122) for judgment on the administrative record. The plaintiffs filed a resistance (Doc. 149) and the defendants filed a reply (Doc.

[1] HHS Secretary Robert F. Kennedy, Jr. and CMS Administrator Mehmet Oz are automatically substituted for their predecessors in accordance with Federal Rule of Civil Procedure 25(d).

[2] The plaintiffs include 20 states, 17 affiliates of LeadingAge (a trade association of non-profit nursing facilities) and two Kansas nursing home facilities. I will refer to all of the plaintiffs collectively as "the plaintiffs."

[3] The defendants are Robert F. Kennedy Jr., in his official capacity as Secretary of the United States Department of Health and Human Services, the United States Department of Health and Human Services, the Centers for Medicare and Medicaid Services and Mehmet Oz in his official capacity as Administrator of the Centers for Medicare and Medicaid Services. I will refer to all of the defendants collectively as "the defendants."

[4] The defendants filed an identical resistance at Doc. 148. I will refer to Doc. 146-1 when discussing the defendants' resistance.

156). The two motions, although procedurally distinct, function as de facto cross-motions, as they raise overlapping arguments and issues that the parties address in corresponding responses and replies. Oral argument is not necessary. *See* Local Rule 7(c).

For the reasons that follow, the plaintiffs' motion (Doc. 118) will be granted as to the 24/7 RN requirement and the hours per resident day requirements. Those requirements will be vacated. The plaintiffs' motion will be denied in all other respects. The defendants' motion (Doc. 122) will be granted as to the enhanced facility assessment requirement and the Medicaid reporting requirements. Those requirements will stand. The defendants' motion will be denied in all other respects.

II. PROCEDURAL HISTORY

On October 8, 2024, the plaintiffs filed a complaint (Doc. 1) alleging that the Biden Administration's Final Rule – "Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting" (Final Rule) – violates various provisions of the APA. *See* Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40876 (May 10, 2024) (to be codified at 42 C.F.R. pts. 438, 442, 483). An amended complaint (Doc. 37), filed October 23, 2024, includes the same claims.

Specifically, the plaintiffs argue that the Final Rule (1) lacks statutory authority, (2) is contrary to law and (3) is arbitrary and capricious. Doc. 37 at 42-61. The plaintiffs seek a declaratory judgment that three of the Final Rule's requirements – the 24/7 RN requirement, the hours per resident day (HPRD) requirements and the enhanced facility assessment (EFA) requirement—exceed CMS's statutory authority, are arbitrary and capricious or otherwise not in accordance with the law in violation of the APA. *Id.* at 61-62. Additionally, they seek an order vacating and setting aside these three

requirements as well as injunctive relief restraining the defendants from taking any action to enforce them. *Id.*

The plaintiffs filed their motion for a preliminary injunction on October 22, 2024. I heard oral arguments on December 5, 2024. On January 16, 2025, I denied the plaintiffs' request for a preliminary injunction, finding that the plaintiffs had not adequately demonstrated irreparable harm. Doc. 95 at 15. Instead, I determined that the interests of justice would be best served by proceeding to the dispositive motions stage. *Id.* at 21. On March 3, 2025, the plaintiffs filed a motion (Doc. 118) for summary judgment and the defendants filed a motion (Doc. 122) for judgment on the administrative record.

III. RELEVANT FACTS

A. Medicaid and Medicare Statutes

In 1965, Congress amended the Social Security Act to establish the Medicaid and Medicare programs. Pub. L. No. 89-97, 79 Stat. 286 (July 30, 1965). Medicare provides health insurance to "nearly 60 million aged or disabled Americans." *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 863 (8th Cir. 2021) (quoting *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019)); *see also* 42 U.S.C. § 1395 *et seq*. Medicaid is a joint federal-state program in which the federal government provides approximately $600 billion to states so they can offer healthcare coverage to low-income individuals. *See* 42 U.S.C. § 1396 *et seq.*; *see also Northport*, 14 F.4th at 863. The Secretary of Health and Human Services (HHS) administers both programs through the Centers for Medicare and Medicaid Services (CMS), a sub-agency of HHS. *See* Centers for Medicare & Medicaid Services, CMS.gov (last visited May 19, 2025).

Nursing homes that receive Medicare and Medicaid funding must comply with certain statutory requirements. *See* 42 U.S.C. § 1395i-3 (Medicare); *see* 42 U.S.C. § 1396r (Medicaid). As the statutory requirements under both statutes are largely the same, these nursing homes are often collectively known as "long-term care" (LTC) facilities.

In addition, CMS has issued consolidated regulations that are applicable to all LTC facilities that participate in Medicare and/or Medicaid. *See* 42 C.F.R. §§ 483.1-.95; *see also Northport*, 14 F.4th at 863.

The Medicare and Medicaid statutes contain identical language regarding nurse staffing. Both statutes require LTC facilities to use the services of a registered professional nurse (RN) for "at least 8 consecutive hours a day, 7 days a week" and to provide "24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1395i-3(b)(4)(C)(i) (Medicare); 42 U.S.C. § 1396r(b)(4)(C)(i)(I)-(II) (Medicaid). Additionally, both the Medicare and Medicaid statutes contain waiver provisions for the LTC facility staffing requirements. 42 U.S.C. §§ 1395i-3(b)(4)(C)(ii), 1396r(b)(4)(C)(ii).

B. Legislative and Rulemaking History Regarding Staffing Requirements

In 1935, Congress passed the Social Security Act. *See* Social Security Act, Pub. L. No. 74-27 (Aug. 14, 1935). It created the foundation of the United States' social safety net, providing old-age benefits and unemployment insurance, among other things. Additionally, it contained a general rulemaking authority permitting the Secretary of the Treasury, Labor and the Social Security Board to "make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the function with which each is charged under this Act." *Id.* at 647 § 1102. In 1965, Congress amended the Social Security Act to create Medicaid and Medicare. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (July 30, 1965). In this legislation, Congress defined an "extended care facility" under the Medicaid and Medicare programs as one that "provides 24-hour nursing service[s] which [are] sufficient to meet nursing needs" and "has at least one registered professional nurse employed full time." *Id.* at 79 Stat. at 317.

The Social Security Act has been amended frequently over the decades. There have been many proposals to amend the accompanying regulations – and as particularly

pertinent here, to impose more stringent staffing requirements for LTC facilities. However, minimum staffing levels were not adopted until the issuance of the Final Rule in 2024. Indeed, in 1972, Congress amended the Social Security Act, and the Department of Health, Education and Welfare (HEW) proposed and adopted regulations to accompany these amendments. *See* Federal Health Insurance for the Aged, 38 Fed. Reg. 18620, 18620 (proposed July 12, 1973) (to be codified at 20 C.F.R. pt. 40) *and* Federal Health Insurance for the Aged and Disabled, 39 Fed. Reg. 2238 (Jan. 17, 1974). The SSA received comments suggesting that "there be a specific ratio of nursing staff to patients." 39 Fed. Reg. at 2239. Nonetheless, it declined to adopt a specific ratio because of the diverse needs and varying operational capacities of different facilities. *Id.*

In 1980, Congress amended the SSA again and the HEW was renamed as the Department of Health and Human Services (HHS), which then assumed responsibility for administering Medicare and Medicaid. *See* Social Security Disability Amendments of 1980, Pub. L. 96–265, 94 Stat. 441 (June 9, 1980). HHS declined to "propose[] any nursing staff ratios or minimum number of nursing hours per patient per day" and instead maintained the existing language that called for "adequate staff to meet patient needs." Conditions of Participation for Skilled Nursing and Intermediate Care, 45 Fed. Reg. 47368, 47371 (proposed July 14, 1980) (to be codified at 42 C.F.R. pts. 405, 442, 483). HHS stated that it "[did] not have enough conclusive evidence to support requiring any specific numerical standards." *Id.* But it noted that some states had chosen to adopt specific standards and that it was "planning to undertake a study on this subject." *Id.* at 47372.

In 1983, HHS commissioned the Institute of Medicine to "study Federal regulations concerning long term care facilities and recommend changes that might enhance the ability of the regulatory system to assure that residents receive satisfactory care." *See* Medicare and Medicaid; Conditions of Participation for Long Term Care Facilities, 52 Fed. Reg. 38582, 38583 (proposed rule Oct. 16, 1987). In 1986, the Institute of Medicine published its report, which recommended amendments to nursing

home regulations ("Institute Report"). Nat'l Library of Med., Inst. of Med., *Improving the Quality of Care in Nursing Homes* (1986), https://archive.ph/KFNCi. However, the Institute Report declined to suggest that staffing ratios be adopted. *Id.* at 102 ("Because of the complexities of case mix—that is, the widely differing needs of individual residents in the same facility—prescribing simple staffing ratios clearly is inappropriate."). Nonetheless, it acknowledged that further studies would be undertaken "to develop an algorithm for relating minimum nursing staff requirements to case mix," which "could provide the basis for a regulatory tool of considerable power." *Id.* at 200-01.

Relying in part on the Institute Report, Congress enacted major reforms to the statutes that governed nursing home participation in Medicare and Medicaid in the Omnibus Budget Reconciliation Act of 1987. Pursuant to this legislation, Congress imposed uniform staffing requirements on LTC facilities participating in Medicare and Medicaid by requiring skilled nursing facilities to "provide 24-hour nursing service which is sufficient to meet nursing needs of its residents" and mandating that a RN be on duty for at least eight hours per day, seven days a week. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4201, 101 Stat. 1330-163 (Dec. 22, 1987). Additionally, Congress added more specific rulemaking language as it relates to LTC facilities. *Id.* at 101 Stat. 1330-171 ("A skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary."). CMS's rulemaking authority has not been altered since 1987, as the Secretary relied on this provision to promulgate the challenged Final Rule in this case. *See* 89 Fed. Reg. at 40879.

In 1990, Congress commissioned the HHS Secretary to "conduct a study" analyzing "the appropriateness of establishing minimum caregiver to resident ratios and minimum supervisor to caregiver ratios for skilled nursing facilities" receiving Medicare and Medicaid funding. *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4801, 104 Stat. 1338-218 (Nov. 5, 1990). Seemingly no conclusive data came from this study, as 26 years later, in 2016, CMS again declined to adopt minimum

staffing ratios or a 24/7 RN requirement. *See* Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688, 68755 (Oct. 4, 2016). CMS noted that it "remain[ed] convinced that additional data will be helpful in determining if and what such ratios should be" regarding minimum staffing. *Id.* In addition, CMS was concerned (1) that a 24/7 RN requirement would cause an increase in statutory waiver requests, (2) that such a requirement could impact the development of innovative care options and (3) that the geographic disparity in nurse supply could make a mandate particularly challenging in rural areas.[5] *Id.*

C. CMS Rulemaking Process and the Final Rule

The Biden Administration sought to "improve the safety and quality of nursing home care" and directed CMS to "conduct a new research study to determine the level and type of staffing needed to ensure safe and quality care and will issue proposed rules within one year."[6] CMS retained Abt Associates to complete this study.[7] Following the Abt Study, CMS issued a notice of a proposed rule in September 2023. It contained four main proposals: (1) a requirement that a RN must be on site for 24 hours per day, 7 days a week, (2) total minimum nurse staffing standards of 0.55 HPRD for RNs and 2.45 HPRD for Nurse Aids (NAs), (3) enhanced facility assessment requirements and (4) Medicaid reporting requirements. Medicare and Medicaid Programs; Minimum Staffing

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[5] Nonetheless, CMS observed that it "would have the discretion to impose a more stringent requirement regarding RN presence." 81 Fed. Reg. at 68755.

[6] *FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes*, THE BIDEN WHITE HOUSE ARCHIVES (Feb. 28, 2022), https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.

[7] ABT ASSOCIATES, Nursing Home Staffing Study Comprehensive Report (June 2023), https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf (hereinafter, Abt Study).

Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 88 Fed. Reg. 61352 (proposed Sept. 6, 2023) (to be codified at 42 C.F.R. pts. 438, 442, 483). CMS received 46,520 comments regarding the proposed rule. *See* 89 Fed. Reg. at 40883.

On May 10, 2024, CMS issued the Final Rule, which largely mirrors the proposed rule. *Id.* at 40876. The Final Rule includes: (1) a requirement that a RN be on site 24 hours per day, 7 days per week, (2) minimum nursing staffing standards of 3.48 for total nurse staffing HPRD, which must include a minimum of 0.55 RN HPRD and 2.45 NA HPRD, (3) revision of the existing facility assessment requirements and (4) Medicaid institutional payment transparency reporting requirements. *Id.* at 40877. Additionally, to ease some of the Final Rule's financial burden, CMS dedicated over $75 million "to launch an initiative to help increase the long-term care workforce." *Id.* at 40885. Moreover, the Final Rule provided additional time and flexibility for LTC facilities to implement the changes, including staggered implementation dates over a five-year period and providing exemptions from the minimum staffing standards. *Id.* at 40886.

In its Final Rule, CMS asserts that various provisions in sections 1819 [42 U.S.C. § 1395i-3] and 1919 [42 U.S.C. § 1396r] of the Social Security Act provide it authority for the HPRD and 24/7 RN requirements. *See* 89 Fed. Reg. at 40890-91. First, CMS states that §§ 1819(d)(4)(B) and 1919(d)(4)(B) of the Social Security Act support its authority to establish these requirements, as these sections "instruct the Secretary to issue such regulations relating to the health, safety, and well-being of residents as the Secretary may find necessary." 89 Fed. Reg. at 40890. Moreover, CMS contends that §§ 1819(b)(2) and 1919(b)(2) provide additional support for CMS's authority to establish these requirements, as those sections "require facilities to provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." *Id.* Finally, CMS asserts that §§ 1819(b)(1)(A) and 1919(b)(1)(A) "require that a SNF or NF must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the safety and quality of life of each

resident," which it asserts provides further support for the Final Rule's staffing requirements. *Id.* at 40891. However, as the plaintiffs assert and the defendants concede, the Secretary's sole rulemaking power to promulgate additional requirements is contained within §§ 1395i-3(d)(4)(b) and 1396r(d)(4)(B) of the Social Security Act, both of which state that LTC facilities must "meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary." *See* Doc. 122-1 at 23-24; *see also* Doc. 149 at 8-9.

Each of the four Final Rule requirements has a different implementation timeline. The 24/7 RN requirement must be implemented by May 11, 2026, for non-rural facilities and by May 10, 2027, for rural facilities. The HPRD requirements must be implemented by May 10, 2027, for non-rural facilities and by May 10, 2029, for rural facilities. The EFA requirement took effect on August 8, 2024, for all facilities. The Medicaid transparency reporting requirements must be implemented by all states and territories with Medicaid-certified facilities by May 10, 2028. 89 Fed. Reg. at 40876.

IV. APPLICABLE STANDARDS

Any party may move for summary judgment regarding all or any part of the claims asserted in a case. Fed. R. Civ. P. 56(a). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(c)).

"However, in a case involving review of a final agency action under the [APA], the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record." *Charter Operators of Alaska v. Blank*, 844 F. Supp. 2d 122, 126–27 (D.D.C. 2012); *see also National Parks Conservation Ass'n v. United States*, 177 F. Supp. 3d 1, 12 (D.D.C. 2016) (same). Indeed, Local Rule 56(h) notes "[o]rdinarily, motions for summary judgment are not appropriate in actions for

judicial review based on an administrative record." N.D. Iowa Rule 56(h); *see also Thomas v. U.S.E.P.A.*, No. 06-cv-115-LRR, 2007 WL 2127881, at *1 (citing Local Rule 56(h) and noting that courts consistently hold that summary judgment does not make procedural sense as agency action "is reviewed, not tried") (collecting cases). The district court's function "is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Charter Operators*, 844 F. Supp. 2d. at 127 (quoting *Occidental Eng'g Co. v. INS,* 753 F.2d 766, 769–70 (9th Cir. 1985)).

The standard of review for a Final Rule under the APA is "whether the challenged agency action is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Ark. Reg'l Organ Recovery Agency, Inc. v. Shalala*, 104 F. Supp. 2d 1084, 1086 (E.D. Ark. 2000) (quoting APA § 706(2)(A)). "In applying that standard, the focal point should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). "Review of an agency action under this standard is 'narrow and a court is not to substitute its judgment for that of the agency.'" *United Food & Comm. Workers Union, Loc. No. 663 v. USDA*, 532 F. Supp. 3d 741, 769 (D. Minn. 2021) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Indeed, "review is limited to the administrative record," as "the district court sits as an appellate tribunal" reviewing the entire case as a question of law." *National Parks Conservation Ass'n*, 177 F. Supp. 3d at 12 (citations omitted) (quotations omitted).

V. ANALYSIS

A. The Parties' Arguments

The plaintiffs argue that the Final Rule is unlawful and should be vacated in its entirety. Doc. 118-1 at 19-20. Specifically, they contend that it contradicts the Medicare and Medicaid statutes and that CMS does not have authority to impose the 24/7 RN and

HPRD requirements. *Id.* at 20-23. If upheld, the plaintiffs argue that the Final Rule raises constitutional doubt regarding the statutes. *Id.* at 23-24. Additionally, the plaintiffs assert that the Final Rule violates the major questions doctrine as it has "enormous economic and political significance and intrudes on state authority." *Id.* at 24-27. Finally, the plaintiffs contend that the Final Rule runs afoul the APA's arbitrary and capricious standard as CMS departed from past practice without explanation, did not consider reliance interests and failed to consider important aspects of the problem. *Id.* at 28. As such, the plaintiffs seek the entry of summary judgment, a declaration that the Final Rule is unlawful and vacatur of it. *Id.* at 39.

The defendants argue that the Final Rule's requirements do not exceed or conflict with CMS's statutory authority and that it does not raise constitutional doubt regarding the statutes. Doc. 122-1 at 23-39, 44-45. Additionally, they contend that the Final Rule does not implicate the major questions doctrine. *Id.* at 39-44. They argue that CMS provided a rational and robust explanation for the Final Rule, the rule is consistent with past practice, reliance interests were considered and compliance is feasible such that it is not arbitrary and capricious. *Id.* at 45-70. Finally, the defendants contend that if any part of the Final Rule is held unlawful, relief should be limited to the unlawful requirements and should not extend beyond the plaintiffs. *Id.* at 71-76.

B. Severability

Before considering the merits, first I must address the issue of severability. S*ee Las Americas Immigrant Advoc. Ctr. v. DHS*, No. CV 24-1702 (RC), 2025 WL 1403811, at *12 (D.D.C. May 9, 2025) (noting that severability is a "threshold" issue to be determined before proceeding to the merits); *see also Carter v. Gallagher*, 337 F. Supp. 626, 627 (D. Minn. 1971) ("First of all, the threshold question of severability must be considered."). The plaintiffs contend that the Final Rule cannot be severed, as they contend "[t]he entire Rule serves to impose the staffing mandates that are unlawful and unauthorized by statute" and "the entire Rule is arbitrary and capricious." Doc. 118-1

at 37. The defendants argue that "[t]he Final Rule's severability clause [] demonstrates that each unchallenged portion of the Rule functions independently of those challenged by Plaintiffs[.]" Doc. 122-1 at 73.

The United States Court of Appeals for the District of Columbia has held that regulations may be severable under certain circumstances. In determining whether severability is appropriate, the court has adopted the following inquiry: "(1) whether the agency intended portions of the regulation to be severable, and (2) 'whether the remainder of the regulation could function sensibly without the stricken provision.'" *Missouri v. Biden*, No. 4:24-CV-00520-JAR, 2024 WL 3104514, at *29 (E.D. Mo. June 24, 2024) (quoting *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001)); *see also Carlson v. Postal Regul. Comm'n*, 938 F.3d 337, 351 (D.C. Cir. 2019) ("[T]he APA permits a court to sever a rule by setting aside only the offending parts of the rule."). "Severability turns on agency intent, meaning that '[w]here there is substantial doubt that the agency would have adopted the same disposition regarding the unchallenged portion if the challenged portion were subtracted, partial affirmance is improper.'" *Nasdaq Stock Mkt. LLC v. SEC*, 38 F.4th 1126, 1144 (D.C. Cir. 2022) (citation omitted).

Similarly, the Supreme Court has upheld portions of Congressional statutes that contain a severability clause. The Court has held that a severability clause "creates a presumption that Congress did not intend the validity of the statute in question to depend on the validity of the constitutionally offensive provision." *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987). Indeed, it has held that "absent extraordinary circumstances, the Court should adhere to the text of the severability or nonseverability clause." *Barr v. Am. Ass'n of Pol. Consultants, Inc.*, 591 U.S. 610, 624 (2020). The Court acknowledged that historically severability clauses were not always honored, but observed that "courts today zero in on the precise statutory text and, as a result, courts hew closely to the text of severability or nonseverability clauses." *Id.*; *cf. United States v. Jackson*, 390 U.S. 570, 585 n.27 (1968) ("[T]he ultimate determination of severability

will rarely turn on the presence or absence of such a clause"). Here, the Final Rule contains a severability clause. *See* 89 Fed. Reg. at 40913 ("Any provision of this final rule held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provisions permitted by law[.]"). Therefore, the presumption of severability applies.

I next must consider whether the provisions of the Final Rule are able to operate independently of one another. Although the 24/7 RN and the HPRD requirements appear to be the focal point of the Final Rule, the Final Rule does not indicate that these staffing standards are the "primary purpose" or "major provisions" of the regulation, which supports a finding of severability. *Cf. Mayor of Baltimore v. Azar*, 973 F.3d 258, 293 (4th Cir. 2020) (finding no severability despite the presence of a severability clause when the language of the final rule labeled certain provisions as major and identified a "primary purpose" of the challenged rule). Additionally, the Medicaid reporting requirement is included in the title of the Final Rule and both that requirement and the EFA requirement are described in the "Summary of Provisions" section. 89 Fed. Reg. at 40877. Such inclusion indicates that these provisions were regarded as significant components of the Final Rule, which further supports a finding of severability.

Importantly, the Final Rule details precisely how the requirements operate independently of each other – refuting the plaintiffs' contention that the severability language is "boilerplate." Doc. 118-1 at 37; *see* 89. Fed. Reg. at 40913 ("[T]he specific HPRD and 24 hour, 7 day a week RN staffing requirements finalized at § 483.35(b)(1) and (c)(1) could independently make improvements in the number of staff present at a LTC facility[;]" the Medicaid reporting provisions "[are] a reporting requirement, and the information about Medicaid expenditures on compensation for direct care and support staff workforce is important for CMS and the public in helping determine whether Medicaid service payments are economic and efficient"); *see also id.* at 40908 ("The facility assessment requirement ensures that each LTC facility assesses the needs of its resident population to determine the resources it needs to provide the care its residents

require . . . Each requirement works independently to achieve the separate goals of a minimum nurse staffing requirement and an assessment of the resources that are required to care for the LTC facility's resident population."). Because each requirement serves a distinct function with independent objectives, I find that each component of the Final Rule can operate separately. *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (holding that severance is appropriate where it "will not impair the function of the statute as a whole and there is no indication that the regulation would not have been passed but for its inclusion"). As such, I will separately consider the plaintiffs' challenges to the four requirements of the Final Rule—the 24/7 RN requirement, the HPRD requirements, EFA requirement and the Medicaid reporting requirements.

C. Conflict with Statutory Language

1. 24/7 RN Requirement

The plaintiffs argue that the 24/7 RN requirement conflicts with the Medicare and Medicaid statutes. These statutes state that LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1396r(b)(4)(C)(i)(II); *see also* § 1395i-3(b)(4)(C)(i). The plaintiffs contend that the Final Rule replaces these statutory requirements with a mandate that an LTC facility have a RN onsite 24 hours a day, 7 days per week. Doc. 118-1 at 21. Additionally, they argue that the 24/7 RN requirement nullifies the statutory waiver, as the Final Rule only permits an eight-hour exemption to the 24-hour requirement, whereas Congress provided waivers for the "at least 8 consecutive hours a day" requirement. *Id.* (citing § 1396r(b)(4)(C)(ii) and § 1395i-3(b)(4)(C)(ii)).

The defendants contend that the Final Rule does not conflict with the statute. They assert that the court would have to delete the words "at least" from the statute to find a conflict, as 24 hours is at least 8 hours. Doc. 122-1 at 28. Additionally, they argue that the 24/7 RN requirement is a permissible exercise of the Secretary's capacious rulemaking power to impose other "requirements relating to the health and safety of

residents . . . as the Secretary may find necessary." *Id.* at 32 (quoting 42 U.S.C. § 1396r(d)(4)(B); *id.* at § 1395i-3(d)(4)(B)). They contend that CMS has repeatedly used this rulemaking authority to set staffing requirements for participation in Medicare and Medicaid programs beyond what is required by the statutes. *See* Doc. 122-1 at 29. Finally, they argue that the Final Rule does not eliminate or modify the existing statutory waiver, as facilities can seek both the statutory waiver and regulatory exemption. *Id.* at 28 n.6.

As an initial matter, I agree with the defendants that the 24/7 RN requirement is not plainly incongruous with the statutory language, nor does it nullify the statutory waiver. Twenty-four hours is, of course, "at least" eight hours per day. Additionally, as explained by CMS, the Final Rule does not swallow the statutory waiver, as both the statutory waiver and regulatory exemption may apply if certain conditions are satisfied. *See* 89 Fed. Reg. at 40899.

However, the 24/7 RN provision replaces the Congressionally-established floor of "at least 8 hours per day" with a floor of 24 hours per day. This is impermissible. The defendants correctly note that the Eighth Circuit has characterized CMS's rulemaking authority that it relied upon to promulgate this requirement, as "capacious[]," *Northport Health Servs. of Ark.,* 14 F.4th at 870, and the Supreme Court has recognized that terms like "appropriate or reasonable" "leave[] agencies with flexibility," *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024) (quotations omitted)). Nonetheless, CMS does not have the authority to rewrite a statute so as to replace one term with another. Congress determined that LTC facilities should have an RN present for at least eight hours per day. CMS's 24/7 RN requirement creates a legal conundrum wherein a LTC facility could be found to have violated the agency's rule for doing precisely what the statute permits (*e.g.*, employing an RN for 12 hours per day). As "neither this court nor the agency is free to ignore the plain meaning of the statute and to substitute its policy judgment for that of Congress," the 24/7 RN requirement exceeds CMS's statutory authority. *Ala. Power Co. v. Costle*, 636 F.2d 323, 365 (D.C. Cir. 1979); *see also MCI*

Telecomms. Corp. v. Am. Tel. & Tel. Co., 512 U.S. 218, 234 (1994) ("[T]he Commission's estimations, of desirable policy cannot alter the meaning of the federal Communications Act of 1934.").

The defendants argue that the Supreme Court has upheld CMS's use of its health and safety rulemaking authority to impose staffing requirements on LTC facilities that extend beyond the express language of the statute. However, the examples they identify are inapposite to the 24/7 RN requirement challenged here. *See* Doc. 122-1 at 30. The defendants rely entirely on *Biden v. Missouri*, 595 U.S. 87 (2022), and contend that the 24/7 RN requirement is akin to the dietician staffing and infection preventionist rules that the Supreme Court identified as permissible uses of CMS's health and safety rulemaking authority. *Id.* Regarding dietician staffing, under the Medicare and Medicaid statues, LTC facilities are required to provide "dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident." 42 U.S.C. § 1396r(b)(4)(A)(iv) (Medicaid); *id.* at § 1395i-3(b)(4)(A)(iv) (Medicare). Pursuant to its health and safety rulemaking authority, CMS adopted regulations that required LTC facilities to employ "[a] qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis" and who "[h]as completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional." 42 C.F.R. § 483.60(a)(1)-(1)(ii) (1989). Additionally, the Medicare and Medicaid statutes require LTC facilities to "establish and maintain an infection control program." 42 U.S.C. § 1396r(d)(3)(A); *see also id.* at § 1395i-3(d)(3)(A). Using the same health and safety rulemaking authority, CMS issued a regulation that requires one or more individuals to be designated as an infection preventionist, each of whom must meet certain qualifications. *See* 42 C.F.R. § 483.80(b) (1989).

These regulations are not analogous to the challenged 24/7 RN requirement. The Medicaid and Medicare statutes impose a general requirement to provide dietary and infection programs but do not specify any staffing requirements. In that context, CMS

acts within its discretion to specify staffing requirements so long as they do not conflict with congressional intent. By contrast, the Medicare and Medicaid statues specify RN staffing details—requiring "at least 8 hours per day"—which CMS effectively overruled with the 24/7 RN requirement. When Congress has already legislated, the agency cannot substitute its judgment for that of the legislature. *Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016) ("Disagreeing with Congress's expressly codified policy choices isn't a luxury administrative agencies enjoy."); *see also Biden v. Nebraska*, 600 U.S. 477, 515 (2023) (Barrett, J., concurring) ("[A] reasonably informed interpreter would expect Congress to legislate on 'important subjects' while delegating away only 'the details.'") (citations omitted).

Similarly, the rule upheld in *Biden v. Missouri*, which required all employees to be vaccinated against COVID-19, is distinguishable from the 24/7 RN requirement. *See* 595 U.S. at 95-96. As the plaintiffs note, unlike the 24/7 RN requirement, there is no language in the Medicare or Medicaid statutes regarding vaccination, nor was there prior legislative or regulatory history about either COVID-19 or vaccinations more generally. *See* Doc. 149 at 15; *see also Missouri*, 595 U.S. at 97 ("[S]uch unprecedented circumstances provide no grounds for limiting the exercise of authorities the agency has long been recognized to have.").

Nor is the defendants' "canon of donut holes" argument persuasive. *See* Doc. 122-1 at 31-32. They contend that the Supreme Court has recognized that there is not a "canon of donut holes" in which "Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception. Instead, when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *Id.* at 31 (quoting *Bostock v. Clayton Cnty., Ga.*, 590 U.S. 644, 669 (2020)). In other words, courts should not invent exceptions to clear statutory language simply because applying the statute in a particular way produces an unexpected or politically sensitive result. *See Bostock*, 590 U.S. at 670 ("Title VII prohibits all forms of discrimination because of sex, however they may manifest themselves or whatever other

labels might attach to them[.]"). As such, the defendants contend that because CMS has broad rulemaking power to establish "other requirements relating to the health and safety of residents . . . as the Secretary may find necessary," the court cannot prevent CMS from promulgating additional staffing requirements. Doc. 122-1 at 31.

However, this "canon of donut holes" is inapplicable where there is a countervailing specific statutory provision. The Supreme Court has explained that:

> where there is, in the same statute, a particular enactment, and also a general one, which . . . would include what is embraced in the former, the particular enactment must be operative, and the general enactment must be taken to affect only such cases within its general language as are not within the provisions of the particular enactment.

See RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 646 (2012) (quoting *United States v. Chase*, 135 U.S. 255, 260 (1890)). The defendants contend that *RadLAX* is inapplicable because there must be a "direct conflict between the 'specific' and 'general' provisions of the statue." Doc. 148 at 16. Because there is not a conflict between CMS's general rulemaking power and the 24/7 RN requirement, they argue that this principle cannot apply. However, the Eighth Circuit has held that such a direct conflict is not necessary; rather "[a] general provision should not swallow a specific one and render it superfluous." *Berndsen v. N. Dakota Univ. Sys.*, 7 F.4th 782, 794 (8th Cir. 2021) (Colloton, J., concurring) (citing *RadLAX*, 566 U.S. at 645); *see also United States v. Kidd*, 963 F.3d 742, 748 (8th Cir. 2020) ("A specific provision generally takes precedence over a general provision adopted earlier . . . especially when applying the general provision would render the later enactment inoperative.").

The Secretary's rulemaking power to "meet such other requirements relating to the health, safety, and well-being of residents . . . as the Secretary may find necessary" and the "at least 8 hours per day" RN requirement were both added to the Medicaid and

Medicare statutes in 1987.[8] *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330-171, 186 (1987). Therefore, the principle that a subsequently enacted specific provision governs is inapplicable here. Nonetheless, the provisions must be read together – giving effect to both, rather than allowing the general to override the specific. Because CMS's 24/7 RN requirement effectively nullifies the specific "at least 8 hours" per day RN requirement, the 24/7 RN requirement violates the Medicare and Medicaid statutes. CMS's general rulemaking authority does not permit it to override explicit Congressional statutory commands.

2. HPRD Requirements

The plaintiffs contend the HPRD requirements conflict with the Medicare and Medicaid statutes. The statutes require that LTCs provide "24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i)(I); *id.* at § 1395i-3(b)(4)(C)(i). In the Final Rule, CMS – relying on its authority to promulgate, "such other requirements relating to the health and safety of residents . . . as the Secretary may find necessary" – requires that LTC facilities "meet or exceed a minimum of 3.48 [HPRD] for total nurse staffing," which must include a "minimum of 0.55 [HPRD] for [RNs]" and a "minimum of 2.45 [HPRD] for nurse aids." 89 Fed. Reg. at 40996. The plaintiffs contend that CMS impermissibly relied upon its general rulemaking power to craft a quantitative rule when Congress provided a qualitative standard. Doc. 149 at 15-16.

The defendants contend that there is no conflict between the HPRD requirements and the Medicare and Medicaid statutes. Doc. 146-1 at 18. They argue that Congress gave CMS the authority to exceed existing statutory requirements in the Omnibus Budget Reconciliation Act of 1990 (1990 Act). *See id.* at n.2; Doc. 122-1 at 17. Moreover, the

[8] Nonetheless, Congress required LTC facilities participating in Medicare and Medicaid to employ an RN full-time since the creation of these programs in 1965.

defendants assert that the Supreme Court has upheld CMS's authority to impose quantitative requirements through rulemaking when a statute only contains a qualitative standard. Doc. 122-1 at 35; *see also* Doc. 156 at 14-15. They argue that Congress' requirement that facilities provide "sufficient staff" cannot be construed to implicitly limit CMS's rulemaking authority. Doc. 122-1 at 34.

Like the 24/7 RN requirement, the HPRD requirements do not plainly conflict with the statutory text. Nonetheless, the requirements set a floor not provided by the statute. The defendants assert that in the 1990 Act, Congress granted CMS authority to impose stricter staffing rules than those contained within the Omnibus Budget Reconciliation Act of 1987 (1987 Act). *Id.* at 29. Indeed, three years after the passage of the 1987 Act, Congress enacted a statute stating, in part, that "[a]ny regulations promulgated and applied" by the HHS Secretary after the 1987 Act "shall include requirements *for providers* of such services that are at least as strict as the requirements applicable *to providers* of such services prior to the enactment of [the 1987 Act]." Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388-218 (Nov. 5, 1990) (emphasis added). However, there is a difference between the Secretary's authority to impose requirements for providers (as provided in the statute) and the authority to mandate a specific number of providers (as mandated by the Final Rule). Requiring a specific level of staff per resident is meaningfully different than establishing additional requirements for providers—such as mandating certain qualifications, vaccinations, trainings, among other things. As such, this argument is unpersuasive.

As the defendants correctly note, however, the Supreme Court has endorsed CMS's quantitative regulations when a statute establishes only a qualitative standard. Doc. 122-1 at 35; *see also* Doc. 156 at 14-15. As discussed above, the statutory text requiring LTC facilities to provide dietary services sets a qualitative standard. *See* 42 U.S.C. § 1396r(b)(4)(A); *id.* at § 1395i-3(b)(4)(A)(iv) ("provide . . . dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident"). The statute does not contain quantitative requirements regarding staffing.

Nonetheless, the Supreme Court found that CMS lawfully supplemented the qualitative standard with a quantitative requirement. *Missouri*, 595 U.S. at 94 (citing 42 C.F.R. § 483.60(a)(1)(ii) (requiring qualified dieticians to have completed at least 900 hours of supervised practice)). The dietician regulations also require LTC facilities to employ "[a] qualified dietician or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis." 42 C.F.R. § 483.60(a)(1). While the Court did not address that requirement, it implicitly sanctioned CMS's power to require the employment of at least one dietician even though the statute includes only a "needs" based standard.

Similarly, the Medicaid and Medicare statutes require LTC facilities to "establish and maintain an infection control program." 42 U.S.C. § 1396r(d)(3)(A); *see also* 42 U.S.C. § 1395i-3(d)(3)(A). The Supreme Court noted that CMS, relying on its health and safety rulemaking authority, "has established long lists of detailed conditions with which facilities must comply to be eligible to receive Medicare and Medicaid funds." *Missouri*, 595 U.S. at 90 (citing 42 C.F.R. § 483.80 (LTC facility infection prevention and control requirements)). Like the dietary service provision, the statutes do not contain specific requirements regarding infection control staffing. Nonetheless, CMS promulgated regulations to require "one or more individual(s)," who works at least part-time, to be designated "as the infection preventionist(s)" and further requires these individuals to complete professional training and meet minimum qualifications. 42 C.F.R. § 438.80(b).

Whereas the dietician and infection control regulations require only the hiring of one individual, and not on a full-time basis, the HPRD provisions contain more detailed and rigid staffing requirements – 3.48 HPRD for total nurse staffing, with a minimum of 0.55 HPRD for RNs and 2.45 HPRD for nurse aids. Nonetheless, in light of the Supreme Court's analysis in *Missouri*, I find that the HPRD requirements do not conflict with the statutory requirements to provide "24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i)(I); *id.* at §

1395i-3(b)(4)(C)(i). Although CMS included more-specific quantitative requirements in the HPRD provisions than in the regulations regarding dietician and infection control staffing, the same general principle applies – an agency is permitted to quantify a general statutory directive through rulemaking.[9] As such, I find that the HPRD requirements do not conflict with the Medicaid and Medicare statutes.

3. EFA and Medicaid Institutional Reporting Requirements

In addition to the 24/7 RN requirement and the HPRD requirements, the Final Rule also contains an EFA requirement and Medicaid reporting requirements. The plaintiffs do not challenge the EFA requirement or the Medicaid institutional reporting requirements as violating the Medicaid and Medicare statutes, nor do they contend that these requirements are contrary to law. *See* Doc. 37 at 42-46, 48-50 (challenging only the 24/7 RN requirement and the HPRD requirements as lacking statutory and being contrary to law).

Nonetheless, in the amended complaint, the plaintiffs indicate that they seek a declaration that the EFA requirement "exceeds CMS's statutory authority" and is "otherwise not in accordance with the law in violation of the APA." Doc. 37 at 61.

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[9] A similar lawsuit in the Northern District of Texas challenged the Final Rule's 24/7 RN requirement and the HPRD requirements. *See AHCA v. Kennedy*, No. 24-cv-114-Z-BR, Doc. 26 (N.D. Tex. June 18, 2024). On summary judgment, the court found that both the 24/7 RN requirement and the HPRD requirements violated the Medicare and Medicaid statutes. *AHCA v. Kennedy*, 24-cv-114-Z-BR, 2025 WL 1032692 (N.D. Tex. Apr. 7, 2025). In discussing the HPRD requirements, the court held that CMS impermissibly set a baseline staffing requirement that does not follow from the text of the statute, as it "ignores residents' nursing needs." *Id.* at *10 (emphasis omitted). The court noted that "the agency likely could remain within its authority if it issued regulations specifying how a facility should analyze the 'nursing needs of its residents[,]'" but stated that CMS cannot "set a baseline that ignores residents' nursing needs." *Id.* (emphasis omitted). As noted above, however, in *Biden v. Missouri*, the Supreme Court found that CMS acted within its health and safety rulemaking authority by setting a baseline staffing requirement when Congress mandated that an LTC facility meet the "dietary needs of each resident." *See* 595 U.S. at 94. Thus, the Court rejected the argument that an agency violates a statutory requirement to consider residents' needs by establishing a staffing baseline through rulemaking.

However, the plaintiffs' briefing in support of their motion, and in opposition to the defendants' motion, makes no argument either the EFA requirement, by itself, or the Medicaid reporting requirements, by themselves, exceed CMS's statutory authority. *See, e.g.*, Doc. 149 at 42-43. As such, I find that this claim has been waived. *See Resol. Tr. Corp. v. Dunmar Corp.,* 43 F.3d 587, 599 (11th Cir. 1995) ("There is no burden upon the district court to distill every potential argument that could be made based upon the materials before it on summary judgment . . . Rather, the onus is upon the parties to formulate arguments; grounds alleged in the complaint but not relied upon in summary judgment are deemed abandoned."); *Briggs v. Univ. of Detroit-Mercy*, 611 F. App'x 865, 870 (6th Cir. 2015) ("[A] plaintiff is deemed to have abandoned a claim when a plaintiff fails to address it in response to a motion for summary judgment."). I therefore find that the EFA requirement and the Medicaid reporting requirements do not violate the Medicare and Medicaid statutes.

D. Major Questions Doctrine

I will next consider whether the Final Rule, through the 24/7 RN requirement and the HPRD requirements, runs afoul of the major questions doctrine.[10] The plaintiffs argue that the major questions doctrine "provides another basis on which the Court should conclude that CMS lacks statutory authority to enact the Rule." Doc. 118-1 at 27. The defendants contend that the Final Rule does not implicate the major questions doctrine. Doc. 122-1 at 39.

The Supreme Court has explained the major questions doctrine as follows:

[10] While plaintiffs seem to challenge the entirety of the Final Rule as violating the major questions doctrine, their arguments rely exclusively on the staffing mandates. *See, e.g.*, Doc. 118-1 at 25 (noting that the staffing mandates will cost $43 billion, which is enough to trigger the major questions doctrine); Doc. 149 at 20 ("The Rule affects the vast majority of LTCs throughout the country and threatens to close many of them which will not be able to comply with the staffing mandates."); *id.* at 21 (observing that "38 states have adopted their own staffing standards" which has "troubling federalism implications"). Therefore, I will analyze the major questions doctrine only as it relates to the 24/7 RN requirement and the HPRD requirements.

> Extraordinary grants of regulatory authority are rarely accomplished through "modest words," "vague terms," or "subtle device[s]." *Whitman [v. American Trucking Associations, Inc.]*, 531 U.S. [457] at 468, 121 S. Ct. 903 [(2001)]. Nor does Congress typically use oblique or elliptical language to empower an agency to make a "radical or fundamental change" to a statutory scheme. *MCI Telecommunications Corp. v. American Telephone & Telegraph Co.*, 512 U.S. 218, 229, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994). Agencies have only those powers given to them by Congress, and "enabling legislation" is generally not an "open book to which the agency [may] add pages and change the plot line." E. Gellhorn & P. Verkuil, Controlling *Chevron*Based Delegations, 20 Cardozo L. Rev. 989, 1011 (1999). We presume that "Congress intends to make major policy decisions itself, not leave those decisions to agencies." *United States Telecom Assn. v. FCC*, 855 F.3d 381, 419 (CADC 2017) (Kavanaugh, J., dissenting from denial of rehearing en banc).
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> Thus, in certain extraordinary cases, both separation of powers principles and a practical understanding of legislative intent make us "reluctant to read into ambiguous statutory text" the delegation claimed to be lurking there. *Utility Air [Regulatory Group v. EPA]*, 573 U.S. [302] at 324, 134 S. Ct. 2427 [(2014)]. To convince us otherwise, something more than a merely plausible textual basis for the agency action is necessary. The agency instead must point to "clear congressional authorization" for the power it claims. *Ibid*.
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> As for the major questions doctrine "label[ ]," . . . it took hold because it refers to an identifiable body of law that has developed over a series of significant cases all addressing a particular and recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted.

West Virginia v. EPA, 597 U.S. 697, 723-24 (2022). Applying the doctrine requires a two-step inquiry. When a statute gives rulemaking authority to an administrative agency, the court must first decide if "Congress in fact meant to confer the power the agency asserted." *Id*. at 721. "In the ordinary case, that context has no great effect on the appropriate analysis." *Id*. However, in "extraordinary cases" a court must look at the "history and the breadth of the authority that [the agency] has asserted" as well as the

"economic and political significance" of the action before deciding that Congress meant to give them that authority. *Id.* (citations omitted); *see also Biden v. Nebraska*, 600 U.S. at 506 (noting that the first question in the major questions doctrine inquiry is whether it is a "question of deep economic and political significance") (cleaned up).

If an agency action is deemed to be extraordinary, the court then looks to see if there is clear congressional authority for the agency's challenged action. An agency must point to "something more than a merely plausible textual basis." *West Virginia,* 597 U.S. at 723; *see also Missouri v. Biden*, 112 F.4th 531, 537 (8th Cir. 2024); *cf. Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014) ("We expect Congress to speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'") (citations omitted) (quotations omitted).

I will first determine whether this is an extraordinary case, which requires examining the history and breadth of CMS's authority as well as the economic and political significance of CMS's action. The plaintiffs contend that the staffing mandates will cost at least $43 billion and alter the nursing home industry, as the Final Rule "affects nearly all LTCs nationwide and will put many of them out of business." Doc. 118-1 at 25. Additionally, the plaintiffs contend that the staffing requirements nullify laws that exist in nearly all states, as "the Rule acknowledges that 38 states and D.C. have adopted their own staffing standards that vary between them." *Id.* at 26 (citing 89 Fed. Reg. at 40881).

The defendants maintain that the major questions doctrine is not applicable because CMS did not assert power beyond what Congress could have reasonably understood to have granted to it. Doc. 146-1 at 22. Indeed, they assert that CMS has frequently exercised its rulemaking authority to issue additional staffing requirements. Doc. 122-1 at 41. Moreover, they contend that neither a $43 billion price tag nor the fact that this federal regulation preempts state laws is sufficient to implicate this doctrine. Doc. 146-1 at 22-23; Doc. 122-1 at 42-43.

Deciding whether a rule triggers the major questions doctrine is neither a simple nor a direct inquiry. Indeed, as then Judge Kavanaugh noted, "[t]o be sure, determining whether a rule constitutes a major rule sometimes has a bit of a 'know it when you see it' quality." *U.S. Telecom Ass'n v. FCC*, 855 F.3d 381, 423 (D.C. Cir. 2017) (Kavanaugh, J., dissenting). Because identifying an "extraordinary" case is a context-dependent judgment, I will examine several instances in recent years in which the Supreme Court has applied or declined to apply the doctrine.

In *Alabama Association of Realtors v. HHS*, 594 U.S. 758 (2021) (per curiam), the Supreme Court applied the major questions doctrine and rejected the CDC's claimed authority to issue a nationwide eviction mortarium in response to the COVID-19 pandemic. The CDC asserted that it had authority to issue such a mortarium pursuant to a statutory provision that authorized the Secretary to "make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases." *Id.* at 761. The Court found that the eviction moratorium rule presented an extraordinary case, and therefore triggered the major questions doctrine, as it would have a nearly $50 billion impact, intruded into landlord-tenant relationships – an area typically in the state law domain—and would affect 80 percent of the country. *Id.* at 764. The court struck down the rule. *Id.*

In *West Virginia v. EPA*, 597 U.S. 697 (2022), the Court invalidated a rule that required coal power plants to switch to cleaner energy sources. Under the Clean Air Act, the Environmental Protection Agency (EPA) had authority "to regulate power plants by setting a 'standard of performance'" to "reflect the 'best system of emission reduction' that the Agency has determined to be 'adequately demonstrated' for the particular category." *Id.* at 706. For the previous 50 years, the EPA had used this authority to set standards to reduce pollution but had never required "generation shifting" as a "system of emission reduction" before adopting the challenged rule. *Id.* at 717. The Court determined that the rule presented an extraordinary case, as the EPA "substantially restructure[d] the American energy market" by relying on power in an "ancillary

provision[]" of a "long-extant statute" to "adopt a regulatory program that Congress had conspicuously and repeatedly declined to enact itself." *Id.* at 724.

Similarly, in *Biden v. Nebraska*, 600 U.S. 477 (2023), the Court found that the HEROES Act did not authorize the Secretary of Education to cancel student loan debt. Relying on the statutory provision that permitted the Secretary to "'waive or modify' existing statutory or regulatory provisions applicable to financial assistance programs," the Secretary sought to establish a student loan forgiveness program to cancel about $430 billion in debt principal. *Id.* at 494, 496. The Supreme Court found that the rule presented an extraordinary case because (1) the "Secretary has never previously claimed powers of this magnitude under the HEROES Act," (2) the Act had only been used once before to waive or modify a provision related to debt cancellation and (3) the economic and political significance of the rule was staggering, as it was estimated to cost taxpayers between $469 and $519 billion. *Id.* at 501-02.

However, the Supreme Court has declined to apply the doctrine in cases that some may view as "extraordinary." As the defendants note, in considering a challenge to CMS's rule requiring all employees, volunteers, contractors and other workers to be vaccinated against COVID-19, the Supreme Court did not apply, or even mention, the major questions doctrine. *See* Doc. 146-1 at 21 (citing *Biden v. Missouri*, 595 U.S. 87 (2022) (per curiam)). Although the dissent noted that "the Government has effectively mandated vaccination for 10 million healthcare workers," the court did not consider the history and breath of CMS's authority, nor did it consider the political and economic consequences of the vaccine requirement. *Id.* at 98 (Thomas, J., dissenting).

The defendants also note that the Supreme Court did not apply or consider the major questions doctrine in *Collins v. Yellen*, 594 U.S. 220 (2021), *Little Sisters of the Poor Saints Peter & Paul Home v. Penn.*, 591 U.S. 657, 675-76 (2020), or *Dep't of Comm. v. New York*, 588 U.S. 752, 776-77 (2019). Doc. 146-1 at 23. In *Collins v. Yellen*, the Court considered whether the Federal Housing Finance Agency (FHFA), as conservator of Fannie Mae and Freddie Mac under the Housing and Economic Recovery

Act of 2008 (HERA) had authority to promulgate "third amendment," which required all Fannie Mae's and Freddie Mac's profits to be paid to the Treasury. 594 U.S. at 227. The plaintiffs, Fannie Mae and Freddie Mac's shareholders, claimed the "third amendment" exceeded FHFA's statutory conservatorship power. The court disagreed, finding that "[t]he Recovery Act grants the FHFA expansive authority in its role as a conservator." *Id.* at 237. Although the Court did not explain why it did not invoke the major questions doctrine, it held that the FHFA had broad powers as a conservator and acted within this role, and the "third amendment" only affected Fannie Mae and Freddie Mac.

Additionally, in *Little Sisters of the Poor*, the Court did not consider the major questions doctrine when it found that the Departments of Health and Human Services, Labor and Treasury (the Departments) did not exceed their statutory authority under the Affordable Care Act (ACA) to exempt certain employs from providing contraceptive coverage to employees. 591 U.S. at 661-63. The ACA states that the Departments should provide "such additional preventative care and screenings. . . as provided for in comprehensive guidelines." *Id.* at 664. Relying on this provision, the Departments issued a rule that "exempted certain employers who have religious and conscientious objections" from the requirement that employers provide contraceptive coverage to their employees. *Id.* at 663. The Court found that the Departments were operating within the ACA's express delegation as "[o]n its face. . . the provision grants sweeping authority to [the Departments] to craft a set of standards defining the preventive care that applicable health plans must cover" and the Departments "ha[ve] virtually unbridled discretion to decide what counts as preventative care and screenings." *Id.* at 676. Again, the Court did not explain why it declined to apply the major questions doctrine. Although access to contraception is an important social issue, the rule did not implicate a broad economic or regulatory transformation as it provided a religious and moral exemption for a small number of employers.

Finally, in *Dep't of Comm. v. New York*, the Court considered the Secretary of Commerce's authority to add a citizenship question to the census. 588 U.S. 752. "In the Census Act, Congress delegated to the Secretary of Commerce the task of conducting the decennial census 'in such form and content as he may determine.'" *Id.* (citation omitted). Again, the Court did not consider the major questions doctrine. However, the crux of the plaintiffs' argument was that the reason for adding the question was pretextual – not whether the Secretary had the authority to add the question in the first place. *Id.* at 785. The court sided with the plaintiffs, finding that it was pretextual.

CMS's 24/7 RN mandate and the HPRD requirements present a complex picture—some aspects of these requirements support treating this as an extraordinary case, while others suggest the opposite. On the one hand, the economic impact of the requirements, federalism concerns and Congress' failure to implement staffing requirements in the past support finding this to be an extraordinary case. The staffing requirements are estimated to cost around $43 billion and will transform the LTC facility industry, potentially forcing many facilities to close because they are unable to comply with the staffing requirements. *See Ala. Assoc. of Realtors*, 594 U.S. at 764 (holding that a rule with a $50 billion economic impact supported a finding that it was an extraordinary case); *see also* Abt Study at 112 (noting that "respondents reported concerns that nursing homes may not be able to achieve required staffing levels, may reduce admissions to meet requirements, or may close entirely"); *cf. Little Sisters of the Poor*, 591 U.S. at 661-63 (declining to apply major questions doctrine when the rule did not have dramatic economic or regulatory consequences).

Moreover, "38 States and the District of Columbia have minimum nursing staffing standards" with "significant variations in their requirements," suggesting that these staffing requirements are intruding into an area typically within state law domain. 89 Fed. Reg. at 40880. This further supports a finding that this is an extraordinary case. *See Ala. Assoc. of Realtors*, 594 U.S. at 764 (holding that a rule which intruded into landlord-tenant relationships, an area typically within state-law domain, supported finding

that the case was extraordinary); *see also West Virginia*, 597 U.S. at 744 (Gorsuch, J., concurring) (finding that agency action triggers the major questions doctrine when it "seeks to intrude into an area that is the particular domain of state law") (cleaned up). Finally, neither Congress nor CMS has adopted staffing minimums in the past. *West Virginia,* 597 U.S. at 724 (applying the major questions doctrine, in part, because "Congress had conspicuously and repeatedly declined to enact itself").[11]

On the other hand, CMS relied on its commonly used, broad rulemaking authority, which contains no restricting language, to promulgate these requirements. This militates against treating this as an extraordinary case. *Cf. Nebraska*, 600 U.S. at 501-02 (applying the major questions doctrine when the Act had only been used once before to waive or modify a provision related to debt cancellation) *and West Virginia*, 597 U.S. at 724 (finding a case extraordinary where the agency relied upon an "ancillary provision[]" of a "long-extant statute"). Moreover, CMS's rulemaking authority does not contain any language constraining its discretion. *See Collins v. Yellen*, 594 U.S. at 237 (choosing not to invoke the major questions doctrine where "[t]he Recovery Act grants FHFA expansive authority in its role as a conservator"); *see also Little Sisters of the Poor*, 591 U.S. at 676 (finding that the agency acted consistent with its regulatory authority where "the [rulemaking] provision grants sweeping authority to [the agency] to craft a set of standards"). Finally, the Supreme Court did not invoke the major questions doctrine regarding CMS's rule requiring healthcare workers to be vaccinated against COVID-19. CMS relied on the same rulemaking power there as it did in promulgating the staffing mandates at issue here. *See Missouri*, 595 U.S. 87.

[11] The failure to adopt minimum staffing standards in the past may have resulted from lack of evidence rather than a finding by CMS that it lacked authority to do so. *See, e.g.*, 45 Fed. Reg. 47111, 47371 (July 14, 1980) (declining to implement a 24/7 RN requirement noting it "[did] not have enough conclusive evidence to support requiring any specific numerical standards"); 81 Fed. Reg. 68688, 68755 (Oct. 4, 2016) (declining to adopt minimum staffing ratios and stating that it "remain[s] convinced that additional data will be helpful in determining if and what such ratios should be").

On balance, I find that this is an extraordinary case. The $43 billion cost, the risk of widespread LTC facility closures and the fact that many states have adopted their own staffing standards while Congress has not done so all support finding this to be an extraordinary case. Taken together, these facts create a meaningfully different scenario than the CMS's COVID-19 vaccine requirement considered in *Biden v. Missouri*, 595 U.S. 87 (2022). Although CMS relied upon its same expansive rulemaking authority in promulgating that rule, it did not have vast economic implications, risk healthcare facility closures or impede into an area typically within state-law domain.

Because I find that this is an extraordinary case, I must determine whether CMS had clear authorization to promulgate these staffing requirements. The Supreme Court has held that for questions of deep economic and political significance, we "expect[] Congress to delegate such authority expressly if at all." *Loper Bright Enters.*, 603 U.S. at 405 (cleaned up); *see also Ala. Assoc. of Realtors*, 594 U.S. at 764 ("Our precedents require Congress to enact exceedingly clear language" in major questions cases). The Court has also observed that Congress does not typically use "oblique or elliptical language" to empower an agency to make a "radical or fundamental change" to a statutory scheme. *MCI Telecommunications Corp.*, 512 U.S. at 229. CMS's general rulemaking power to promulgate "such other requirements as the Secretary deems necessary" does not constitute clear authorization to mandate rigid staffing requirements for LTC facilities. Therefore, I find that CMS did not have authority to promulgate the 24/7 RN requirement and the HPRD requirements pursuant to its health and safety rulemaking authority.[12]

[12] Because I have found that the 24/7 RN requirement and the HPRD requirements exceed CMS's statutory authority, I need not consider the plaintiffs' argument that the Final Rule casts constitutional doubt on the Medicare and Medicaid statutes. *See* Doc. 118-1 at 23-24; *Nw. Austin Mun. Util. Dist. No. One v. Holder*, 557 U.S. 193, 197 (2009) ("Our usual practice is to avoid the unnecessary resolution of constitutional questions."). I also decline to consider the plaintiffs' arguments that the staffing requirements are arbitrary and capricious, as such a finding would be superfluous. *PDK Lab'ys Inc. v. U.S. D.E.A.*, 362 F.3d 786, 799 (D.C. Cir. 2004) (Roberts, J., concurring) ("[I]f it is not necessary to decide more, it is necessary not to decide more[.]").

E. Arbitrary and Capricious Rulemaking (EFA and Medicaid Reporting Requirements)

The plaintiffs nominally challenge the EFA and Medicaid reporting requirements as being arbitrary and capricious. *See* Doc. 118-1 at 32 (noting that "the organizational and provider plaintiffs" "explain how the EFAs are arbitrary and unduly burdensome"). Indeed, the plaintiffs do not independently challenge the Medicaid reporting requirements in the complaint. *See* Doc. 37 at 42-62 (failing to mention the Medicaid reporting requirements in any of the "Claims for Relief" or "Prayer for Relief"). Moreover, the only time the EFA requirement is mentioned in the complaint is under "Failure to Consider Important Aspects of the Problem." Doc. 37 at 56-61.

In response to the defendants' motion for judgment on the administrative record, the plaintiffs contend that "each of the arbitrary and capricious grounds for vacatur also applies to the EFA and the transparency reporting requirements." Doc. 149 at 43. They contend that the complaint contains "multiple paragraphs describing the infirmities of the [EFA and Medicaid reporting] requirements." *Id.* at 42. Additionally, the plaintiffs allege that CMS failed to consider reliance interests and important aspects of the problem and did not explain its sharp departure from past practice in mandating the EFA and Medicaid reporting requirements. *Id.* at 43.

The defendants maintain that the plaintiffs did not meet their Federal Rule of Civil Procedure Rule 8 burden with respect to the EFA and Medicaid reporting requirements. They assert that the plaintiffs' attempts to fix their pleading deficiencies through their briefing is impermissible. Doc. 156 at 32. And, in any event, they contend that the paragraphs of the complaint cited by the plaintiffs do not advance legal arguments. *Id.* Finally, the defendants assert that even if the plaintiffs had met their Rule 8 burden, CMS's "well-explained rationale and fulsome consideration of the burdens of these provisions easily meets the deferential standard that an agency act 'within a zone of reasonableness.'" *Id.* at 33.

I agree with the defendants that the plaintiffs' conclusory assertions regarding the EFA and Medicaid reporting requirements are insufficient to support a finding that these requirements are arbitrary and capricious. I will address the Medicaid reporting requirements first. As an initial matter, the complaint does not contend that the Medicaid reporting requirements are arbitrary and capricious, nor does it ask for such a finding in the prayer for relief. *See* Doc. 37. The paragraphs of the complaint that the plaintiffs cite as "evidence" of their arguments are unpersuasive. *See* Doc. 149 at 42. In the complaint, the plaintiffs note that "states have their own enhanced reporting requirements" and indicate that the reporting requirements will cost the states $183,851 in the first year. Doc. 37 at 6, 41. The defendants correctly observe that these statements are not legal arguments. Instead, they are simply regurgitations of facts concerning the costs of the reporting requirements. As such, I find that no claims were asserted regarding the Medicaid reporting requirement in the complaint.

The plaintiffs seemingly rely on their assertion that "[t]he Rule is a single policy, in pursuit of one goal: to coerce LTCs into hiring additional staff." Doc. 118-1 at 38. As I have already found the Final Rule to be severable (*see supra* Section V.B), this argument is unpersuasive. The plaintiffs' attempts to insert additional arguments regarding the Medicaid reporting requirements in their briefing is improper. Indeed, the Eighth Circuit, along with other circuits, has held that asserting a new claim at the summary judgment stage is improper. *See Thomas v. United Steelworkers Local 1938*, 743 F.3d 1134, 1140 (8th Cir. 2014) ("It is well-established that parties cannot amend their complaints through briefing or oral advocacy.") (quoting *S. Walk at Broadlands Homeowner's Ass'n v. OpenBand at Broadlands, LLC,* 713 F.3d 175, 184 (4th Cir. 2013)); *see also Thomas*, 743 F.3d at 1140 ("[A] plaintiff may not amend his complaint through arguments in his brief in opposition to a motion for summary judgment.") (quoting *Anderson v. Donahoe*, 699 F.3d 989, 997 (7th Cir. 2012)). As such, the plaintiffs' motion for summary judgment as to the Medicaid reporting requirements is denied.

While the plaintiffs make marginally more robust arguments regarding the EFA requirement, they do not come close to the required showing that it is arbitrary and capricious. First, they make scant legal arguments regarding the EFA requirement in the complaint. As noted above, the only time the EFA requirement is mentioned is under the "Failure to Consider Important Aspects of the Problem," where the plaintiffs note that "the EFA imposes unreasonable administrative burdens on the facilities and subjects them to vague requirements that could result in steep civil penalties." Doc. 37 at 61. Additionally, the plaintiffs did not make any arguments as to how the EFA requirement is arbitrary and capricious in their motion for summary judgment. They simply state that "[t]he organizational and provider plaintiffs" "explain how the EFAs are arbitrary and unduly burdensome." Doc. 118-1 at 32. These bare assertions are inadequate. *See Johnson Tr. of Operating Eng'rs Loc. #49 Health & Welfare Fund v. Charps Welding & Fabricating, Inc.*, 950 F.3d 510, 524 (8th Cir. 2020) ("Conclusory assertions and citations to one's own arguments are insufficient to survive summary judgment.").

The only actual arguments that the plaintiffs made regarding the arbitrary and capricious nature of the EFA requirement was in response to the defendants' motion for judgment on the administrative record. *See* Doc. 149 at 42-44. Even if that was an appropriate place for arguments to be first marshalled, the arguments are not persuasive. First, the plaintiffs contend that the EFA requirement was "designed to implement even more onerous staffing requirements." *Id.* at 43. This is not supported by the text of the Final Rule. Rather, prior to the Final Rule, LTC facilities were required to "conduct and document a facility-wide assessment to determine what resources are necessary to care for its resident population" which must be reviewed and updated annually. 89 Fed. Reg. at 40905. Although CMS noted that it "expect[s] that most facilities will" "staff above the minimum standard" "in line with strengthened [EFA] requirements," the Final Rule's EFA requirement does not impose additional staffing minimums nor did CMS fail to consider the implications of such. *Id.* at 40892. Indeed, CMS frequently "acknowledge[d] the workforce challenges in LTC facilities," (*see e.g.*, *id.* at 40885,

40888, 40910), considered comments which "demonstrated a diversity of opinions on the proposed changes," (*id.* at 40906) explained the total costs of the rule (*id.* at 40878) and detailed the costs and administrative burdens of the EFA requirement (*id.* at 40937-39).

Considering the "highly deferential" and "narrow standard of review" that I must apply in evaluating claims that an agency's action is arbitrary and capricious, I find that CMS "acted within a zone of reasonableness," "reasonably considered the relevant issues and reasonably explained the[ir] decision" to modify the EFA requirement. *Firearms Regul. Accountability Coal., Inc. v. Garland*, 112 F.4th 507, 519 (8th Cir. 2024). As such, the plaintiffs have failed to demonstrate that the EFA and Medicaid institutional reporting requirements are the result of arbitrary and capricious rulemaking.

F. Remedy

Having determined that the 24/7 RN requirement and the HPRD requirements violate the Medicare and Medicaid statutes, I now turn to the parties' dispute over the proper scope of relief. The plaintiffs seek vacatur of the Final Rule. Doc. 118-1 at 36-37. The defendants assert that the court "should do no more than issue declaratory relief as to the specific provision deemed unlawful." Doc. 156 at 34. They argue that the court should not vacate any portion of the Final Rule, as they maintain that relief should not extend beyond the parties to the case. Doc. 122-1 at 74-75. Nonetheless, if the court decides that vacatur is the appropriate remedy, the defendants request that it "should apply only to the portions of the Final Rule held to be unlawful." Doc. 156 at 34.

The defendants correctly note that the APA does not specify vacatur as the appropriate remedy when a court finds that a rule violates the APA. *See United States v. Texas*, 599 U.S. 670, 695 (2023) (Gorsuch, J., concurring) ("§ 706(2) of the APA . . . does not say anything about 'vacating' agency action ('wholesale' or otherwise). Instead, it authorizes a reviewing court to 'set aside' agency action."). Indeed, I have deep concerns about a single United States District Judge taking actions that have the effect of operating as a nationwide injunction, applying beyond the parties to the

particular case. For that reason, had I concluded that a preliminary injunction was appropriate, I would have limited that form of relief to the parties to this case.

At this stage, however, I have made a final determination that CMS lacked the authority to promulgate the HPRD requirements and 24/7 RN requirement. The Eighth Circuit has held that "[u]pon ultimate success in an [APA] challenge, the default remedy is to set aside or vacate the rule" unless the rule is severable. *Missouri v. Trump*, 128 F.4th 979, 997 (8th Cir. 2025);[13] *see also O.A. v. Trump*, 404 F. Supp. 3d 109, 118 (D.D.C. 2019) ("When a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual [plaintiffs] is proscribed.") (quoting *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998)). Because I have found that the Final Rule is severable (*see supra* section V.B.), I find that the appropriate remedy in this context is to vacate the 24/7 RN and HPRD requirements. This vacatur applies writ large and is not limited to the plaintiffs in this case. *O.A.*, 404 F. Supp. 3d at 153 ("[T]he proper remedy is to set the Rule aside, and the legal consequences of that result are not limited 'to the individual' plaintiffs.").

VI. CONCLUSION

For the reasons stated herein:

1. The plaintiffs' motion (Doc. 118) for summary judgment is **granted in part** and **denied in part**. It is **granted** as to the HPRD requirements and the 24/7 RN requirement at 42 C.F.R. §§ 483.35(b)(1) and 483.35(c), which are hereby **vacated**

[13] The defendants cite *U.S. Steel Corp. v. EPA*, 649 F.2d 572 (8th Cir. 1981), for the proposition that "vacatur is not a required or appropriate remedy in every APA case." Doc. 122-1 at 74. In that case, the Eighth Circuit left the challenged provisions "in effect pending completion of further administrative proceedings." *U.S Steel Corp.*, 649 F.2d at 577. However, that case concerned the EPA's failure to comply with the notice and comment requirements of 5 U.S.C. § 553(b)(B). *Id.*; *see also* Doc. 149 at 45. Importantly, the court did not find that the EPA's rule was unlawful or contrary to the statute. *U.S. Steel Corp.*, 649 F.2d at 577. Instead, the court directed the EPA to comply with the notice and comment procedures. *Id.*

pursuant to 5 U.S.C. § 706(2). It is **denied** as to the EFA and Medicaid institutional reporting requirements

2. The defendants' motion (Doc. 122) for judgment on the administrative record is **granted in part** and **denied in part**. It is **granted** as to the EFA and Medicaid institutional reporting requirements, which shall remain in the Final Rule. It is **denied** as to the HPRD requirements and the 24/7 RN requirement.

3. Because this order disposes of all pending claims, the Clerk of Court shall enter judgment in accordance with this order and shall **close this case**.

IT IS SO ORDERED this 18th day of June, 2025.

Leonard T. Strand
United States District Judge