IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS AMARILLO DIVISION

AMERICAN HEALTH CARE ASSOCIATION, et al.,

Plaintiffs,

v.

2:24-CV-114-Z-BR (lead) 2:24-CV-171-Z (consolidated)

ROBERT F. KENNEDY, JR., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Before the Court are Plaintiffs' Motion for Summary Judgment ("Motion") (ECF No. 57), filed October 18, 2024, and Defendants' Cross-Motion for Summary Judgment ("Cross-Motion") (ECF No. 80), filed November 15, 2024. Having considered the Motions, briefing, and relevant law, the Court GRANTS Plaintiffs' Motion and DENIES Defendants' Cross-Motion. Accordingly, the staffing requirements in the Final Rule published in 89 Fed. Reg. 40876 (May 10, 2024) and codified at 42 C.F.R. Section 483.35(b)(1) and 483.35(c) are VACATED per 5 U.S.C. Section 706(2).

INTRODUCTION

Society has a duty to care for its elderly. Nursing homes play a necessary role. But failures plague them. See, e.g., Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40876, 40833 (May 10, 2024) (recounting personal stories of nursing home failures). These failures include "inadequate staffing levels, poor infection control, failures in oversight and regulation, and deficiencies that result in actual patient harm" and a "pervasive . . . undervaluing [of] the lives of older adults." NAT'L ACADS. OF SCIS., ENG'G &

MED., THE NATIONAL IMPERATIVE TO IMPROVE NURSING HOME QUALITY: HONORING OUR COMMITMENT TO RESIDENTS, FAMILIES, AND STAFF 2 (2022).

These deficiencies deserve an effectual response. But any regulatory response must be consistent with Congress's legislation governing nursing homes. The Final Rule's challenged provisions are not. Though the Final Rule attempts to remedy chronic nursing home deficiencies, it does so deficiently. It requires nursing homes participating in Medicare or Medicaid to have a registered nurse on staff at least twenty-four hours a day, although Congress set the baseline at eight hours a day. And it attempts to require every participant nursing home to achieve minimum staffing hours only based on a facility's number of residents, although Congress mandated consideration of a facility's individual nursing needs. Though rooted in laudable goals, the Final Rule still must be consistent with Congress's statutes. To allow otherwise permits agencies to amend statutes though they lack legislative power. Separation of powers demands more than praiseworthy intent.

BACKGROUND

I. Medicare and Medicaid Programs

Congress amended the Social Security Act in 1965 to create Medicare and Medicaid. See Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286. Medicare provides health insurance to those sixty-five years and older. 42 U.S.C. § 1395c. The federal government runs Medicare. Medicaid provides health insurance to low-income people. 42 U.S.C. §§ 1396-1, 1396a.

Medicaid is a joint federal-state program. *Miller v. Gorski Wladyslaw Est.*, 547 F.3d 273, 277 (5th Cir. 2008) ("Under this system of 'cooperative federalism,' if a state agrees to establish a Medicaid plan, the federal government agrees to pay a specified percentage of the total amount the state plan spends on medical assistance." (quoting *Harris v. McRae*, 448 U.S. 297, 308 (1980))).

Private providers, government healthcare facilities, or individual healthcare professionals offer healthcare services under these programs. Participation in either program is voluntary. Miller, 547 F.3d at 277; True Health Diagnostics, LLC v. Azar, 392 F. Supp. 3d 656, 660 (E.D. Tex. 2019). If healthcare providers or states choose to participate, they agree to comply with federal statutes and regulations governing them. See 42 U.S.C. §§ 1395cc, 1396a. The Secretary of Health and Human Services administers the programs through the Center for Medicare and Medicaid Services ("CMS"). Ark. Dep't of Health & Hum. Servs. v. Ahlborn, 547 U.S. 268, 275 (2006). Congress empowered the Secretary to issue rules and regulations "as may be necessary to the efficient administration of the functions" he has under the Social Security Act. 42 U.S.C. §§ 1302(a), 1395hh ("The Secretary shall prescribe such regulations as may be necessary to carry out the administration of [Medicare].").

Nursing homes often participate in both programs. Under Medicare, they must meet statutory and regulatory requirements for "skilled nursing facilities." 42 U.S.C. § 1395i-3. Under Medicaid, they must meet statutory and regulatory requirements for "nursing facilities." 42 U.S.C. § 1396r. Nursing homes participating in either or both programs are "long-term care" facilities that must meet a consolidated set of regulations. 42 C.F.R. § 483.1 (2024). 97.8% of nursing homes participate in Medicare and 95.4% participate in Medicaid. See ECF No. 57-1 at 11–12 & n.2.

II. Historic Nursing Home Regulations

Congress, along with various agencies, has regulated participating nursing homes. Congress at first required all nursing homes under either program to "provide[] 24-hour nursing service which is sufficient to meet nursing needs in accordance with the [facility's policies], and has at least one registered professional nurse employed full time." 42 U.S.C. §§ 1395x(j)(6), 1396a(a)(28) (1976). Congress did not further mandate how to accomplish this requirement.

The Social Security Administration proposed regulations to carry out Congress's requirements. Federal Health Insurance for the Aged: Skilled Nursing Facilities, 38 Fed. Reg. 18620 (July 12, 1973). These proposed regulations used the same language as the statute and required the full-time nurse work "during the day tour of duty 5 days a week." *Id.* at 18625. The Social Security Administration rejected a proposal to impose "a specific ratio of nursing staff to patients." Skilled Nursing Facilities, 39 Fed. Reg. 2238, 2239 (Jan. 17, 1974). That is "because the variation from facility to facility in the composition of its nursing staff, physical layout, patient needs and the services necessary to meet those needs preclude[d] setting such a figure." *Id.*

The Department of Health and Human Services ("HHS") proposed revising the regulations once it took over administering Medicare and Medicaid in 1980. See Conditions of Participation for Skilled Nursing and Intermediate Care Facilities, 45 Fed. Reg. 47368 (July 14, 1980). But again, the agency declined to "propose[] any nursing staff ratios or minimum number of nursing hours per patient per day." Id. at 47371. This time, the agency admitted "[o]ne of the reasons" it declined was because it "was not sure how much staffing will be required" and did "not have enough conclusive evidence to support requiring any specific numerical standards." Id.

So HHS commissioned a multi-year study, in part, to examine the issue. See Medicare and Medicaid; Conditions of Participation for Long Term Care Facilities, 52 Fed. Reg. 38582, 38583 (Oct. 16, 1987) (discussing the Institute of Medicine study to evaluate "Federal regulations concerning long term care facilities" and examine how states regulate the facilities). The Institute of Medicine study concluded that "because of the complexities of case mix... [and] the wildly differing needs of individual residents in the same facility," "prescribing simple staffing ratios clearly is inappropriate." INST. OF MED., IMPROVING THE QUALITY OF CARE IN NURSING HOMES 102 (1986). The study recommended further data

collection "to develop an algorithm for relating minimum nursing staff requirements to case mix"—not to implement a flat hours-to-resident staffing ratio. *Id.* at 200 (expressing interest in "an empirically derived algorithm used to estimate the daily nursing time requirements for a resident based on his/her assessment scores and service needs"). In short, the Institute for Medicine evaluated current regulations and recommended that while a fine-tuned, facility-specific algorithm for minimum staffing requirements could be appropriate with more data, "simple staffing ratios" like "nurse-to-resident ratios" were "inappropriate" because they do not account for "wildly differing needs." *Id.* at 101, 102.

The study, and myriad other concerns, prompted Congress to enact substantial revisions to the statutes governing nursing home participation in Medicare and Medicaid. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, §§ 4201-4218, 101 Stat. 1330, 1330-160 to 1330-221; H.R. REP. No. 100-391, pt. 1, at 452 (1987) (explaining that the Institute of Medicine's finding that many nursing homes provide "shockingly deficient" sparked changes "to improve the quality of care for Medicaid-eligible nursing home residents").

Congress's changes were extensive and particularized. It consolidated a former two-tier division between skilled nursing facilities and intermediate care facilities with only a "nursing facilities" ("NFs") designation for Medicaid and "skilled nursing facilities" ("SNFs") in Medicare. Id. § 4211(a), 101 Stat. at 1330-183 to 1330-203. It then required both NFs and SNFs to "provide 24-hour nursing service which is sufficient to meet nursing needs of [their] residents" and to "employ the services of a registered professional nurse at least during the day tour of duty (of at least 8 hours a day) 7 days a week." Id. § 4201(a), 101 Stat. at 1330-163; see also id. § 4211(a), 101 Stat. at 1330-186 (requiring Medicaid NFs "provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of [their] residents, and . . . use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a

week"). A committee rejected a proposal to require a registered nurse on-site twenty-four hours a day, seven days a week. 133 Cong. Rec. 28998 (1987). And Congress let die a separate bill requiring the same. H.R. 3543, 100th Cong. (1987). NFs and SNFs could only escape these requirements through a detailed process that allowed the Secretary to waive them. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4201(a), 101 Stat. 1330, 1330-163; id. § 4211(a), 101 Stat. at 1330-186.

Congress also granted the Secretary regulatory authority to "assure that requirements" for NFs and SNFs "are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys." *Id.* § 4201(a)(3), 101 Stat. at 1330-172, § 4211(c), 101 Stat. at 1330-200. Additionally, Congress granted the Secretary regulatory authority over NFs and SNFs to craft "requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as [he] may find necessary." *Id.* § 4201(a)(3), 101 Stat. at 1330-171; § 4211(b), 101 Stat. at 1330-196.

Congress later ordered the Secretary to conduct a study examining whether Congress should impose "minimum caregiver to resident ratios . . . for skilled nursing facilities . . . and nursing facilities." Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4801(e)(17)(B), 104 Stat. 1388-218 to 1388-219. Congress ordered the Secretary to complete the study before January 1, 1992, and to provide "recommendations regarding appropriate minimum ratios." *Id.* § 4801(e)(17)(B), 104 Stat. at 1388-219. The Secretary missed the deadline by ten years but finally pronounced that "insufficient" data existed, and questions remained about "the feasibility of establishing staff ratios." Letter from Tommy G. Thompson, Sec'y of Health & Hum. Servs., to J. Dennis Hastert, Speaker of the House of Representatives 1 (Mar. 19, 2002), reprinted in Off. Of Assistant Sec'y for Plan. & Evaluation, Dep't of Health & Hum. Servs., State Experiences with Minimum Nursing Staff Ratios for

NURSING FACILITIES: FINDINGS FROM CASE STUDIES OF EIGHT STATES A-1 (2003). Thus, the Secretary opined that Congress should not "establish[] minimum ratios" yet. *Id.* at 2.

III. The Statute and Regulations

Together, Congress's past enactments require each Medicare or Medicaid nursing home to "provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents" and to "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)(I)—(II), 1395i-3(b)(4)(C)(i). For Medicare, the Secretary may waive the 8-hours-a-day, 7-days-a-week requirement. *Id.* § 1395i-3(b)(4)(C)(ii). For Medicaid, a particular state may waive either or both requirements and the Secretary may also exercise the waiver power. *Id.* § 1396r(b)(4)(C)(ii), (iii).

HHS promulgated regulations that duplicated Congress's mandate in relevant parts. HHS required nursing homes to have "sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." 42 C.F.R. § 483.30 (2016). This meant each "facility must provide services by sufficient numbers [of different types of nurses] on a 24-hour basis to provide nursing care to all residents." *Id.* § 483.30(a). For registered nurses specifically, HHS required each facility "use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week." *Id.* § 483.30(b). In 2016, CMS declined to depart from its statute-mirroring regulations and impose mandatory staffing ratios and a 24-hour registered nurse requirement. Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688, 68754–56 (Oct. 4, 2016). It refused because (1) it could not identify the proper ratio, (2) nursing homes were too varied to have a blanket number, (3) nursing homes might be unable to find sufficient staff, and (4) nursing homes might only staff to the minimum. *Id.* at 68755–56. Before the Final Rule at issue here, congressional

mandates governed licensed nursing services and registered nurse hour requirements, as implemented by the regulations.

IV. The Rule

In February 2022, the Biden Administration announced its intent to establish a minimum nursing home staffing requirement to "ensure[] that all nursing home residents are provided safe, quality care." Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes, The White House (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/ [https://perma.cc/EYP8-8M7W]. It ordered a research study to "determine the level and type of staffing needed to ensure safe and quality care." Id.

CMS published the research study in June 2023. Admin. Rec. at 69982. The study concluded that higher staffing is related to better quality care but that there was no "clear evidence basis for setting a minimum staffing level." *Id.* at 69993. Further, the study identified other factors beyond staffing levels, such as "[r]esident care needs, which vary depending on acuity, clinical complexity, and other resident characteristics, [that] could also directly influence quality of care." *Id.* at 70006. And it recognized that "workforce shortages and current hiring challenges could present barriers to nursing home compliance with a new federal staffing requirement." *Id.* at 70003. Thus, nursing home "staffing levels are a 'critical factor' in determining nursing home quality of care," but "no obvious plateau at which quality and safety are maximized [n]or 'cliff' below which quality and safety steeply decline" exists. *Id.* at 69990, 69993 (internal quotation omitted).

CMS proposed a rule mandating a staffing plateau three months later. Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 88 Fed. Reg. 61352 (Sept. 6, 2023).

The proposed rule first independently proposed to "require an RN to be on site 24 hours per day and 7 days per week to provide skilled nursing care to all residents" *Id.* at 61353; ECF No. 80-1 at 18. Second, it "propose[d] individual minimum nurse staffing standards of 0.55 hours per resident day (HPRD) for RNs and 2.45 HPRD for NAs." 88 Fed. Reg. at 61357. It clarified that "meeting the 24/7 requirement does not also count as meeting the 0.55 RN HPRD and 2.45 NA HPRD [requirements] and vice versa." *Id.* at 61376. The proposed rule elicited 46,520 comments. Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40876, 40883 (May 10, 2024).

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CMS promulgated the Final Rule in May 2024. Id. at 40876. The Final Rule contained some modifications from the proposed rule "to provide additional flexibility and time for facilities to implement the[] changes." Id. at 40886. First, the Final Rule "staggered implementation dates over a period of up to five years." Id. Second, it added a "total nurse staffing standard" and added "exemptions from the minimum staffing standards." Id. The total nurse staffing standard required "at a minimum, 3.48 total nurse staffing hours per resident day (HPRD)." Id. at 40877. Underscoring that these minimum staffing standards disregard a facility's individual resident needs and cases, CMS declared that "facilities must meet the minimum 3.48 total nurse staffing, 0.55 RN, and 2.45 NA HPRD standards regardless of the individual facility's resident case-mix, as they are the minimum standard of staffing." Id.

* * *

Thus, the Final Rule put in place the two provisions challenged here. The first provision mandates that a "facility must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week that is available to provide direct resident care" ("24/7 Requirement").

42 C.F.R. § 483.35(c)(1) (2024). The second provision requires facilities to comply with three separate minimum staffing standards ("HPRD Requirements"). First, the "facility must meet or exceed a minimum of 3.48 hours per resident day for total nurse staffing." *Id.* § 483.35(b)(1). Second, to do so, a facility must have a "minimum of 0.55 hours per resident day for registered nurses." *Id.* § 483.35(b)(1)(i). Third, a facility must have a "minimum of 2.45 hours per resident day for nurse aides." *Id.* § 483.35(b)(1)(ii).

Rural facilities must comply with the 24/7 Requirement before May 10, 2027. 89 Fed. Reg. at 40913. They must comply with the 3.48 total hours provision of the HPRD Requirements before May 10, 2027. *Id.* And they must comply with the remainder of the HPRD Requirements before May 10, 2029. *Id.* Nonrural facilities must comply with the 24/7 Requirement before May 10, 2026. *Id.* They must comply with the 3.48 total hours provision of the HPRD Requirements before May 10, 2026. *Id.* And they must comply with the remainder of the HPRD Requirements before May 10, 2027. *Id.*

V. Procedural History

Plaintiffs challenged the Final Rule's 24/7 Requirement and HPRD Requirements on May 23, 2024, and amended their complaint on June 18, 2024. ECF Nos. 1, 26. Texas also filed suit challenging the Final Rule against the same Defendants on August 14, 2024. ECF No. 52 at 1. Upon unopposed motion, the Court consolidated the two cases under Federal Rule of Civil Procedure 42. *Id.* at 2. Plaintiffs filed their Motion for Summary Judgment on October 18, 2024. ECF No. 57. Defendants filed their Cross-Motion for Summary Judgment and response to Plaintiffs' summary judgment motion on November 15, 2024. ECF No. 80. Plaintiffs responded to Defendants' Cross-Motion on December 13, 2024, and Defendants replied on January 17, 2025. ECF Nos. 96, 99. The Motion and Cross-Motion are now ripe.

LEGAL STANDARD

Summary judgment is appropriate if the movant shows no genuine dispute of material fact exists, and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). The moving party bears the initial burden of demonstrating both. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). A genuine dispute of material fact exists if "the evidence is such that a reasonable jury could return a verdict for the non-moving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

Summary judgment "is particularly appropriate in cases in which the court is asked to review or enforce a decision of a federal administrative agency." Girling Health Care, Inc. v. Shalala, 85 F.3d 211, 214–15 (5th Cir. 1996). "Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record." Hi-Tech Pharmacal Co., Inc. v. FDA, 587 F. Supp. 2d 13, 18 (D.D.C. 2008). And the court's role in an APA case is to "sit[] as an appellate tribunal." Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001); see also Amin v. Mayorkas, 24 F.4th 383, 391 (5th Cir. 2022). In such a posture, the "entire case on review is a question of law, and only a question of law." Marshall Cnty. Health Care Auth. v. Shalala, 988 F.2d 1221, 1226 (D.C. Cir. 1993). So summary judgment in an APA case "merely serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." Oceana, Inc. v. Locke, 831 F. Supp. 2d 95, 106 (D.D.C. 2011). Judicial review under the APA is limited to the administrative record. 5 U.S.C. § 706.

ANALYSIS

The APA demands courts "hold unlawful and set aside" agency action "not in accordance with law" and "in excess of statutory jurisdiction." 5 U.S.C. § 706(2)(A), (C). When

doing so, the "court shall decide all relevant questions of law" and "interpret . . . statutory provisions." Id. § 706. After Loper Bright, the "text of the APA means what it says." 144 S. Ct. at 2262. Courts interpret the meaning of statutes and evaluate whether agencies are within their bounds. Agencies possess "only the authority that Congress has provided" because they are "creatures of statute." Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., 595 U.S. 109, 117 (2022).

I. The 24/7 Requirement Exceeds CMS's Statutory Authority

Plaintiffs argue the 24/7 Requirement impermissibly replaces Congress's mandate that nursing homes "use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." ECF No. 57-1 at 33-34; 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i). They claim it "alters this statutory requirement in two distinct ways." ECF No. 57-1 at 33-34. First, it replaces eight with twenty-four. Second, it changes the statute's language of "use the services" of an RN to instead require an RN be "available to provide direct resident care." *Id.* at 34 (quoting 89 Fed. Reg. at 40997).

Defendants respond that other provisions grant the power to impose the 24/7 Requirement—not the provision requiring at least eight hours a day, seven days a week. ECF No. 80-1 at 23 (invoking 42 U.S.C. Sections 1396r(d)(4)(B) among others); see also 89 Fed. Reg. at 40891 (relying on "separate authority" to impose the 24/7 Requirement and not the statute's 8 hours/7 days provision). They reference several provisions they claim grant authority to issue the requirements. First, in 42 U.S.C. Section 1396r(d)(4)(B), Congress empowered the Secretary to implement "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as [he] may find necessary." Second, in 42 U.S.C. Section 1396r(f)(1), Congress declared "[i]t is the duty and responsibility of the Secretary to assure that requirements . . . are adequate to protect the health, safety,

welfare, and rights of residents and to promote the effective and efficient use of public moneys." Medicare's provisions are similar. See 42 U.S.C. § 1395i-3(d)(4)(B), (f)(1).

Defendants claim these provisions "are broadly worded to give HHS significant leeway in deciding how best to safeguard... residents' health and safety." ECF No. 80-1 at 21 (quoting Northport Health Servs. of Ark., LLC v. U.S. Dep't of Health & Hum. Servs., 14 F.4th 856, 870 (8th Cir. 2021)). The 24/7 Requirement is valid under these provisions, they argue, and does not conflict with Congress's 8 hours/7 days requirement because Congress used the words "at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1396r(b)(4)(C)(i) (emphasis added); ECF No. 80-1 at 24. Defendants claim Plaintiffs must "read the words 'at least' out of the statute entirely" to prevail. ECF No. 80-1 at 24. Because "at least" is there, they claim they have "discretionary authority" to "fill up the details of [the] statutory scheme" and impose higher requirements if they choose. Loper Bright, 144 S. Ct. at 2263 (internal quotation omitted); ECF No. 80-1 at 23.

A. The 24/7 Requirement Amends Congress's Baseline

CMS lacks authority to issue a regulation that replaces Congress's preferred minimum hours with its own. That is exactly what the 24/7 Requirement does. Congress took it upon itself to set the minimum hours nursing homes "must use the services of a registered professional nurse." 42 U.S.C. § 1396r(b)(4)(C)(i)(II). It set that level at "at least 8 consecutive hours a day." Id. The 24/7 Requirement in effect amends the statute because it strikes Congress's "8," and replaces it with the agency's "24." 42 C.F.R. § 483.35(c)(1) ("[T]he facility must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week" (emphasis added)). But agencies lack the power to amend statutes, regardless of other provisions that may grant authority to regulate the space. Agencies may add detail to and enforce statutes. See Loper Bright, 144 S. Ct. at 2263. That does not extend to replacing Congress's number with a different one. "That would let the agency amend [a] scheme delineated by statute."

Nat'l Horsemen's Benevolent & Protective Ass'n v. Black, 107 F.4th 415, 432 (5th Cir. 2024).

Agencies lack statutory amendment power.

Defendants' arguments to the contrary are unavailing. They argue various provisions of Medicare and Medicaid "expressly delegate" "discretionary authority" to "fill up the details of a statutory scheme." ECF No. 80-1 at 23 (quoting Loper Bright, 144 S. Ct. at 2263). Congress routinely enacts statutes that grant agencies the authority "to prescribe rules to 'fill up the details' of a statutory scheme" or to "give meaning to a particular statutory term." Loper Bright, 144 S. Ct. at 2263 (quoting Wayman v. Southard, 23 U.S. (10 Wheat.) 1, 23 (1825)). Defendants point to several Medicare and Medicaid provisions that do just that. Congress requires nursing homes to "provide (or arrange for the provision of)... 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). The agency's regulations "fill up the details" and explain how nursing homes must fulfill that statutory requirement. 42 C.F.R. § 483.60(a)(1) (2024). In the same way, Congress required nursing homes to "establish and maintain an infection control program." 42 U.S.C. § 1396r(d)(3)(A). Again, the agency's regulations "fill up the details" and explain nursing homes comply with that requirement when they employ a specially trained "[i]nfection preventionist" to oversee that program. 42 C.F.R. § 483.80(b) (2024).

None of these examples exhibit the agency replacing a statutory command with one of its own. Instead, they are within the normal realm of agencies adding details and specific requirements to Congress's less specific mandates. In its example regulations, the agency explains what compliance with the statute is: employing a qualified dietitian or a trained infection preventionist. Defendants' examples are inapposite because they do not demonstrate the agency replacing Congress's specific terms with different ones. The provisions Defendants cite provide them the authority to issue these regulations. See Biden

v. Missouri, 595 U.S. 87, 94 (2022) ("[T]he Secretary routinely imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves . . . [and] has always justified these sorts of requirements by citing his authorities to protect patient health and safety.").

Here, the Court need not decide whether the provisions Defendants cite would grant the authority the agency claims to issue the 24/7 Requirement. It is true "Congress has authorized the Secretary to impose conditions on the receipt of Medicaid and Medicare funds that 'the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services." Missouri, 595 U.S. at 93 (quoting 42 U.S.C. § 1395x(e)(9)). But, the agency's exercise of that authority in the 24/7 Requirement plainly changes the minimum hours requirement Congress set as a statutory baseline. Congress did not grant statutory amendment authority nor stay silent on the base number of hours a nursing home must use an RN's services. It answered eight. Congress reserved to itself that decision. And it has always done so. Moreover, it has rejected attempts to change the number. See 133 Cong. Reg. 28998 (1987); H.R. 3543, 100th Cong. (1987); see also West Virginia v. Env't Prot. Agency, 597 U.S. 697, 743 (2022) (Gorsuch, J., concurring) (explaining rejected congressional proposals "may be a sign that an agency is attempting to 'work [a]round' the legislative process" (alteration in original) (quoting Nat'l Fed'n of Indep. Bus. v. Occupational Safety & Health Admin., 142 S. Ct. 661, 668 (2022) (Gorsuch, J., concurring))). In Defendants' other examples, Congress did not specify what "dietary services" would meet its mandate nor did it explain what metrics an "infection control program" must satisfy. See 42 U.S.C. § 1396r(b)(4), (d)(3)(A). So the agency exercised proper authority to explain them.

Agencies may exercise general authority to explain details of a statutory scheme but may not use the same authority to *amend* the statute because of a basic rule of law

proposition: It cannot be the case that the governed break the law when they comply with Congress's law as written. That is why the 24/7 Requirement runs afoul of Section 706.

A nursing home, reading the law Congress passed, discerns it must supply an RN at least eight hours a day, seven days a week. So it employs one for that period. But then it discovers it is noncompliant because it is not meeting CMS's 24-hour baseline. In that case, full compliance with the politically accountable branch means breaking the decrees of the nonpolitically accountable one. That is not how the relationship between Congress and agencies works. Agencies can, for example, explain what compliance with providing "dietary services" or establishing an "infection control program" looks like via regulation. 42 U.S.C. § 1396r(b)(4), (d)(3)(A). But it cannot "rewrite clear statutory terms to suit its own sense of how the statute should operate." In re Benjamin, 932 F.3d 293, 300 (5th Cir. 2019). Doing so would place nursing homes in the untenable position of fully complying with a statute while simultaneously violating the regulation. Whatever authority Defendants' cited provisions grant, it is not that.

For this reason, Defendants' argument that Plaintiffs' position would require reading the words "at least" out of the statute fails. Congress setting a baseline that nursing homes "use the services of a [RN] for at least 8 consecutive hours a day" only means nursing homes must meet that bottom line. It does not mean the agency is free to raise that line higher. Congress's authorization for nursing homes to employ an RN for more than eight hours daily is not authorization for the agency to demand more. Congress chose the specific baseline, and the agency cannot invoke general authority to change that specific line. See RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 645–46 (2012) (explaining that the "[g]eneral language of a statutory provision . . . will not be held to apply to a matter specifically dealt with in another part of the same enactment" (alteration in original) (quoting D. Ginsberg & Sons, Inc. v. Popkin, 285 U.S. 204, 208 (1932))); cf. Antonin Scalia & Bryan A. Garner,

READING LAW: THE INTERPRETATION OF LEGAL TEXTS 183 (2012) ("[T]he specific provision comes closer to addressing the very problem [of what the RN baseline is] and is thus more deserving of credence.").

Defendants' "general delegation of authority does not give [them] license to alter the [statute's] unambiguous terms." Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs., 120 F.4th 494, 508 (5th Cir. 2024). Little is more unambiguous than the statute here. Congress set the baseline number of hours a nursing home must employ an RN at "8." 42 U.S.C. § 1395i-3(b)(4)(C)(i). The agency changed the number. But in doing so, it amended the statute and rendered a nursing home's compliance with the statute a lawbreaking endeavor. It meant nursing homes could not "be sure of the rules that bind them." Loper Bright, 144 S. Ct. at 2285 (Gorsuch, J., concurring) (highlighting the fear that if "bureaucrats" assign new meaning "without any legislative revision" then people could never be sure of how to comply with the law). Only Congress can amend its laws because "the Constitution promises[] the American people are sovereign and they alone may, through democratically responsive processes, . . . revise federal legislation." Loper Bright, 144 S. Ct. at 2279 (Gorsuch, J., concurring) (emphasis added). The agency admits the 24/7 Requirement "revises" Congress's requirement. 89 Fed. Reg. at 40898. Thus, it cannot stand.

II. The HPRD Requirements Strike Consideration of Factors Congress Requires

Plaintiffs argue the HPRD Requirements fail for many of the same reasons. They claim Congress has "opted for a flexible qualitative standard" when it required nursing homes to provide nursing services "sufficient to meet the nursing needs of [their] residents." ECF No. 57-1 at 36; 42 U.S.C. § 1395i-3(b)(4)(C)(i). Instead, Plaintiffs argue, the HPRD Requirements put a blanket mandate across all nursing homes, disregarding their individual "nursing needs." 42 U.S.C. § 1395i-3(b)(4)(C)(i). The HPRD Requirements "substitute[]

CMS's current policy views for Congress's considered judgment" and "replac[e] that flexible standard with a rule of almost comical rigidity and specificity." ECF No. 57-1 at 36. They do so by "requiring every nursing home in the country to provide 'a minimum of 3.48 hours per resident day for total nurse staffing[,] including but not limited to—(i) [a] minimum of 0.55 hours per resident day for registered nurses; and (ii) [a] minimum of 2.45 hours per resident day for nurse aids." *Id.* (quoting 89 Fed. Reg. at 40996). This blanket requirement fails to "accommodate[] the wide variation in resident needs across different States, localities, and facilities." *Id.* Plaintiffs claim the agency has no such authority to replace a flexible standard with a universal, unflinching one.

Defendants think they do. And they invoke the same provisions invoked vis-à-vis the 24/7 Requirement: 42 U.S.C. Section 1396r(d)(4)(B), which grants the authority to implement "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary" and 42 U.S.C. Section 1396r(f)(1) wherein Congress declared "[i]t is the duty and responsibility of the Secretary to assure that requirements . . . are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys." See also 42 U.S.C. § 1395i-3(d)(4)(B), (f)(1). They note Plaintiffs do not contest whether these provisions grant CMS the authority to impose the HPRD Requirements. ECF No. 80-1 at 27. They advance that Plaintiffs' argument is flawed because the HPRD Requirements do not substitute the agency's policy views for Congress's as the HPRD Requirements "are not a 'rigid one-size-fits all' approach." Id. at 28 (quoting ECF No. 57-1 at 37). They are not a onesize-fits-all approach because they are based on "the actual number of residents in the facility" and thus "adjusted for [the] size of [the] facility." Id. at 28 (quoting 89 Fed. Reg. 40908–09). Because a nursing home may still need to impose higher staffing to have sufficient staff, the HPRD Requirements and Congress's flexible standard can "comfortably coexist."

Id. They again point to the same examples where the agency has "fill[ed] up the details" of a congressional mandate. Id. at 29–30.

Again, this is not a "fill up the details" scenario. Id. at 29. Congress requires nursing homes 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) (emphasis added); id. § 1395i-3(b)(4)(C)(i). The text reveals factors that nursing homes must consider. It requires determination of the "nursing needs" of a facility's residents. The "nursing needs" necessarily encompass a range of detailed evaluations. "Resident care needs [can] vary depending on acuity, clinical complexity, and other resident characteristics," to name a few. Admin. Rec. at 70006. "[H]igher-acuity or more clinically complex residents" can affect what a facility's "nursing needs" are. Id. The agency has agreed these factors can affect a facility's nursing needs in the past. See, e.g., 39 Fed. Reg. at 2239 (rejecting requirements like the HPRD Requirements "because the variation from facility to facility in the composition of its nursing staff, physical layout, patient needs and the services necessary to meet those needs precludes setting such" a regulation). Indeed, one of Defendants' cited studies admits a need for more data "to develop an algorithm for relating minimum nursing staff requirements to case mix." INST. OF MED., IMPROVING THE QUALITY OF CARE IN NURSING HOMES 102 (1986). Instead of imposing blanket ratios across all facilities, the study recommended a more fine-tuned algorithm capable of considering sufficient factors that affect the nursing needs of a facility. Defendants claim they have sufficient data now. ECF No. 80-1 at 34 ("Now that adequate data is available ").

But the HPRD Requirements do not exhibit adequate data are available because they do not account for an individual facility's nursing needs. If adequate data were available, the regulation would produce a minimum staffing level that considered the "case-mix" of a facility. But the agency proclaims the HPRD Requirements do not consider a facility's nursing needs. 89 Fed. Reg. at 40877 ("[T]he standards themselves will be implemented and enforced independent of a facility's case-mix."). The HPRD Requirements set one rule for all. Defendants' argument that it is not a blanket rule because it considers a facility's number of residents is not convincing. The HPRD Requirements mandate a certain number of staffing hours per facility resident for different types of nursing staff. Every nursing home must comply, aside from the exemption provisions. To comply, nursing homes must count their residents and then multiply by CMS's cutoff number for each nursing staff type to calculate the total hours required per day. See 42 C.F.R. § 483.5 (defining hours per resident day as "the total number of hours worked by each type of staff divided by the total number of residents as calculated by CMS").

The agency lacks authority to eliminate consideration of a facility's nursing "needs" when prescribing minimum staffing standards. 42 U.S.C. § 1396r(b)(4)(C)(i)(I). Congress stipulated that the "[r]equired nursing care" standard must contemplate "the nursing needs of [a facility's] residents." *Id.* at § 1396r(b)(4)(C), (b)(4)(C)(i)(I). This provision specifically governs the minimum standard of nursing care. *See RadLax*, 566 U.S. at 646. But the HPRD Requirements in effect strike that portion of the statute. They do not consider the nursing "needs" of a facility's residents. 42 U.S.C. § 1396r(b)(4)(C)(i)(I). Instead, they mandate hoursper-resident-day ratios for all facilities. In so doing, they set a baseline staffing requirement that does not follow the statute's terms. True, other requirements may demand a facility staff higher than the baseline HPRD Requirements. *See* 89 Fed. Reg. at 40891 ("We expect that many facilities will need to staff above the minimum standards to meet the acuity needs of their residents depending on case-mix and as mandated by the facility assessment required at § 483.71."). But whether other requirements comply with the statute or not, CMS cannot set a baseline that neglects "needs" Congress mandated. 42 U.S.C. § 1396r(b)(4)(C)(i)(I).

Again, none of this determines the scope of authority Defendants' cited provisions grant. Those provisions do textually grant broad authority. Cf. Missouri, 595 U.S. at 93. But no matter how broad that authority, it cannot authorize altering Congress's exercise of its own authority. That is what the HPRD Requirements do when they set minimum staffing levels flouting the factors Congress requires be considered. Of course, agencies can "fill up the details" of a statutory scheme, just as the agency did when it issued regulations on nursing homes' infection control programs and dietary services. ECF No. 80-1 at 29. This may even mean adding additional requirements Congress did not contemplate. See, e.g., Missouri, 595 U.S. at 93–96 (holding the agency could require healthcare workers to receive the coronavirus vaccination though Congress never specifically imposed healthcare-worker vaccination requirements). Here, the agency likely could remain within its authority if it issued regulations specifying how a facility should analyze the "nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i). That would likely constitute "fill[ing] up the details" of a statutory scheme. Loper Bright, 144 S. Ct. at 2263 (internal quotation omitted). But it may not set a baseline that ignores residents' nursing needs. An agency exercise of discretionary authority to elucidate details can never mean stripping away statutory text. "Filling up" details is not statutory substitution. Addition is not subtraction. Agencies may add to statutes consistent with their delegated authority and other laws. They may never cut statutes to replace them with their own requirements.

III. Major Questions Doctrine and Arbitrary and Capricious Review

Plaintiffs raise the major questions doctrine as a separate argument against CMS's assertion of authority in the Final Rule. ECF No. 57-1 at 38-41. The major questions doctrine requires "clear congressional authorization" instead of "a merely plausible textual basis" when agencies "claim[] the power to resolve a matter of great political significance" or "seek[] to regulate a significant portion of the American economy or require billions of dollars in

spending by private persons or entities." West Virginia, 597 U.S. at 723; id. at 743, 744 (Gorsuch, J., concurring) (internal quotations omitted). And when, as here, Congress repeatedly declines to authorize the challenged agency action, then that "may be a sign that an agency is attempting to 'work [a]round' the legislative process to resolve for itself a question of great political significance." West Virginia, 597 U.S. at 743 (Gorsuch, J., concurring) (alteration in original) (quoting Nat'l Fed'n of Indep. Bus. v. Occupational Safety & Health Admin., 595 U.S. 109, 122 (2022) (Gorsuch, J., concurring)).

However, because the Final Rule contravenes statutory provisions aside from the agency's claim of authority, the Court need not examine "ambiguous statutory text" to discern whether "the delegation claimed to be lurking there" exists. *Id.* at 723 (quoting *Util. Air Regul. Grp. v. Env't Prot. Agency*, 573 U.S. 302, 324 (2014)). The major questions doctrine uses context to aid "interpreting the scope of a delegation." *Biden v. Nebraska*, 600 U.S. 477, 513 (2023) (Barrett, J., concurring). However, when Congress itself legislates "the details," the question of whether it "delegat[ed] [them] away" answers itself. *Id.* at 515 (quoting *Wayman*, 23 U.S. (10 Wheat.) 1 (1825)). For that reason, the Court need not address those arguments here.

For the same reason, because the Final Rule's challenged provisions contravene Congress's prescriptions, the Court "does not consider the parties' remaining arguments regarding arbitrary and capricious rulemaking." Tenn. Walking Horse Nat'l Celebration Ass'n v. U.S. Dep't of Agric., No. 2:24-CV-143, 2025 WL 360895, at *4 (N.D. Tex. Jan. 31, 2025) (citing Nat'l Ass'n of Priv. Fund Managers v. Sec. & Exch. Comm'n, No. 4:24-CV-250, 2024 WL 4858589, at *8 (N.D. Tex. Nov. 21, 2024)). Judicial restraint counsels "if it is not necessary to decide more, it is necessary not to decide more." PDK Lab'ys Inc. v. U.S. Drug

Enft Agency, 362 F.3d 786, 799 (D.C. Cir. 2004) (Roberts, J., concurring in part and in the judgment).

IV. Vacatur Is the Appropriate Relief

Judicial restraint is relevant for considering the appropriate relief as well. Defendants argue that if this Court holds the 24/7 Requirement and the HPRD Requirements contrary to the APA, then any relief should be curtailed to the parties and challenged provisions. ECF No. 80-1 at 57–58. They also contend that the APA "does not authorize any particular form of relief." Id. at 56 (emphasis in original); see also Transcript of Oral Argument at 36, United States v. Texas, 599 U.S. 670 (2023) (No. 22-58) (Chief Justice Roberts reacting "[w]ow" in response to this argument). But see Texas, 599 U.S. at 686, 701–02 (Gorsuch, Thomas & Barrett, JJ., concurring) (questioning vacatur while recognizing it is not a universal injunction and that whether the APA authorizes vacatur is not "open and shut" with "[t]houghtful arguments and scholarship" on both sides).

The Supreme Court "will have to address" the "serious questions" about vacatur and universal injunctions "sooner or later." *Id.* at 702. Until then, the Fifth Circuit's precedents govern this Court. The Fifth Circuit has consistently held that "vacatur under [Section] 706(2) [is] a remedy that affects individuals beyond those who are parties to the immediate dispute." *Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 951 (5th Cir. 2024), *cert. granted*, No. 24-316, 2025 WL 65913 (U.S. Jan. 10, 2025), *and cert. denied sub nom. Braidwood MGMT. Inc. v. Becerra*, No. 24-475, 2025 WL 76462 (U.S. Jan. 13, 2025). It "empowers courts to set aside—*i.e.*, formally nullify and revoke—an unlawful agency action." *Data Mktg. P'ship, LP v. U.S. Dep't of Lab.*, 45 F.4th 846, 859 (5th Cir. 2022) (quoting Jonathan F. Mitchell, *The Writ-of-Erasure Fallacy*, 104 VA. L. REV. 933, 950 (2018)). And it operates nationwide because it "operates on the status of agency action in the abstract." *Braidwood*, 104 F.4th at 951.

Compare Texas v. Biden, 646 F. Supp. 3d 753, 780 (N.D. Tex. 2022) (vacating because "a geographically-limited [remedy] would be ineffective" (alteration in original) (quoting Texas v. United States, 40 F.4th 205, 229 n.18 (5th Cir. 2022))), with Texas v. Bureau of Alcohol, Tobacco, Firearms, and Explosives, 737 F. Supp. 3d 426, 444 (N.D. Tex. 2024) (preliminarily enjoining only as to plaintiff parties).

As the Fifth Circuit has "repeatedly described it," vacatur is the default "remedy for unlawful agency action." *Id.* at 952 (citing cases). It does not require consideration of the equities because as the Fifth Circuit "conceptualizes it," it is not "a remedy familiar to courts sitting in equity." *Id.* Because the "default rule is that vacatur is the appropriate remedy," this Court finds no reason to depart pending changes in precedent. *Data Mktg.*, 45 F.4th at 859.

But a question remains about what this Court must vacate. Defendants argue vacatur should be limited to the challenged provisions of the Final Rule. Plaintiffs challenge the 24/7 Requirement and the HPRD Requirements only. ECF Nos. 57-1 at 11; 96 at 41. And the Final Rule contains a severability clause. 89 Fed. Reg. at 40913. This Court has not analyzed the unchallenged provisions of the Final Rule to determine if they flout the APA. And the "severance and invalidation of [the challenged requirements] will not impair the function of [Medicare and Medicaid participation conditions] as a whole." K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 294 (1988). Even more, the Final Rule itself reveals that "there is no indication that the regulation would not have been passed but for" the "inclusion" of the offending provisions. Id.; see also 89 Fed. Reg. at 40913. Thus, vacatur is limited to the 24/7 Requirement and the HPRD Requirements.

CONCLUSION

Accordingly, the Court **GRANTS** Plaintiffs' Motion and **DENIES** Defendants' Cross-Motion. The 24/7 Requirement and the HPRD Requirements at 42 C.F.R. Section 483.35(b)(1) and 483.35(c) are **VACATED** per 5 U.S.C. Section 706(2).

SO ORDERED.

April <u>7</u>, 2025

MATTHEW J. KACSMARYK

UNITED STATES DISTRICT JUDGE

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