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

AMERICAN HEALTH CARE ASSOCIATION, et al., *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, et al., *Defendants*.	Case No. 2:24-cv-0114-Z-BR (lead) Case No. 2:24-cv-0171-Z (consolidated)

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND RESPONSE TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Rule 56.3 and Federal Rule of Civil Procedure 56, Defendants respectfully cross-move for summary judgment on all counts of Plaintiffs' respective complaints. *See* ECF No. 26[1] (amended complaint of American Health Care Association, LeadingAge, Texas Health Care Association, Arbrook Plaza, Booker Hospital District, and Harbor Lakes Nursing & Rehabilitation Center); No. 2:24-cv-171, ECF No. 1 (complaint of the State of Texas).

The grounds for this motion, including all matters required by Local Rule 56.3, are set forth in the accompanying memorandum in support of Defendants' cross motion for summary judgment and in opposition to Plaintiffs' motion for summary judgment, and the administrative record underlying this action.

[1] All docket citations are to the lead case, No. 2:24-cv-00114-Z-BR, unless otherwise noted.

Dated: November 15, 2024

Respectfully submitted,

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AMERICAN HEALTH CARE ASSOCIATION, et al.,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 2:24-cv-00114-Z-BR (lead)
Case No. 2:24-cv-171-Z (consolidated)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Thousands of Americans enter nursing homes every year. Many are elderly and suffer from multiple chronic conditions; others seek admission because injury or surgery has left them unable to care for themselves and thus reliant on dedicated nursing staff. To protect these vulnerable residents, Congress granted the Secretary of Health and Human Services ("HHS") expansive authority to regulate the activities of nursing homes treating patients covered by Medicare and Medicaid. In accordance with Congress's directive and in response to health and safety concerns and extensive new research demonstrating that nurse staffing levels are closely correlated with the health, safety, and quality of care of residents, the Centers for Medicare & Medicaid Services ("CMS") promulgated a rule establishing minimum staffing standards necessary for the health, safety, and well-being of the 1.2 million residents receiving services in Medicare and Medicaid certified Long-Term Care ("LTC") facilities each day. *Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting* , 89 Fed. Reg. 40876 (May 10, 2024) ("Final Rule").

As relevant here, the Final Rule protects the health and safety of nursing home residents through two independent requirements on facilities' participation in the Medicare and Medicaid programs: (1) by requiring that covered facilities have a registered nurse ("RN") "onsite 24 hours per day, for 7 days a week," 89 Fed. Reg. 40997 (the "24/7 RN requirement"); and (2) by requiring that facilities maintain at least 0.55 hours per resident per day ("HPRD") of RN staffing, 2.45 HPRD of nurse aide ("NA") staffing, and 3.48 HPRD total nurse staffing, 89 Fed. Reg. 40877 (the "HPRD requirements"). These requirements reflect the agency's reasoned consideration of a voluminous record of nursing home staffing research, including new data gathered during and after the COVID-19 public health emergency demonstrating the positive relationship between RN and NA staffing levels and resident health and safety. They also mark the culmination of a decades-long process, beginning with Congress's passage of the landmark Federal Nursing Home Reform Act in 1987

("FNHRA"), Pub. L. No. 100-203, 101 Stat. 1330 (1987), and continuing through repeated efforts by Congress and HHS to gather the data necessary to support promulgation of minimum staffing standards by the agency. Having now gathered that previously-unavailable data and considered a wealth of new research, the Secretary promulgated the 24/7 RN and HPRD requirements of the Final Rule to fulfill his statutory duty to assure that the requirements which govern nursing homes are adequate to protect the health, safety, and well-being of residents.

Nevertheless, Plaintiffs—American Health Care Association, LeadingAge, Texas Health Care Association, Arbrook Plaza, Booker Hospital District, Harbor Lakes Nursing & Rehabilitation Center, and the State of Texas—ask this Court to strike down the 24/7 RN and HPRD requirements. They claim that these requirements exceed CMS's authority under the Medicare and Medicaid statutes, and are arbitrary and capricious in violation of the Administrative Procedure Act ("APA"). *See generally*, Mem. in Supp. of Pls.' Mot. for Summ. J., ECF No. 57-1 ("Pls.' MSJ"). Both of these arguments fail.

As explained below, the Supreme Court has squarely held that the Secretary's authority to establish regulatory requirements for participation in the Medicare and Medicaid programs related to nursing home residents' health and safety extends to rules pertaining to the healthcare workforce itself. CMS's Final Rule is a permissible exercise of that delegated authority because the 24/7 RN and HPRD requirements are both reasonably related to resident health and safety, and not inconsistent with any other statutory provisions. And contrary to Plaintiffs' suggestion, the administrative record before CMS at the time of its decision amply demonstrates the need for the minimum staffing standards chosen by the agency.

Plaintiffs may be unhappy with the policy embodied in the Final Rule, or the effect the Final Rule may have on their business practices. But that does not make for a successful APA challenge. As a legal matter, Plaintiffs' claims lack merit, and the Court should enter judgment for Defendants.

BACKGROUND

I. MEDICARE AND MEDICAID

Under the Social Security Act, the Medicare and Medicaid programs provide health insurance coverage for persons who are elderly, have a severe disability, or have low income. *See* 42 U.S.C. §§ 1395-1396w-5. Medicare is operated by the federal government, and Medicaid is a joint federal-state program. Under both Medicare and Medicaid, health care services are provided by private organizations, governmental health care facilities (such as Indian Health Service facilities, public hospitals and community clinics), and health care professionals that meet the statutory and regulatory requirements for participation. Participation in both programs is voluntary. *See Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991). If a provider or practitioner chooses to participate, it enters into an agreement under which it consents to be bound by the program's conditions of participation. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396a(a)(78); *United States v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039, 1044 (5th Cir. 1984).

Medicare and Medicaid are administered by the Secretary of HHS, acting through CMS. *See, e.g.*, 42 U.S.C. §§ 1395i-3, 1395kk, 1395hh, 1396a, 1396r. Congress has entrusted the Secretary with "exceptionally broad authority" in administering both programs. *Wis. Dep't of Health & Family Servs. v. Blumer*, 534 U.S. 473, 497 (2002) (*quoting Schweiker v. Gray Panthers*, 453 U.S. 34, 43-44 (1981)); *see also Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 156 (2013) ("Congress vested in the Secretary large rulemaking authority to administer the Medicare program."); *Ark. Dep't of Health & Hum. Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006) (noting that administration of Medicaid "is entrusted to the Secretary of Health and Human Services . . . who in turn exercises his authority through the Centers for Medicare [&] Medicaid Services"). This includes the authority to issue rules and regulations "as may be necessary to the efficient administration of the functions with which" he is charged under the Act. 42 U.S.C. § 1302(a); *accord* 42 U.S.C. § 1395hh(a)(1).

II. LONG-TERM CARE FACILITIES

LTC facilities, often called nursing homes, provide residential nursing services, medication, rehabilitation, and other services for elderly and disabled persons. LTC facilities that participate in Medicare are officially known as "skilled nursing facilities," 42 U.S.C. § 1395i–3(a), and those that participate in Medicaid are officially known as "nursing facilities," *id.* § 1396r(a).[1]

In FNHRA, part of the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330 (1987), Congress substantially revised the statutes regarding the participation of nursing homes in the Medicare and Medicaid programs. Those changes were prompted by concerns about the treatment and condition of residents. The House Budget Committee, for example, was "deeply troubled by persistent reports that, despite [a] massive commitment of Federal resources, many nursing homes receiving Medicaid funds are providing poor quality care to . . . elderly and disabled Medicaid beneficiaries." H.R. Rep. No. 100-391, pt. 1, at 448, 452 (1987). The committee cited a report by the General Accounting Office indicating that "41 percent of skilled nursing facilities and 34 percent of intermediate care facilities were out of compliance during three consecutive inspections with one or more of the Medicaid requirements most likely to affect patient health and safety," and that "[n]ursing homes can remain in the Medicare and Medicaid programs for years with serious deficiencies that threaten patient health and safety by taking corrective action to keep from being terminated each time they get caught." *Id.* at 451 (quotation omitted). The committee also cited a report by the Institute of Medicine of the National Academy of Sciences, finding that "in many . . . government-certified nursing homes, individuals who are admitted receive very inadequate—sometimes shockingly deficient—care that is likely to hasten the deterioration of their physical, mental, and emotional health," and that "the poor-quality [nursing] homes outnumber the

[1] Because there is no material difference between the two for purposes of this case, Defendants refer to both as "nursing homes" or "LTC facilities" throughout this memorandum.

very good homes." *Id.* at 452 (citing Nat'l Library of Med., Inst. of Med., *Improving the Quality of Care in Nursing Homes* 2 (1986), *available at* https://archive.ph/KFNCi) ("Institute of Medicine Study").

Thus, FNHRA effectuated a "major overhaul" of the requirements for nursing home participation in the Medicare and Medicaid programs. *Id.* Among other things, Congress established over 100 conditions that nursing homes would have to meet to participate in these programs. *See generally* 42 U.S.C. §§ 1395i–3(g), 1396r(g); *Beverly Health & Rehab. Servs., Inc. v. Thompson*, 223 F. Supp. 2d 73, 79 (D.D.C. 2002). These include the requirement that facilities provide nursing services, rehabilitative services, medically-related social services, pharmaceutical services, and other services "to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." 42 U.S.C. §§ 1395i-3(b)(4)(A), 1396r(b)(4)(A). Congress also required that participating facilities provide "24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents," and that such 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); *accord id.* § 1395i-3(b)(4)(C)(i).

In establishing these requirements for program participation, however, FNHRA also preserved and significantly expanded the Secretary's role in relation to the participation of nursing homes in Medicare and Medicaid. Specifically, Congress required that the Secretary must, among other things, ensure that the requirements for nursing homes and the enforcement of those requirements are "adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys." *Id.* §§ 1395i-3(f)(1), 1396r(f)(1). Congress also authorized the Secretary to impose "such other requirements relating to the health and safety [and well-being] of residents . . . as [he] may find necessary." *Id.* §§ 1395i- 3(d)(4)(B), 1396r(d)(4)(B). CMS has long utilized these authorities to establish additional staffing requirements that LTC facilities wishing to participate in Medicare or Medicaid must meet. *See, e.g.*, 42 C.F.R. § 483.60(a)(1) (requiring employment of a

"qualified dietitian or other clinically qualified nutrition professional"); *id.* § 483.80(b) (requiring employment of a credentialed "[i]nfection preventionist"); *id.* § 483.70(e)(1) (requiring employment of "those professionals necessary to carry out" various facility-administration requirements); *see also id.* § 483.80(d) (requirements regarding vaccination of LTC staff); *id.* § 483.70(o)(2) (requirements for social work staff).

The Final Rule, like these other rules setting minimum requirements for nursing home staffing, ensures that federal funds are used only to pay for the purposes that Congress intended.

III. THE LTC FACILITY STAFFING RULEMAKING

The staffing requirements Plaintiffs challenge here mark one step of a decades-long effort, involving both Congress and HHS alike, to gather the data necessary to support promulgation and future refinement of minimum LTC facility staffing standards by CMS. *See, e.g.*, Institute of Medicine Study at 200-01 (recognizing that CMS had authority to incorporate "minimum nursing staff requirements" for LTC facilities "into its regulatory standards" if "convincing evidence becomes available"); Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4801(e)(17)(B), 104 Stat. 1388, 1388-218 (1990) (requiring CMS to study "the appropriateness of establishing minimum caregiver to resident ratios and minimum supervisor to caregiver ratios for [LTC] facilities"); *Reform of Requirements for Long-Term Care Facilities*, 81 Fed. Reg. 68688, 68756 (Oct. 4, 2016) (recognizing that CMS could evaluate whether to promulgate staffing standards "once a sufficient amount [of data] is collected and analyzed[]").

Most recently, CMS commissioned Abt Associates to perform a research study ("2022 Abt Study") to determine the level and type of staffing needed to ensure safe and quality care for nursing home residents. *See* AR_00069983; Abt Associates, *Nursing Home Staffing Study Comprehensive Report*, available at https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf. The 2022 Abt Study found that increased nursing home staffing improves

resident health and safety. AR_00069990 ("[N]urse staffing levels are a 'critical factor' in determining nursing home quality of care."); *id.* ("nursing homes with higher staff-to-resident ratios provide better care" and "have also had greater success in addressing the COVID-19 pandemic"); AR_00069995 ("[A]s minimum required nurse staff HPRD increase, there is a corresponding increase in potential quality and safety improvements, and a decrease in expected delayed and omitted care.").

A. The Proposed Rule

In response to continuing concerns regarding the health and safety of nursing home residents illuminated by the 2022 Abt Study and other findings showing ongoing "chronic understaffing in LTC facilities," and in particular "insufficient numbers of [RNs] and [NAs], as evidenced from, *inter alia*, a review of data collected since 2016 and lessons learned during the COVID-19 Public Health Emergency," CMS issued a notice of proposed rulemaking announcing its intent to explore promulgation of minimum staffing standards for LTC facilities. *Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting Proposed Rule*, 88 Fed. Reg. 61352 (Sept. 6, 2023) ("Proposed Rule"). *See also id.* at 61359-65 (further detailing the "systematic literature review," "qualitative analysis," "quantitative analysis," "cost and savings analysis," and "listening sessions" reviewed by CMS and Abt as support for the requirements proposed).

In its Proposed Rule, CMS proposed "individual minimum staffing type standards, based on case-mix adjusted data for RNs and NAs, to supplement the existing 'Nursing Services' requirements . . . to specify that facilities must provide, at a minimum, 0.55 RN [HPRD] and 2.45 NA HPRD." *Id.* at 61353. As CMS explained, "the evidence and findings from the 2022 [Abt] Study demonstrated that there was a statistically significant difference in safety and quality care at 0.45 HPRD for RNs and higher including 0.55 HPRD[,]" and "there was a statistically significant difference in safety and quality care at 2.45 HPRD and higher for NAs." *Id.* at 61357. And because "the 2022 [Abt] Study did not demonstrate an association between [licensed practical nurse/licensed vocational nurse

("LPN/LVN")] HPRD, at any level, and safe and quality care," *id.*, CMS chose not to propose a separate LPN/LVN staffing standard. CMS also sought comments on whether a total nurse staffing standard should also be required. *Id.* at 61353.

Based on the findings of the 2022 Abt Study and other literature, *id.* at 61376, CMS also proposed to independently "require an RN to be on site 24 hours per day and 7 days per week to provide skilled nursing care to all residents in accordance with resident care plans." *Id.* at 61353. *See also id.* at 61372 (citing comments to a prior rulemaking, stating that "24-hours RN coverage was necessary . . . to 'anticipate, identify and respond to changes in [a resident's] condition'"). In response to its notice of proposed rulemaking, CMS received over 46,000 public comments expressing a range of views. 89 Fed. Reg. 40883. *See also* AR_00000209-69362.

B. The Final Rule

Having now gathered previously-unavailable data and considered a wealth of new research and public comments, *see* 89 Fed. Reg. 40880, the Secretary promulgated the challenged requirements of the Final Rule to fulfill his statutory duty to assure that the requirements which govern federally-funded nursing homes are adequate to protect the health, safety, and well-being of residents. *See id.* at 40890.

Based on concerns raised during the rulemaking process about workforce challenges and costs, CMS announced a $75 million grant program and staffing campaign in tandem with the Final Rule to expand the nursing workforce. *Id.* at 40885-86. CMS also modified the Proposed Rule to "provide additional flexibility and time for facilities to implement these changes" through staggered implementation dates, finalized inclusive hardship exemptions, and a 3.48 HPRD total nurse staffing standard that allows facilities flexibility to choose how to staff beyond the minimum RN and NA HPRD requirements to meet the specific needs of their residents. *Id.* at 40886, 40888.

The Final Rule's total cost estimates closely tracked CMS's estimates in the Proposed Rule, and the expected benefits exceed those anticipated by the Proposed Rule, including "increased community discharges, reduced hospitalizations, and emergency department visits, with a minimum estimated savings of gross costs of $318 million per year for Medicare starting in year 3." *Id.* at 40878.

Plaintiffs challenge the Final Rule's 24/7 RN and HPRD requirements. Pls.' MSJ 5. The finalized 24/7 RN requirement, as its name suggests, "require[s] an RN to be on site 24 hours per day and 7 days per week." 89 Fed. Reg. 40877. And the Final Rule's HRPD requirements state that a facility "must provide, at a minimum 3.48 total nurse staffing [HPRD] of nursing care, with 0.55 RN HPRD and 2.45 NA HPRD." *Id.* The Final Rule also provides for exemptions from the minimum HPRD standards and 8-hours per day of the 24/7 RN requirement on a case-by-case basis.[2] Exemption eligibility is based on the following criteria: (1) workforce unavailability, as measured by having a nursing workforce per labor category that is a minimum of 20% below the national average for the applicable nurse staffing type; (2) the facility's good faith efforts to hire and retain staff; (3) the facility's documentation of its financial commitment to staffing; (4) the facility's posting of a notice of its exemption status in a prominent and publicly viewable location in each resident facility; and (5) the facility's provision of individual notice of its exemption status and the degree to which it is not in compliance with the HPRD requirements to its residents and the Office of the State Long-Term Care Ombudsman. *Id.* at 40877-78.[3]

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[2] An independent statutory waiver for all RN hours over 40 hours per week is also available to qualifying facilities, *see* 42 U.S.C. §§ 1396r(b)(4)(C)(ii), 1395i-3(b)(4)(C)(ii). The Final Rule "does not purport to eliminate or modify the existing statutory waiver." 89 Fed. Reg. 40878.

[3] However, a facility will not be eligible for an exemption if it: (1) has failed to submit Payroll Based Journal ("PBJ") data; (2) is a Special Focus Facility; (3) has been cited for widespread insufficient staffing with resultant resident actual harm or a pattern of insufficient staffing with resultant resident actual harm; or (4) has been cited at the "immediate jeopardy" level of severity with respect to insufficient staffing within the 12 months preceding the survey during which non-compliance is identified. 89 Fed. Reg. 40878.

LEGAL STANDARDS

Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "In the context of a challenge to an agency action under the [APA], summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency's action is supported by the administrative record and consistent with the APA standard of review." *Am. Stewards of Liberty v. Dep't of the Interior*, 370 F. Supp. 3d 711, 723 (W.D. Tex. 2019) (alterations and quotation marks omitted). Under the APA, an agency action may not be set aside unless it is "arbitrary," "capricious," or "not in accordance with law." 5 U.S.C. §706. In such cases, "the focal point for judicial review 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) (*per curiam*). "The agency's decision does not have to be ideal so long as the agency gave at least minimal consideration to relevant facts contained in the record." *Wright v. United States*, 164 F.3d 267, 268-69 (5th Cir. 1999) (*per curiam*).

ARGUMENT

I. THE FINAL RULE FITS SQUARELY WITHIN THE SECRETARY'S AUTHORITY TO PROTECT THE HEALTH, SAFETY, AND WELL-BEING OF LTC FACILITY RESIDENTS

The Social Security Act grants the Secretary of HHS authority to issue rules and regulations "as may be necessary to the efficient administration of the functions with which" he is charged under the Act. 42 U.S.C. § 1302(a); *see also* 42 U.S.C. § 1395hh(a)(1); 89 Fed. Reg. 40996 (citing both provisions as authority for the Final Rule). Alongside this broad grant of "general rule-making authority," Congress also gave the Secretary "specific rulemaking authority with respect to nursing homes," *Resident Councils of Washington v. Leavitt*, 500 F.3d 1025, 1033 (9th Cir. 2007) (citing 42 U.S.C. §§ 1395i–3(f), 1396r(f)), and expressly charged the Secretary with the responsibility to issue regulations and establish "such other requirements relating to the health and safety of residents or relating to the

physical facilities thereof as the Secretary may find necessary." 42 U.S.C. §§ 1396r(d)(4)(B), (f)(1) (cited at 89 Fed. Reg. 40879, 40996); *see also* 42 U.S.C. §§ 1395i-3(d)(4)(B), (f)(1) (same). These provisions operate "capaciously," and "are broadly worded to give HHS significant leeway in deciding how best to safeguard LTC residents' health and safety." *Northport Health Servs. of Ark., LLC v. U.S. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021) (discussing 42 U.S.C. § 1395i-3).

When a statute grants such "broad authority," *Mourning v. Family Publications Service, Inc.*, 411 U.S. 356, 365 (1973) (quotation marks omitted), a rule issued pursuant to it "will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" 411 U.S. at 369 (quoting *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 280-81 (1969)). The Fifth Circuit has applied this "reasonably related" standard in reviewing an attack on the Secretary's authority under the Social Security Act. *Baylor Univ. Med. Ctr. v. Heckler*, 758 F.2d 1052, 1062 (5th Cir. 1985).

There can be no genuine dispute that the Final Rule falls within the authority Congress has conferred upon the agency under this standard. Congress created the Medicare and Medicaid programs to provide health care to the populations covered under each program. *See Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993); *see also* 42 U.S.C. § 1396-1. The purpose of providing health care to these populations is to advance and maintain residents' health. It is therefore unsurprising that Congress instructed the Secretary to administer these programs so as to ensure that LTC facility residents' health and safety is protected, *see* 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B), and regulatory requirements concerning nursing home staffing fall squarely within the Secretary's delegated rulemaking authority. *See* 89 Fed. Reg. 40890 (finding that the challenged "requirements are necessary for resident health, safety, and well-being"). The Secretary's Final Rule, like the agency's prior rules addressing nursing home staffing before it, ensures that federal funds are used only to pay for the purposes that Congress intended.

Indeed, CMS has for years regularly exercised its statutory authority to protect resident health and safety by promulgating additional regulatory requirements pertaining to LTC facility staffing, including, for example: by requiring that all facilities "employ on a full-time, part-time or consultant basis those professionals necessary to carry out" various facility-administration requirements, 42 C.F.R. § 483.70(e)(1); by requiring LTC facilities to employ an "[i]nfection preventionist" with specialized training in infection prevention and control, *id.* § 483.80(b); by tying the sufficiency of an LTC facility's nursing staff level to the results of a facility assessment delimited by regulation, *id.* §§ 483.35, 483.71; and by establishing numerous requirements relating to the qualifications of the LTC facility workforce generally, beyond that which would be required by the statute alone. *See, e.g.*, *id.* §§ 483.80(d) (vaccination requirements for LTC facility staff); 483.70(o)(2) (work experience requirement for mandatory social work staff). *Cf. id.* §§ 482.12, 482.22 (regulating hospital hiring, staffing, and budgeting under analogous "health and safety" authority, 42 U.S.C. § 1395x(e)(9)). On Plaintiffs' view, all of those conditions are invalid because they are not specifically set forth in statute. Pls.' MSJ 27. But the Supreme Court squarely rejected that argument just two years ago when considering CMS's healthcare worker COVID-19 vaccination rule in *Biden v. Missouri*, 595 U.S. 87 (2022) (*per curiam*).

In *Missouri*, the Supreme Court explained that the Secretary's statutory authority "to promulgate, as a condition of a facility's participation in the programs, such 'requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution,'" encompasses not only the powers of a "bookkeeper," but also the power to impose requirements that relate to LTC facilities' "healthcare workers themselves," even when such requirements go beyond those otherwise specified by Congress. *Missouri*, 595 U.S. at 90-91, 94 (quoting 42 U.S.C. § 1395x(e)(9) and citing 42 U.S.C. §§ 1395i–3(d)(4)(B), 1396r(d)(4)(B) as analogous). *Cf. Rasulis v. Weinberger*, 502 F.2d 1006, 1010 (7th Cir. 1974) (noting that Congress "explicitly empowered" the Secretary to establish health and safety standards to protect hospital patients in an analogous

portion of the Social Security Act). That is precisely what the Secretary has done by promulgating the 24/7 RN and HPRD requirements at issue in this case. Plaintiffs' contrary arguments misapprehend the relevant statutes and mischaracterize the Final Rule.

A. The 24/7 RN Requirement Is Authorized By Statute

Like any other question of statutory interpretation, the Court's analysis of CMS's statutory authority to promulgate the 24/7 RN requirement "begins with the statutory text"—and, where the text is clear, it "ends there as well." *National Ass'n of Mfrs. v. Dep't of Def.*, 583 U.S. 109, 127 (2018) (citation omitted). Here, the Secretary's authority to adopt the 24/7 RN requirement flows directly from the unambiguous text of the statute, 42 U.S.C. §§ 1396r, 1395i-3.

As explained above, "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)). These statutory authorities thus "expressly delegate" to the Secretary "discretionary authority" both to "fill up the details of a statutory scheme," and to "regulate subject to the limits imposed by a term or phrase that leaves agencies with flexibility." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2263 (2024) (cleaned up); *see* 144 S. Ct. at 2263 n.6 (listing "appropriate and necessary" and for the "protection of public health" as examples of phrases expressly delegating discretion). That much is uncontested in this case; Plaintiffs correctly concede that Congress has given CMS express "authority to fill up the details of the statutory scheme" through the delegations cited in the Final Rule. Pls.' MSJ 29 (quotation marks omitted) (citing 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B), 1396r(b)(2), 1395i-3(b)(2), 1396r(b)(1)(A), 1395i-3(b)(1)(A); *Loper Bright*, 144 S. Ct. at 2263).

CMS's 24/7 RN requirement is a permissible exercise of that delegated authority because it is "reasonably related" to the resident health and safety purposes of FNHRA. *Baylor Univ. Med. Ctr.*, 758 F.2d at 1062. *See* 89 Fed. Reg. 40890 ("[t]he Secretary has concluded that these HPRD levels and RN

onsite 24/7 requirements are necessary for resident health, safety, and well-being"). To the extent that Plaintiffs disagree with the Secretary's determination that 24/7 RN coverage is necessary for resident health and safety, that argument goes to whether the agency's decision was arbitrary or capricious (*see infra* Part II), not to any lack of authority. *See Kisor v. Wilkie*, 588 U.S. 558, 632 (2019) (Kavanaugh, J., concurring) ("To be sure, some cases involve regulations that employ broad and open-ended terms like "reasonable," "appropriate," "feasible," or "practicable." Those kinds of terms afford agencies broad policy discretion, and courts allow an agency to reasonably exercise its discretion to choose among the options allowed by the text of the rule. But that is more *State Farm* than *Auer*.") (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983)); *Loper Bright*, 144 S. Ct. at 2263 (similar).

Instead of meaningfully contesting the existence of CMS's statutory authority itself, Plaintiffs' argument amounts to a claim that the 24/7 RN requirement is an impermissible exercise of CMS's delegated authority because it purportedly conflicts with other portions of FNHRA—specifically with Congress's requirement that an LTC facility "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); *accord id.* § 1395i-3(b)(4)(C)(i). *See* Pls.' MSJ 29-30 (arguing that "the statutory 8/7 requirement" is "inconsistent with" the 24/7 RN requirement) (citation omitted). For Plaintiffs to prevail on this argument, however, this Court would need to read the words "at least" out of the statute entirely. *See* 42 U.S.C. §§ 1396r(b)(4)(C)(i),1395i-3(b)(4)(C)(i) (requiring "*at least*" 8/7 RN coverage) (emphasis added). The Court cannot do so. *See 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951) (courts are not "to add nor to subtract, neither to delete nor to distort [the words]" Congress has used).

Read in full, the unambiguous text of FNHRA plainly permits the Secretary to promulgate the 24/7 RN requirement as necessary for resident health and safety, and that requirement is not

inconsistent with Congress's directive 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), 1395i-3(b)(4)(C)(i) (emphasis added). After all, there can be no dispute that 24 hours is "at least 8" hours. *Id.* By using the words "at least", the statute ensures that the Secretary cannot use his delegated authority to require *less* RN coverage, but it does not prohibit him from requiring *more* coverage using his independent power to establish "other requirements relating to the health and safety of residents." *Id.* §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B).

CMS's decision to exercise its delegated authority to "fill up the details" of a statutory requirement poses no APA problem, even within the realm of nursing home staffing. *Loper Bright*, 144 S. Ct. at 2263. Indeed, Congress regularly uses necessary-but-not-sufficient language like "at least" to preserve room for CMS to set additional health and safety requirements in the future. For example, Congress requires LTC facilities 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 permissibly incorporate that statutory requirement and go further—they require the facility to employ "[a] qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis," and further require specific qualifications for this employee. 42 C.F.R. § 483.60(a)(1). Similarly, while the statute requires that LTC facilities merely "establish and maintain an infection control program," 42 U.S.C. § 1396r(d)(3)(A), CMS's regulations additionally require facilities to employ an "[i]nfection preventionist" to oversee that program, and require that this employee have specialized training in "infection prevention and control." 42 C.F.R. § 483.80(b). The Supreme Court itself cited both of these staffing rules as permissible uses of CMS's health and safety regulatory authority in *Missouri*, noting that "the Secretary has always justified these sorts of requirements by citing his authorities to protect patient health and safety." 595 U.S. at 90, 94 (citing 42 C.F.R. §§ 483.80, 483.60(a)(1)(ii)). *Compare also* 42 U.S.C.

§ 1396r(b)(7) (requiring large LTC facilities to employ a social worker "with *at least* a bachelor's degree in social work or similar professional qualifications") (emphasis added), *with* 42 C.F.R. § 483.70(o) (requiring facilities to employ a social worker with both a bachelor's degree *and* "[o]ne year of supervised social work experience in a health care setting working directly with individuals"). Plaintiffs provide no grounds to differentiate those indisputably permissible exercises of CMS's regulatory authority from the provisions of the Final Rule at issue here.

Nor can Plaintiffs credibly argue that by requiring "at least" 8/7 RN coverage, Congress intended to implicitly remove the ability to promulgate additional RN coverage requirements from the Secretary's broad grant of health and safety rulemaking authority. As the Supreme Court has recognized, there is no "such thing as 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." *Bostock v. Clayton Cnty*, 590 U.S. 644, 669 (2020). Here, the plain text of FNHRA sets out such a broad rule: that CMS may establish "other requirements relating to the health and safety of residents . . . as the Secretary may find necessary," 42 U.S.C. § 1396r(d)(4)(B), absent actual "inconsisten[cy]" with the statute, 42 U.S.C. § 1302(a). Had Congress intended to except from CMS's broad authority the ability to require a *higher* level of RN coverage than specified in the statute, it could have said so. *See City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) ("Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion."). It did not. Instead, Congress expressly granted CMS the authority to expand upon the statutory requirements by promulgating additional requirements deemed necessary to the health and safety of LTC facility residents, 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B), and left the door open to a regulatory 24/7 RN coverage requirement by using the words "at least" in its statutory 8/7 RN

coverage mandate. 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i).[4] "[C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there. When the words of a statute are unambiguous, then, this first canon is also the last: judicial inquiry is complete." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 461-62 (2002) (quotation omitted).

B. The HPRD Requirements Are Authorized by Statute

The Final Rule's HPRD requirements—which require "a minimum of 3.48 [HPRD] for total nurse staffing[,] including but not limited to (i) [a] minimum of 0.55 [HPRD] for registered nurses; and (ii) [a] minimum of 2.45 [HPRD] for nurse aides," 89 Fed. Reg. 40996—fall comfortably within CMS's statutory authority for similar reasons. As explained *supra* 10-12, the Secretary has authority to, *inter alia*, impose "requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary," 42 U.S.C. §§ 1396r(d)(4)(B); *see also id.* § 1395i-3(d)(4)(B). He properly exercised that power in the Final Rule by requiring participating LTC facilities to meet a baseline floor HPRD staffing level in addition to maintaining staff sufficient to meet their residents' needs, after finding that such requirements were "necessary for resident health, safety, and well-being," 89 Fed. Reg. 40890. *See also infra* Part II.

Here too, Plaintiffs do not meaningfully contest that nurse staffing levels are reasonably related to resident health and safety such that CMS has authority to regulate them. *See* Pls.' MSJ 29 (conceding that CMS has "authority 'to "fill up the details" of [the] statutory scheme"') (quoting *Loper Bright*, 144 S. Ct. at 2263). Rather, they again argue that the Final Rule is impermissible because it purportedly

[4] That Congress *did* prohibit CMS from using its rulemaking power to require *less* than 8/7 RN coverage, *see* 42 U.S.C. §§ 1302(a), 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i), further demonstrates that Congress knew how to impose such a limitation and chose not to here. *See Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").

conflicts with Congress's independent statutory requirements for LTC staffing—namely, the requirement that "[a]n LTC facility must provide nursing services 'sufficient to meet the nursing needs of its residents.'" Pls.' MSJ 30 (quoting 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i)).[5]

Plaintiffs' argument rests on a flawed premise: that the "Final Rule impermissibly substitutes CMS's current policy views for Congress' considered judgment, replacing that flexible [statutory] standard with a rule of almost comical rigidity and specificity." *Id.* As explained in the Final Rule, however, CMS's HPRD requirements are not a "rigid one-size-fits-all" approach, *id.* 31:

> Because HPRD involves an assessment of the total number of hours worked by each type of staff compared to the actual number of residents in the facility, it is automatically adjusted for size of facility. With the facility assessment requirement, each individual LTC facility assesses its own resident population and the resources needed to care for them, which will often result in facilities needing to staff higher than the minimum staffing requirements. Thus, neither of these requirements is "one-size-fits-all" because they are tailored to each LTC facility.

89 Fed. Reg. 40908-09. As CMS explained, "if the facility assessment indicates that a higher HPRD for either total nursing staff or an individual nursing category is necessary for 'sufficient staffing', the facility must comply with that determination to satisfy the requirement for sufficient staffing as set forth at § 483.35(a)(1)." *Id.* at 40908. *See also infra* 34-35.

The Secretary's HPRD requirements thus comfortably coexist with Congress's independent "sufficient to meet the nursing needs of [] residents" mandate. 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i). Contrary to Plaintiffs' suggestion, Pls.' MSJ 31, Congress's requirement that facilities

[5] Plaintiffs also argue that the 0.55 HPRD RN requirement "conflicts with Congress' decision to set the statutory requirement for RN staffing at 8 consecutive hours per day." Pls.' MSJ 30-31. However, Plaintiffs again ignore the statutory text and read the words "at least" out of Congress's 8/7 RN requirement. *Compare id. with* 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i). Because the Final Rule's requirement that a facility both employ 24/7 RN services and staff at a level of 0.55 RN HPRD or greater does not conflict with the statutory requirement to "use the services of a registered professional nurse for *at least* 8 consecutive hours a day," Plaintiffs' argument fails for the same reason as its opposition to the 24/7 RN requirement itself. 42 U.S.C. § 1396r(b)(4)(C)(i) (emphasis added). *See supra* 13-17.

provide "sufficient staff" cannot be read to implicitly limit CMS's use of its delegated health and safety authority to set HPRD requirements. *Bostock*, 590 U.S. at 669 (there is no "such thing as 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"). Nor do the challenged HPRD requirements purport to alter or relieve facilities' statutory obligation to staff at a level sufficient to meet the nursing needs of residents. Rather, the Final Rule independently requires facilities to meet baseline HPRD staffing levels found "necessary" for "the health and safety of residents" in accordance with 42 U.S.C. §§ 1395i- 3(d)(4)(B), 1396r(d)(4)(B). As the Supreme Court has recognized, words like "necessary" and for the "protection of public health" act to preserve, rather than curtail, agency authority to "fill up the details" of the statutory scheme via rulemaking. *Loper Bright*, 144 S. Ct. at 2263, n.6.

Here too, the Code of Federal Regulations is replete with instances where agencies have promulgated regulations to "fill up the details" of a statutory scheme when found "necessary" for health and safety pursuant to delegated authority, even when the statute would otherwise merely require regulated parties to behave "sufficiently" or "appropriately." For example, in the context of nursing home staffing, Congress requires that an LTC facility:

> [E]stablish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection, and [] be designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

42 U.S.C. § 1396r(d)(3). Under Plaintiffs' theory of the case, that statutory requirement would be "a flexible qualitative standard[,]" leaving CMS no room to further regulate a facility's infection control regime. Pls.' MSJ 30, 32 (complaining that "it will no longer be sufficient for a nursing home to satisfy the statutory requirement"). But the Court in *Missouri* squarely rejected that argument, stating that CMS's "health and safety" regulatory authority permitted the Secretary to specify additional infection control requirements on top of those articulated by Congress when approving CMS's healthcare

workforce COVID-19 vaccination rule. *Missouri*, 595 U.S. at 93-95 (concluding that CMS's vaccination requirement did not exceed the Secretary's "health and safety" authority, even though the statute itself would not have independently required COVID-19 vaccination). *See also, supra* 5-6, 12, 15-16 (citing further examples).

Because the textual basis for CMS's statutory authority is thus unambiguous, Plaintiffs' argument that "Congress has extensively considered whether to impose staff-to-patient ratios on LTC facilities, and [] has repeatedly chosen not to do so" is beside the point. Pls.' MSJ 30. For one, "[t]here is no need to consult extratextual sources when the meaning of a statute's terms is clear. Nor may extratextual sources overcome those terms. The only role such materials can properly play is to help 'clear up . . . not create' ambiguity about a statute's original meaning." *McGirt v. Oklahoma*, 591 U.S. 894, 916 (2020) (quoting *Milner v. Dep't of the Navy*, 562 U.S. 562, 574 (2011)). And in any event, Congress's decision not to impose different staffing standards in the past provides no indication as to whether CMS possesses the authority to do so today. To the contrary, the available legislative history makes clear that on each prior occasion when more stringent nurse staffing requirements were considered by Congress, the decision not to move forward was motivated by a lack of available data.

The Institute of Medicine's 1986 report on nursing homes is illustrative of this point. *See* Institute of Medicine Study at 200-01. Plaintiffs and the Supreme Court alike have correctly acknowledged that this study's conclusions on staffing formed the basis for Congress's landmark FNHRA. *See* Pls.' MSJ 8; *Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 181 (2023). And in the study, the Institute expressly recognized that although then-available data was inadequate, the Executive Branch—*not Congress alone*—possessed sufficient authority to set "minimum nursing staff requirements" for LTC facilities if and when such data "becomes available." Institute of Medicine Study at 200-01 ("[If convincing evidence becomes available that some approaches to staffing and

training are distinctly superior (in quality of care/life and cost) to others, *the HCFA*[6] will be in a position to incorporate the desirable approaches into its regulatory standards." (emphasis added)). CMS's own longstanding position accords with this understanding. *See* Letter from Sec'y Tommy G. Thompson to Rep. Hastert 1 (Mar. 19, 2002), reprinted as Appendix 1, *available at* https://archive.ph/wip/KQWPt ("Thompson Letter") (declining to promulgate staffing ratios due to prior "reservations about the reliability of staffing data at the nursing home level," not a lack of authority); 81 Fed. Reg. 68756 (recognizing that CMS could reevaluate whether to promulgate staffing rules "once a sufficient amount [of data] is collected and analyzed"). *See also Loper Bright*, 144 S. Ct. at 2265 ("exercising independent judgment is consistent with the 'respect' historically given to Executive Branch interpretations").

In short, CMS drew a strong, direct, and evidence-based link between the challenged requirements of the Final Rule and the health and safety of LTC facility residents. *See* 89 Fed. Reg. 40890; *infra* Part II. Thus, there can be no serious argument that the Rule does not fall within the broad grants of statutory authority enacted by Congress, which, *inter alia*, make it "the duty and responsibility of the Secretary to assure that requirements which govern the provision of care . . . are adequate to protect the health, safety, welfare, and rights of residents," 42 U.S.C. § 1395i-3(f)(1), and permit him to establish any additional requirements relating to the health, safety, and well-being of LTC facility residents as he finds necessary, *id.* §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B). Because the challenged requirements of the Final Rule fall within CMS's statutory authority and do not otherwise conflict with the statute, they are a permissible exercise of the Secretary's rulemaking authority.

[6] The Health Care Financing Administration ("HCFA") was renamed the Centers for Medicare and Medicaid Services in 2001. *See* Press Release, U.S. Dept. of Health & Human Services, *The New Centers for Medicare & Medicaid Services (CMS)* (June 14, 2001).

C. The Final Rule Does Not Implicate The Major Questions Doctrine

Because Plaintiffs' lack of statutory authority challenge fails at its premise, their fallback reliance on the major questions doctrine, which Plaintiffs invoke "to the extent there were any doubt about whether CMS has the authority it claims," Pls.' MSJ 32, necessarily fails as well. The major questions doctrine applies only "in certain extraordinary cases," when an agency tries to achieve "a radical or fundamental change to a statutory scheme" by claiming "an unheralded power representing a transformative expansion in [its] regulatory authority." *West Virginia v. EPA*, 597 U.S. 697, 723-24 (2022) (quotation marks omitted). The issue is thus not whether agencies are asserting "highly consequential power," but rather whether they are asserting "highly consequential power *beyond what Congress could reasonably be understood to have granted*." *Id.* (emphasis added). Two requirements must therefore be met. First, an agency must be claiming an "[e]xtraordinary grant[] of regulatory authority" by asserting "extravagant statutory power over the national economy." *Id.* (quotation marks omitted). Second, this claim must reflect "a 'fundamental revision of the statute, changing it from [one sort of] scheme of . . . regulation' into an entirely different kind[.]" *Biden v. Nebraska*, 600 U.S. 482, 502 (2023) (quoting *West Virginia*, 597 U.S. at 728).[7] Unless both criteria are met, the major questions doctrine does not apply. *Id.*

Plaintiffs do not dispute that establishing a minimum required floor for LTC staffing protects the "health and safety" of those facilities' residents, as those words are ordinarily understood. 42 U.S.C. §1396r(d)(4)(B); *accord id.* § 1395i-3(d)(4)(B). Instead, citing *Mayfield v. United States Department of Labor*, 117 F.4th 611, 616 (5th Cir. 2024), Plaintiffs focus exclusively on the economic and political significance of the Final Rule, arguing that the major questions "doctrine comes into play whenever

[7] Notably, the Supreme Court in *Biden v. Nebraska* first concluded that the agency was asserting a new type of authority that Congress likely did not intend, 600 U.S. at 500-02, and only then determined that this assertion had "staggering" economic and political significance, 600 U.S. at 502.

an agency 'claims the power to resolve a matter of great political significance' or 'seeks to . . . require billions of dollars in spending by private persons or entities.'" Pls.' MSJ 33 (quoting *Mayfield*, 117 F.4th at 616). But the economic and political significance of an agency action alone cannot trigger the major questions doctrine, so long as the action "fits neatly within the language of the statute" and aligns with the agency's established role. *Missouri*, 595 U.S. at 93-94. Plaintiffs' approach is thus inconsistent with the Supreme Court's articulation of the doctrine, and with the Fifth Circuit's decision in *Mayfield* itself. *See* 117 F.4th at 617 (recognizing that major-questions analysis turns not only on economic and political significance, but also "on whether the agency has previously claimed the authority at issue.").

The Supreme Court spoke to the breadth of the exact statutory authorities at issue in this case just two years ago, when it upheld CMS's COVID-19 healthcare worker vaccination rule on the grounds that Congress had plainly "authorized the Secretary to promulgate, as a condition of a facility's participation in the [Medicare and Medicaid] programs, such 'requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.'" *Missouri*, 595 U.S. at 90 (quoting 42 U.S.C. § 1395x(e)(9), citing §§ 1395i–3(d)(4)(B), 1396r(d)(4)(B)). Rejecting the same argument Plaintiffs make here, the Supreme Court explained that despite its wide-ranging impact, CMS's vaccination requirement was not "surprising" because "addressing infection problems in Medicare and Medicaid facilities is what [the Secretary of HHS] does." *Id.* at 95 (majority opinion). And if it poses no major-questions problem for CMS to rely on its Section 1395i–3(d)(4)(B) and 1396r(d)(4)(B) "health and safety" authorities to promulgate vaccination requirements that allegedly "put more than 10 million healthcare workers to the choice of their jobs or an irreversible medical treatment," *id.* at 108 (Alito, J., dissenting), it is *a fortiori* permissible for CMS to use the same authority to promulgate the Final Rule—which by Plaintiffs' own admission would affect only a small portion of the healthcare industry and have a total workforce impact only a fraction of the size found

permissible in *Missouri*. *See* Pls.' MSJ 34 ("[a]ll told, facilities would need to hire approximately 15,906 additional RNs . . . and 77,611 additional NAs") (citation omitted).

Plaintiffs' arguments to the contrary are unavailing in light of *Biden v. Missouri*. First, Plaintiffs point to the fact that "Congress has not altered the statutory staffing requirements for LTC facilities since 1990," arguing that the major questions doctrine is trigged because "by promulgating the Final Rule, CMS has 'adopt[ed] a regulatory program that Congress ha[s] conspicuously and repeatedly declined to enact itself.'" *Id.* at 33-34 (quoting *West Virginia*, 597 U.S. at 724). But this argument ignores that through FNHRA, Congress expressly left it to CMS "to 'fill up the details' of [the] statutory scheme" (as Plaintiffs concede), *id.* at 29 (citation omitted), having determined that the agency was well-positioned to gather data and promulgate staffing requirements if and when such requirements were found "necessary" by the Secretary to protect resident "health and safety." 42 U.S.C. §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B). Plaintiffs have thus shown no evidence of "Congress' consistent judgment to deny [CMS] this power." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000). Indeed, Plaintiffs identify no action Congress has actually taken to limit CMS's ability to set a floor for nursing home staffing. *Cf. Nat'l Fed'n of Indep. Bus. v. OSHA*, 595 U.S. 109, 119 (2022) (citing "a majority vote of the Senate disapproving the regulation"). As the Institute of Medicine recognized in its 1986 report forming the basis for FNHRA: "[i]f convincing evidence becomes available that some approaches to staffing and training are distinctly superior (in quality of care/life and cost) to others, [CMS]"—not Congress alone—"will be in a position to incorporate the desirable approaches into its regulatory standards." Institute of Medicine Study at 201. Now that adequate data is available, *infra* Part II, CMS's long-recognized authority to require LTC facilities to satisfy certain minimum staffing standards to ensure the health and safety of residents—as it did here—is not "an issue of great political significance[]" within the meaning of the major questions doctrine. Pls.' MSJ 33.

Plaintiffs' economic significance argument fares no better. As explained above, the Final Rule affects only a small portion of the healthcare industry, and by Plaintiffs' own admission has a total workforce impact only a fraction of the size found permissible in *Missouri*. *See id.* at 34. The expected cost of the requirements Plaintiffs challenge—approximately $4.3 billion annually on average over the next 10 years, "not includ[ing] adjustments for any exemptions that [CMS] may provide, which could reduce the rule's cost," 89 Fed. Reg. 40955—is also dwarfed by "the recent cases applying the doctrine based on economic significance," which "have involved hundreds of billions of dollars of impact." *Mayfield*, 117 F.4th at 616 (rejecting major questions doctrine assertion for rule affecting 1.2 million workers with $472 million impact the first year alone). The "gap between the economic impact" in cases where the doctrine applies and this case is thus "too large to warrant applying the major questions doctrine here based on economic significance." *Id.* (citing *Nebraska*, 600 U.S. at 483 ($430 billion impact); *West Virginia*, 597 U.S. at 715 ($1 trillion by 2040)).

Plaintiffs themselves concede that Congress has expressly delegated to CMS "authority 'to "fill up the details" of [the] statutory scheme"' of nursing home regulation, Pls.' MSJ 29 (quoting *Loper Bright*, 144 S. Ct. at 2263), including by promulgating "requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary," 42 U.S.C. §1396r(d)(4)(B); *accord* 42 U.S.C. § 1395i-3(d)(4)(B) (cited at Pls.' MSJ 28). Just as in *Missouri*, it is not "surprising" that CMS would use this authority "to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients' health and safety." 595 U.S. at 90, 95. Accordingly, CMS's Final Rule cannot be construed as an extraordinarily economically or politically significant assertion of "power beyond what Congress could reasonably be understood to have granted." *West Virginia*, 597 U.S. at 724. The major questions doctrine provides no basis to invalidate agency action where the statute "specifically authorizes the [agency] to make decisions like th[e] one" under review. *United States v. White*, 97 F.4th 532, 540 (7th Cir. 2024); *see Florida v. HHS*, 19 F.4th 1271,

1288 (11th Cir. 2021) (major questions doctrine did not apply because "a broad grant of authority" that "plainly encompasses the [agency's] actions . . . does not require an indication that specific activities are permitted"); *Nebraska*, 600 U.S. at 511 (Barrett, J., concurring).

II. THE RECORD AMPLY SUPPORTS DEFENDANTS' DECISION TO ADOPT THE FINAL RULE

Just as Plaintiffs cannot show that CMS lacked authority to issue the Final Rule, so too do they fail to show that CMS's decision to promulgate the 24/7 RN and HPRD requirements was arbitrary or capricious. *See* Pls.' MSJ 35-45. CMS proffered a full and rational explanation for the challenged requirements, and Plaintiffs' arguments do not establish otherwise.

A. CMS Provided A Rational And Robust Explanation For Adopting The Final Rule

Under the arbitrary-and-capricious review standard of the APA, the agency need only "articulate a satisfactory explanation for [the] action including a rational connection between the facts found and the choice made." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 682 (2020) (quotation omitted). Applying this "deferential" standard, a court "simply ensures that the agency has acted within a zone of reasonableness," and "may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021); *10 Ring Precision, Inc. v. Jones*, 722 F.3d 711, 723 (5th Cir. 2013) (a court must "uphold an agency's action if its reasons and policy choices satisfy minimum standards of rationality" (quotation omitted)). CMS's detailed account of the reasons for establishing the 24/7 RN and HPRD requirements easily satisfies this test.

CMS collected information over a number of years identifying ongoing health and safety issues linked to understaffing in nursing homes. 88 Fed. Reg. 61352. The research revealed disturbing incidents of residents not being taken to the restroom or bathed for extended periods of time, frequent falls, lack of basic services like feeding or changing, "and even abuse in cases where no one was

watching." *Id.* at 61356; 89 Fed. Reg. 40880. Hundreds of thousands of deaths in LTC facilities during the COVID-19 pandemic laid bare the sweeping extent of the problem, with the ensuing evidence showing that facilities with higher staffing had fewer COVID-19 cases and deaths. 88 Fed. Reg. 61356. Decades of research gathered by CMS confirmed that increased staffing results in better health and safety outcomes for residents. *Id.* at 61356-57; 89 Fed. Reg. 40879. Having identified a need for increased staffing at some LTC facilities to meet the health and safety needs of nursing home residents, CMS proposed minimum staffing standards to address this gap. 88 Fed. Reg. 61352.

Specifically, CMS proposed requiring facilities to have an RN onsite 24/7 and to maintain minimum HPRD levels for RN and NA staffing. *See id.* at 61353. CMS relied on copious research to make this proposal, including an extensive 2022 Abt Study, thousands of public comments, "academic and other literature, PBJ System data,[8] and detailed listening sessions with residents and their families, workers, health care providers, and advocacy groups." *Id.* at 61353; 89 Fed. Reg. 40877. *See also* 88 Fed. Reg. 61359-65 (detailing the "systematic literature review," "qualitative analysis," "quantitative analysis," "cost and savings analysis," and "listening sessions" reviewed by CMS and Abt and that support the requirements of the Final Rule).

As CMS explained, the 2022 Abt Study demonstrated that "Total Nurse Staffing [HPRD] of 3.30 or more," "RN [HPRD] of 0.45 or more," and "NA HPRD of 2.45 or more" all "have a strong association with safety and quality care." 89 Fed Reg. 40881. The 2022 Abt Study further "identified that basic care tasks, such as bathing, toileting, and mobility assistance, are often delayed when LTC facilities are understaffed, which is not sufficient to meet the nursing needs of residents." 88 Fed. Reg. 61356. And as CMS explained, "NAs" are the employees who "spend the most time providing care

[8] Payroll Based Journal ("PBJ") is a system used by CMS to track and report staffing information submitted by nursing homes that provides detailed data on the hours worked by different staff members within a facility, allowing for evaluation of staffing levels and quality of care provided.

to residents by assisting with activities of daily living (for example, feeding, bathing, and dressing)." *Id.* at 61367. Because the 2022 Abt Study found that "LPN/LVN hours per resident day, at any level, do not appear to have any consistent association with safety and quality of care," CMS did not propose a separate LPN/LVN HRPD requirement. 89 Fed. Reg. 40881.

In addition, in 2022, the National Academies of Science, Engineering, and Medicine ("NASEM") published a report that recommended direct-care RN coverage 24 hours a day, 7 days a week. *See* NASEM, *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff*, (2022), https://doi.org/10.17226/26526 (cited at 88 Fed. Reg. 61371). The 2022 Abt Study confirmed this conclusion, leading CMS to propose the 24/7 RN requirement. *See* AR_00070015 ("All but one article explicitly noted that nursing home reform should include 24/7 RN coverage in every nursing home" (citing sources)).

After reviewing the research and considering and responding to thousands of comments, CMS's Final Rule modified its Proposed Rule accordingly, adding a baseline total nurse HPRD requirement and finalizing a staggered implementation timeline and hardship exemptions to "provide additional flexibility and time for facilities to implement these changes[.]" 89 Fed. Reg. 40885-86, 40888. CMS's final rule incorporated these findings and requires "an RN to be on site 24 hours per day and 7 days per week," and that each facility "must provide, at a minimum 3.48 total nurse staffing [HPRD] of nursing care, with 0.55 RN HPRD and 2.45 NA HPRD," providing for exemptions on a case-by-case basis. *Id.* at 40877.

CMS documented its rationale in a Proposed Rule and Final Rule that encompass hundreds of pages in the Federal Register. 88 Fed. Reg. 61352-61429; 89 Fed. Reg. 40876-41000. This process resulted in a rational, well-balanced rule that is research-based and thoroughly explained, far exceeding the APA's requirement that the agency articulate a "rational connection between the facts found and the choice made." *Little Sisters of the Poor*, 591 U.S. at 682.

B. Plaintiffs Fail To Establish That The Final Rule Is Arbitrary Or Capricious

Plaintiffs contend that the rule is arbitrary and capricious for a number of reasons, but none is persuasive. First, the Final Rule is consistent with longstanding agency policy and does not represent a change of course. Second, even if the rule were a departure from prior policy, CMS sufficiently explained good reasons to reassess. Third, the Final Rule recognizes variability in facility needs and maintains staffing flexibility. Fourth, compliance with the Final Rule is feasible. Finally, Plaintiffs' other arguments regarding the underlying research, staff type, facility geography, and state laws fail. CMS's reasoned explanation for its decision in light of the record before it easily meets the "deferential" standard for arbitrary-and-capricious review. *See Prometheus Radio Project*, 592 U.S. at 423.

1. The Final Rule Is Consistent With CMS's Longstanding Position On Minimum Staffing Standards

CMS has been publicly considering nursing home staffing rules for decades and has consistently taken the position that increased staffing yields better health and safety outcomes for residents. *See* Abt Associates, *Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes* at 15 (2001), *available at* https://www.justice.gov/sites/default/files/elderjustice/legacy/2015/07/12/Appropriateness_of_Minimum_Nurse_Staffing_Ratios_in_Nursing_Homes.pdf ("2001 Abt Study") ("Strong evidence supports the relationship between increases in nurse staffing ratios and avoidance of critical quality of care problems.") (cited at 88 Fed. Reg. 61359); Institute of Medicine Study at 101-03 ("Greater numbers of nurses have been associated with improved resident outcomes in research studies."); AR_00069687 ("Over the past 25 years, numerous research studies have documented a significant relationship between higher nurse staffing levels, particularly RN staffing, and the better outcomes of care."); AR_00070630 ("(CMS) has long identified staffing as one of the vital components of a nursing home's ability to provide quality care.").

For example, CMS's 2015 proposed rule regarding Reform of Requirements for Long-Term Care Facilities "included a robust discussion regarding the long-standing interest in increasing the required hours of nurse staffing per day and the various literature surrounding the issue of minimum nurse staffing standards in LTC facilities." 89 Fed. Reg. 40879; 80 Fed. Reg. 42168, 42201, 42242 (July 16, 2015). CMS's prior declination to establish minimum staffing standards was due to a lack of data necessary to determine where to set the minimum standards and to reliably enforce any minimum standards, not because such a rule was unnecessary or ineffective. *See* 81 Fed. Reg. 68756 (recognizing that CMS could reevaluate whether to promulgate staffing rules "once a sufficient amount [of data] is collected and analyzed"); 2001 Abt Study at 10, 17 ("[C]urrent data sources for the reporting of nursing home staffing, OSCAR and State Medicaid Cost Reports, are often inaccurate."); *id.* at 7 ("[T]here is the question of whether the existing nurse staffing data are sufficiently accurate for determining compliance with any nurse staffing requirement that might be implemented."); Institute of Medicine Study at 19 ("If more effective regulation and more rational public policy are to be developed in the long-term care area, serious efforts will have to be made to obtain the necessary data.").

The implementation of the Payroll Based Journal ("PBJ") system in 2016 has since provided more reliable data than was previously available. *See* 89 Fed. Reg. 40879-80 ("Since issuing the 2016 final rule . . . we have collected several years of mandated PBJ System data, which was unavailable at the time, and new evidence from the literature."); AR_00070631 ("CMS has developed a system for facilities to submit staffing information—Payroll Based Journal (PBJ) . . . [which] allows staffing information to be collected on a regular and more frequent basis than previously collected . . . [and] is auditable to ensure accuracy."). This data has now been utilized for studies that informed the staffing standards in this Final Rule that CMS has long contemplated. The Final Rule is therefore entirely consistent with CMS's years-long research efforts, and so is a rational choice for CMS to make. *See Prometheus Radio Project*, 592 U.S. at 423.

Plaintiffs characterize the Final Rule as an unexplained break from CMS's prior position, but it is no departure at all. When the statements cited by Plaintiffs are presented in context, the consistency of the agency's position is apparent. For example, Plaintiffs cite a 1974 rule establishing conditions for participation in Medicare, *inter alia*. There, CMS declined to adopt a comment suggesting "a specific ratio of nursing staff to patients." 39 Fed. Reg. 2238, 2239 (Jan. 17, 1974). But the Final Rule here is not inconsistent—CMS has still not adopted such a fixed standard. It has set several *minimum* HPRD staffing requirements, but has not suggested that this is the *optimal or required* staffing ratio for every facility. *See infra* Part B.3. This is not merely a semantic difference. Given the wide variety in case-mix and acuity among facilities nationwide, the Final Rule emphasized that "a higher total, RN, and NA staffing level will likely be required" if "the acuity needs of residents in a facility require a higher level of care, as the acuity needs in many facilities will[.]" 89 Fed. Reg. 40877. Setting a *minimum* standard below which the health and safety needs of residents are not met is altogether different than requiring a fixed ratio of nursing staff to patients for all facilities. The 1974 rule expressed some skepticism about a minimum standard, but did not assess it in great detail, instead opting to implement quarterly staffing reports to monitor the adequacy of staffing. 39 Fed. Reg. 2239.

In 1980, CMS declined to implement a minimum nursing staff ratio for the express reason that it did not have enough data to know "how much staffing will be required." 45 Fed. Reg. 47371 (July 14, 1980). Again, the 1986 Institute of Medicine Study (in the very next sentence after the excerpt Plaintiffs cite) notes that the reason the Institute of Medicine did not advocate minimum standards was the lack of sufficient data to set those standards. Institute of Medicine Study at 101-03, ("[I]nsufficient evidence of the validity and reliability of the algorithms is available."); *id.* at 102 ("Until standardized resident assessment data become generally available, and some careful empirical studies have been completed, prescribing sophisticated staffing standards in the regulations will not be possible."). And yet again in 2002, HHS Secretary Thompson's stated reason for declining to

implement the recommendations of the 2001 Abt Study was his "serious reservations about the reliability of staffing data at the nursing home level." Thompson Letter.

Once more in 2016, CMS noted that while it was not implementing minimum standards "at this time," it "remain[ed] convinced that additional data will be helpful in determining if and what such ratios should be" and cited "concerns about the validity of self-reported staffing data." 81 Fed. Reg. 68755. CMS discussed "abundant research that associates increased RN staffing with improved quality of care." 80 Fed. Reg. 42200. It described the 2001 Abt Study as reporting that "facilities with staffing levels below 4.1 [HPRD] for long stay residents may provide care that results in harm and jeopardy to residents" and that 4.1 HPRD of nursing care were needed "to ensure that processes of nursing care are adequate." *Id.* at 42200. The 2016 Rule expressly noted that "CMS has begun mandatory, payroll-based collection of staffing information from long-term care facilities," along with other data because CMS "believe[s] this information, once a sufficient amount is collected and analyzed, could greatly assist us in re-evaluating this issue," 81 Fed. Reg. 68756. While CMS has long recognized the need for more data, to portray CMS as having been previously opposed to minimum staffing standards on the merits is inaccurate.

The extensive explanation the agency provided for taking an action long contemplated and consistent with decades of research more than satisfies the "minimum standards of rationality" required under the APA. *10 Ring Precision*, 722 F.3d at 723; *Stephens Cnty. Hosp. v. Becerra*, No. 19-CV-3020, 2021 WL 4502068, at *7 (D.D.C. Sept. 30, 2021) (finding HHS decision not arbitrary or capricious because it was "fully consistent with past agency guidance" and "there was no shift in 'longstanding policies[]'").

2. Even If The Final Rule Were A Departure From The Agency's Prior Position, CMS Had Good Reason To Reevaluate And Fully Explained Its Decision

Assuming, *arguendo*, that the Final Rule did represent a change in position, however, lessons learned from the staggering number of nursing home resident deaths during the COVID-19 public

health emergency in addition to the availability of new, more reliable data provided a strong basis for CMS to reassess its alleged prior policy. Hundreds of thousands of nursing home residents died during the coronavirus pandemic. LTC facility residents' deaths account for nearly a quarter of all COVID-19 deaths in the country, although the 1.2 million nursing home residents (as of July 2023)[9] represent just 0.003% of the U.S. population of 333,287,557 (in 2022).[10] The record shows that although understaffing in nursing homes has been identified for decades as the primary cause of poor care, the pandemic-related deaths of so many residents made it impossible to continue ignoring the critical issue: the primary problem in nursing homes is understaffing. CMS cited a 2020 study involving all of Connecticut's 215 nursing facilities that found that 20 additional minutes of registered nurse care per resident per day was associated with 22% fewer cases of COVID-19 among residents and 26% fewer resident deaths from COVID-19. 89 Fed. Reg. 40880.

In addition to the lessons learned from the pandemic, by 2024, CMS had collected several years of PBJ data, unavailable in 2016, as well as "new evidence from the literature." *Id.* at 40880. Academic studies continued to document the critical importance of staffing for nursing home quality in general and during the COVID-19 pandemic in particular. *Id.* (citing studies). In addition, CMS cited the slowly recovering nursing home workforce and new academic research documenting that a considerable amount of facility reimbursement, now diverted to owners' profits, could be redirected to paying for additional staff. *Id.*

When an agency changes a policy, it need not demonstrate "that the reasons for the new policy are *better* than the reasons for the old one[,]" but only that "the new policy is permissible under the

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[9] Priya Chidambaram and Alice Burns, *A Look at Nursing Facility Characteristics Between 2015 and 2023*, KFF (Jan. 5, 2024), https://www.kff.org/medicaid/issue-brief/a-look-at-nursing-facility-characteristics/.

[10] U.S. Census Bureau, Press Release, *Growth in U.S. Population Shows Early Indication of Recovery Amid COVID-19 Pandemic* (Dec. 22, 2022), https://www.census.gov/newsroom/press-releases/2022/2022-population-estimates.html.

statute, that there are good reasons for it, and that the agency *believes* it to be better[.]" *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Here, the harsh lessons of the pandemic paired with newly available reliable data about nursing home staffing easily meet the threshold of a "good reason" to implement new policy. *Id.* Adopting minimum staffing standards that studies show are effective in improving resident health and safety, after witnessing hundreds of thousands of people die in nursing homes due to understaffing during a pandemic, is hardly an "'[u]nexplained inconsistency'" or inexplicable change in policy. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 212 (2016) (quoting *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)).

3. The Final Rule Recognizes Variability Among Facilities And Maintains Facilities' Staffing Flexibility

Plaintiffs paint the rule as "rigid" and as adopting a "one-size-fits-all" approach, but that view ignores the role of the minimum staffing standards in the broader regulatory scheme. The Final Rule does not dictate the correct staffing level for any particular facility, but rather, it sets the floor. In light of the health and safety concerns and research cited in the Final Rule, CMS determined that staffing at or above the rule's minimum levels is necessary for resident health and safety. *See* 89 Fed. Reg. 40882 (the Final Rule "establish[es] a consistent and broadly applicable national floor (baseline) at which residents are at a significantly lower risk of receiving unsafe and low-quality care"). *Id.* But the Final Rule does not displace the requirement that a facility provide staffing "sufficient to meet the nursing needs of its residents." 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i–3(b)(4)(C)(i). Those provisions remain in place and require a facility to assess its own particular case-mix and acuity and staff the facility accordingly, including by exceeding the minimum staff levels if necessary. *See* AR_00069386 ("[T]he numerical staffing levels are a floor—not a ceiling—for safe staffing."); 89 Fed. Reg. 40892 ("[F]acilities are also required to staff above the minimum standard, as appropriate, to address the specific needs of their resident population . . . . We expect that most facilities will do so in line with strengthened facility assessment requirements[.]"); *supra* 18-19.

In other words, the Final Rule's minimum standards are a necessary but not sufficient condition to satisfy the conditions of participation for Medicare and Medicaid. *See, e.g.*, 81 Fed. Reg. 68755 ("[A] minimum staffing level is one that avoids placing individual residents unnecessarily at risk because of insufficient numbers of staff to provide even the most basic care."). In many cases, facilities will need more staff than the minimum standards require. 89 Fed. Reg. 40883 ("[A]ny numeric minimum staffing requirement is not a target and facilities must assess the needs of their resident population and make comprehensive staffing decisions based on those needs. Often, that will require higher staffing than the minimum requirements."); AR_00069386 ("Nursing homes caring for residents with more acute needs may well have to hire more workers than the minimum standards in order to provide a safe environment."). And in cases where the minimum standards are not feasible, exemptions are available. 42 C.F.R. § 483.35(h). For these reasons, the Final Rule is not a rigid prescription, but a safety net that allows facilities to maintain flexibility while ensuring care is at or above a minimum standard necessary for resident health and safety.

4. Compliance With The Final Rule Is Feasible

Plaintiffs claim that the Final Rule is arbitrary because of alleged compliance challenges, primarily a purported workforce shortage, implementation costs, and insufficient availability of hardship exemptions. But compliance challenges do not render an agency's decision arbitrary. Rather, an agency's decision is arbitrary or capricious if it "relies on improper factors, fails to consider key information, offers a decision that the record does not support, or lacks plausibility." *Citizens for Clean Air & Clean Water in Brazoria Cnty. v. U.S. Dep't of Transp.*, 98 F.4th 178, 190 (5th Cir. 2024) (citing *State Farm*, 463 U.S. at 43). Notably, Plaintiffs do not claim CMS's decision is arbitrary for any of these reasons. Instead, Plaintiffs' arguments boil down to a concern that compliance will be difficult. But CMS conducted a thorough examination of the likely impact and potential compliance challenges of minimum staffing standards—including all the issues raised by Plaintiffs—and offered a reasoned

explanation for its decision to adopt the standards based on the record evidence. That is all the APA requires. The agency's decision is therefore firmly "within a zone of reasonableness." *See Missouri*, 595 U.S. at 96 (quoting *Prometheus Radio Project*, 592 U.S. at 423).[11]

Workforce Shortage. Plaintiffs claim the minimum staffing standards will be "impossible" to achieve due to a workforce shortage, Pls.' MSJ 40, but in fact, for the majority of LTC facilities, compliance will be simple. Many facilities already meet one or more of the minimum standards. ASPE (Assistant Secretary for Planning and Evaluation, HHS) wrote in a recent report that, as of May 2024, 78% of facilities currently provide at least 24 hours of total RN staffing per day, 59% of facilities currently staff at or above 3.48 HPRD total nurse staffing, and 50% of facilities currently staff at or above 0.55 registered nurse (RN) hours per resident day. ASPE, *Nurse Staffing Estimates in US Nursing Homes, May 2024* (June 28, 2024), available at 1, https://aspe.hhs.gov/sites/default/files/documents/8e343af705b07063ad7effcc84ba370a/nurse-staffing-estimates-us-nhs.pdf. That means most facilities already meet at least some of these minimum requirements, and those that do not may only need to staff a few more nurses or a few more shifts to meet the minimums. The biggest area of need will be for additional NA hours, as just 30% of facilities currently staff at or above 2.45 HPRD of nurse aide time. *Id.* at 1. But NA licensure is a relatively quick process, generally requiring just a few weeks of training, and millions of dollars in grant funding is being provided for nurse education. 42 C.F.R. § 483.152(a)(1); 89 Fed. Reg. 40887. Plaintiffs seize

[11] It is worth noting that Plaintiffs AHCA and LeadingAge have themselves called for 24/7 RN coverage in recent years. *See* AHCA/NCAL, *Care For Our Seniors Act*, https://www.ahcancal.org/Advocacy/Documents/Care%20for%20Our%20Seniors%20Act%20-%20Overview.pdf, at 4. ("Research shows a positive association between RN hours and overall quality. [The Care For Our Seniors Act] support[s] a new federal requirement that each nursing home have a RN on-staff 24 hours a day and will provide recommendations on how to effectively implement this requirement."); AHCA, *Care For Our Seniors Act*, https://www.ahcancal.org/Advocacy/Documents/24-Hour-RN.pdf.

upon the statistic that, under the Final Rule, 79% of facilities would have to increase staffing, but that statistic counts *all* facilities that are out of compliance in any way, even those that meet three out of the four minimum requirements, for instance, and may only need to hire a single NA (after a three-week training course) or RN to be fully compliant.[12] This statistic also does not account for facilities that may qualify for an exemption under the Final Rule as discussed *infra* 41-43.

In any event, CMS acknowledged and seriously grappled with the concerns about nursing staff availability raised during the rulemaking process. *See* 89 Fed. Reg. 40885 ("We acknowledge the workforce challenges in LTC facilities."); AR_00070482-562; (MO nursing workforce report); AR_00070567-69 (study of nurse workforce projections); AR_00070460-470 (article on nursing staff availability); AR_00069880-84 (HRSA workforce projections). CMS found that there are more than 100,000 nursing home workers who left employment during the pandemic, sometimes voluntarily, sometimes laid off by facilities that had fewer residents needing care. 89 Fed. Reg. 40885 ("Workforce challenges may have contributed to the drop in staff, but it appears to have been caused by multiple factors, such as the drop in the number of nursing home residents."). But it also found that "[t]he number of staff is improving[.]" *Id.*

Nursing home staffing declined from 1,587,000 in February 2020 to 1,344,700 in January 2022 before increasing to 1,462,300 in March 2024. U.S. Bureau of Labor Statistics, *All Employees, Skilled Nursing Care Facilities*, [CES6562310001], retrieved from FRED, Federal Reserve Bank of St. Louis,

[12] The ASPE study found that for-profit facilities have the largest opportunity for improvement under the Final Rule. Smaller (fewer than 100 beds) and nonprofit facilities "were more likely to staff at or above the minimum RN, NA, and total nurse HPRD requirements than larger or for-profit nursing homes." ASPE, *Nurse Staffing Estimates in US Nursing Homes, May 2024* (June 28, 2024) at 1, https://aspe.hhs.gov/sites/default/files/documents/8e343af705b07063ad7effcc84ba370a/nurse-staffing-estimates-us-nhs.pdf. Additionally, the study found "similar percentages of rural and urban facilities currently staff at or above the final rule's NA and total nurse HPRD minimum requirements[.]" *Id.* at 9. ASPE concludes that "[t]ogether, these studies and our analysis highlight opportunities for for-profit nursing homes to enhance safety and quality of care through greater investments in staffing." *Id.*

https://fred.stlouisfed.org/series/CES6562310001; 89 Fed. Reg. 40880, 40885. As CMS explained in the Final Rule, these individuals represent an ample pool of workers, already trained, who could return to employment in a nursing home if salaries, benefits, and working conditions were favorable. 89 Fed. Reg. 40880 (citing an Illinois study that found nursing homes "were much more profitable than claimed but that 63 percent of those profits were hidden and directed to related parties of the owner. If those hidden profits were instead put toward staffing . . . the share of facilities in compliance with the [RN] requirements of the proposed rule would rise."); *see also id.* at 40876 ("Minimum staffing standards can thus help prevent staff burnout, thereby reducing staff turnover[.]"); AR_00073308 ("For nurses, what would attract them to one hospital over another or keep them from leaving the field is having enough other trained nurses and support staff.").

Furthermore, CMS is planning to provide significant funding to grow the nursing workforce. In tandem with the Final Rule, the agency announced the pendency of a $75 million campaign to expand the nursing workforce by providing financial incentives to work in nursing homes. 89 Fed. Reg. 40887. Once finalized, this funding will be dedicated to recruiting, training, retaining, and transitioning workers into nursing home staff through scholarships and tuition reimbursement. AR_00069384. As the Final Rule notes, "[o]ther parts of the Federal Government are also investing in the nursing workforce," including the Department of Labor, which provided "$80 million in grants last year as part of its Nursing Expansion Grant program[.]" 89 Fed. Reg. 40887. Rather than ignoring the workforce challenges as Plaintiffs suggest, CMS has studied and addressed them in the Final Rule, taking concrete steps to ensure compliance is feasible.

CMS also adopted a delayed implementation timeline to ease the compliance burden on facilities. The HPRD and 24/7 RN requirements do not become effective for several years, depending on the specific requirement and whether the facility is located in a rural or non-rural area. *Id.* (discussing "staggered implementation of these requirements over a period of up to 5 years for rural

facilities and 3 years for non-rural facilities to allow all facilities the time needed to prepare and comply with the new requirements"). The extended implementation timeline means that there is more than enough time to identify, train, and hire additional staff, especially when the largest category of nursing staff that is needed in most states, certified NAs, requires only the federal minimum of 75 hours of training for licensure. 42 C.F.R. § 483.152(a)(1).

Finally, if compliance is not feasible for a facility even after delayed implementation, hardship exemptions are available. 89 Fed. Reg. 40897-98. This regulatory hardship exemption is in addition to the statutory waiver process, and is meant to "provide temporary relief to facilities that are having workforce issues." *Id.* at 40888. CMS wants and expects facilities to come into compliance with the 24/7 RN and HPRD requirements, so it has "built in these flexibilities for facilities while still prioritizing resident safety and quality of care." *Id.*; s*ee also id.* at 40883. ("[I]n establishing numerical minimum staffing standards our goal is to ensure that they are both implementable and enforceable[.]"). *See also infra* 41-43.

The agency's fulsome responses to comments, significant grant funding initiative, delayed implementation timeline, and hardship exemptions provide ample record evidence that CMS has seriously considered and addressed potential compliance challenges arising from the nursing workforce. *See Louisiana ex rel. Guste v. Verity*, 853 F.2d 322, 327 (5th Cir. 1988) (decision not arbitrary "so long as the agency gave at least minimal consideration to relevant facts contained in the record.").

Implementation Costs. CMS also carefully considered the costs of the Final Rule and reasonably determined that the costs are outweighed by the rule's benefits and are not prohibitive. 89 Fed. Reg. 40878, 40970, 40949-50; AR_00069996. Though the costs to LTC facilities of implementing the rule are not insignificant, Medicare and Medicaid spend decidedly more on nursing home care

yearly. In 2021, Medicare paid $44.1 billion for care in skilled nursing facilities.[13] In 2022, Medicaid spent $191.3 billion for care in freestanding nursing care facilities and continuing care retirement communities.[14] Combined, that means Medicare and Medicaid spent approximately $235.4 billion over a year on nursing home care. CMS estimated the average annual cost of the minimum staffing standards would be approximately $4.3 billion—just 2% of the $235.4 billion in government dollars that facilities received in a single year, and those revenues are only expected to increase. Fiore, Jacqueline A., *et al.*, *National Health Expenditure Projections, 2023-32: Payer Trends Diverge As Pandemic-Related Policies Fade*, 43 Health Affairs, Vol. 43, Issue 7 (July 2024), https://doi.org/10.1377/hlthaff.2024.00469. In any event, the fact that an agency rule increases costs does not make the rule arbitrary. *See W. Virginia Min. & Reclamation Ass'n v. Babbitt*, 970 F. Supp. 506, 520 (S.D. W.Va. 1997) (rejecting argument that an agency decision was arbitrary because it allegedly imposed a "prohibitively expensive standard that may be impossible to achieve").

Furthermore, the additional costs will be factored into Medicare and Medicaid reimbursement. Section 1888(e)(5)(A) of the Social Security Act requires the Secretary to establish a "market basket" that reflects the changes over time in the prices of an appropriate mix of goods and services included in covered skilled nursing facility services. 42 U.S.C. § 1395yy(e)(5)(A); 89 Fed. Reg. 64048, 64065 (Aug. 6, 2024). The skilled nursing facility "market basket" is used to compute the broader "market basket" percentage increase that is used to update the skilled nursing facility Federal per diem rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. 89 Fed. Reg. 64048, 64065. Through this process, expenditures in labor costs will be incorporated into the mix of goods and

[13] Colello, Kirsten J, *Who Pays for Long-Term Services and Supports?* (CRS Report No. IF10343), (Sept. 19, 2023) *available at* https://crsreports.congress.gov/product/pdf/IF/IF10343#:~:text=For%202021%2C%20more%20than%20half,SNF%20services%20(%2444.1%20billion).

[14] Cms.gov, National Health Expenditures 2022 Highlights at 2, *available at* https://www.cms.gov/files/document/highlights.pdf.

services reflected in the market basket, and any associated impact of this mix would be reflected in the rate increase in payments to Medicare facilities. Medicaid, by contrast, is a joint federal-state program, which "provides to state governments federal funds that the state, after establishing a federally approved plan, uses to pay for medical aid for the poor and disadvantaged." *Baylor Univ. Med. Ctr.*, 736 F.2d at 1044. To the extent that the challenged requirements of the Final Rule impose additional costs on Medicaid-participating facilities, States are therefore likewise able to utilize the federal grant funding provided to them by adjusting their reimbursement schemes accordingly.

A rule that imposes new requirements on a regulated industry is rarely cost-free, but the record here shows that the agency rigorously examined the potential costs as it formulated the Final Rule and ultimately determined that those costs were outweighed by the rule's benefits for resident health and safety. The APA requires no more.

Hardship Exemption Availability. CMS has considered situations in which a facility may not be able to meet the minimum staffing standards despite good faith efforts and has provided for a hardship exemption. Plaintiffs argue that the exemption is "wholly inadequate" because it cannot be proactively sought and is too limited. *See* Pls.' MSJ 44-45. But as CMS explained in the Final Rule, an exemption cannot be proactively sought because the process is designed to holistically consider a facility's compliance in conjunction with the annual survey. 89 Fed. Reg. 40902-03. The survey considers *all* factors that determine a facility's eligibility for a hardship exemption, including any other alleged deficiencies that might be disqualifying. *Id.* at 40902-03, 40877-78. Rather than conduct a duplicative survey each time a facility asserts hardship, the process is undertaken in a more efficient manner by pairing it with the standard annual survey, ensuring that safety and quality of care is maintained and that federal funds are used only to pay for the purposes that Congress intended. That reasoned design is neither arbitrary nor capricious.

Relatedly, Plaintiffs complain that they "face a perpetual risk of being sanctioned for non-compliance." Pls.' MSJ 45. But this argument overlooks the distinction between a citation and an enforcement action. If the annual survey finds a facility noncompliant, that facility will receive a citation, based on which the facility may qualify for a hardship exemption so long as the facility's noncompliance did not result in widespread or a pattern of insufficient staffing that actually harmed or resulted in "immediate jeopardy" level of harm to residents. 42 C.F.R. Part 488; 89 Fed. Reg. 40878. If the facility receives an exemption, it will be considered in compliance and not face enforcement action related to this requirement. *See generally* 42 C.F.R. Part 488, Subpart F. Thus, while a facility cannot proactively apply for a hardship exemption, those facilities that qualify will be considered in compliance for that regulation, aside from extreme cases of resident harm or jeopardy.

As for Plaintiffs' concern that the exemption is too limited, the agency has determined that a significant number of facilities are likely to meet the workforce availability criterion of the exemption. 89 Fed. Reg. 40953; AR_00069366-81. CMS found that:

> Based only on being located in an area with nurse staff shortage, a preliminary analysis of the data suggests that more than 29 percent of facilities would be eligible for an 8-hour exemption from the 24/7 RN requirement and the 0.55 RN HPRD requirement, 23 percent of facilities would be eligible for an exemption from the 2.45 NA HPRD requirement, and 22 percent of facilities would be eligible for an exemption from the total nurse staff requirement. Among rural facilities, more than 67 percent of facilities would be eligible for an 8-hour exemption from the 24/7 RN requirement and a total exemption from the 0.55 RN HPRD requirement, 19 percent would be eligible for an exemption from the 2.45 NA HPRD requirement, and 40 percent would be eligible for an exemption from the 3.48 total nurse staff HPRD requirement.

89 Fed. Reg. 40953. To be exempt, a facility must also show good faith effort to hire and retain staff and document its financial commitment to doing so, but those requirements are fully within the facility's control. *Id.* at 40877. The exemption will therefore be sufficiently available to those facilities that are putting forth good faith efforts to hire staff but are unable to meet the requirements due to hardship.

5. Plaintiffs' Other Arbitrary And Capricious Arguments Are Similarly Unavailing

Plaintiffs offer several other arguments why the Final Rule is arbitrary, but they are not persuasive.

First, Plaintiffs' claim that the 2022 Abt Study does not support the Final Rule is incorrect. In contrast to Plaintiffs' characterization that the study found "no support" for the rule, Pls.' MSJ 39, the study in fact found that increased nursing home staffing improves resident health and safety. AR_00069990 ("[N]urse staffing levels are a 'critical factor' in determining nursing home quality of care."); *id.* ("nursing homes with higher staff-to-resident ratios provide better care" and "have also had greater success in addressing the COVID-19 pandemic"); AR_00069995 ("[A]s minimum required nurse staff HPRD increase, there is a corresponding increase in potential quality and safety improvements, and a decrease in expected delayed and omitted care."). Plaintiffs' selective quotes from the 2022 Abt Study merely acknowledge that the study's literature review found *existing* literature at the time of the study had not yet established the level at which a minimum staffing standard should be set. AR_00069993 ("*Recent literature* underscores the relationship between nursing home staffing and quality outcomes . . . . However, it does not provide a clear evidence basis for setting a minimum staffing level.") (emphasis added); AR_00070015 ("*Existing literature* on nursing home staffing has focused on the ways in which increased staffing produces better outcomes, but it has not identified a minimum staffing level required for adequate care quality.") (emphasis added). *See also*, *supra* Part B.1-2. But the 2022 Abt Study *added* to the existing literature and presented options for CMS to consider in setting the minimum standard. *See* AR_00069994-66 (presenting four options for agency consideration as minimum staffing requirements). Thus, while the then-existing literature may not have established bases for where to set the minimum, the 2022 Abt Study—in conjunction with the larger body of research on nurse staffing—did. And CMS relied on all of that research in promulgating the Final Rule.

In any event, Plaintiffs' argument reduces to a dispute over where to draw the line for a minimum staffing rule. But an agency "is not required to identify the optimal threshold with pinpoint precision. It is only required to identify the standard and explain its relationship to the underlying regulatory concerns." *WorldCom, Inc. v. FCC*, 238 F.3d 449, 461-62 (D.C. Cir. 2001). The Secretary did so here. *See* 89 Fed. Reg. 40991 ("Ultimately, we chose the comprehensive 24/7 RN, 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD requirements in this final rule to strike a balance between ensuring resident health and safety, while preserving access to care, including discharge to community-based services."); *see also id.* (explaining CMS's consideration and rejection of various alternatives).

Second, the Final Rule did not arbitrarily discount the role of LPN/LVNs. Rather than ignoring this issue, CMS closely studied the impact of different staffing types on health and safety outcomes of residents and chose to focus on the most efficacious. Studies showed increased staffing of RNs and NAs had the biggest impact on health and safety outcomes of residents, so the agency reasonably chose to start there. *See id.* at 40881 (RN and NA HPRD "have a strong association with safety and quality care"). Meanwhile, increased staffing of LPN/LVNs was found to have negligible impact on health and safety of residents. *See id.* at 40881 ("LPN/LVN hours per resident day, at any level, do not appear to have any consistent association with safety and quality of care."); *id.* at 40893 (There is "insufficient research evidence" to support establishing a minimum standard for LPN/LVNs.). CMS acknowledged the important contributions of LPN/LVNs in the Final Rule, but reasonably decided to follow the data and set minimum requirements that would most impact resident health and safety. *See id.* at 40881 ("[W]e recognize that LPN/LVN professionals undoubtedly provide important services to LTC facility residents[.]"); *id.* at 40892. Additionally, the contributions of LPN/LVNs count toward the 3.48 total nurse staffing HPRD requirement. *Id.* at 40893. The record reflects CMS's

well-considered decision to focus on the most efficacious staffing standards to meet the health and safety needs of residents.

Third, the Final Rule does not "pit[] urban and rural areas against each other" in competition for limited nursing staff. Pls.' MSJ 44. Plaintiffs have themselves asserted that, even prior to the Final Rule, nursing staff are already in universally high demand. *See id.* at 22-23, 40-41. It follows then, that if a demand for nursing staff in urban areas were to draw nurses away from rural areas, that phenomenon would already be occurring. The Final Rule is thus not the cause of urban and rural facilities' purported competition for nursing home staff, and so the rule cannot be arbitrary on this basis. But even if the Final Rule did lead nurses who would have otherwise worked in rural facilities to choose to work in urban facilities, the delayed implementation schedule accounts for that possibility. The combination of significant new grant funding for nursing education, 89 Fed. Reg. 40887, and the relatively short licensure process for NAs, 42 C.F.R. § 483.152(a)(1), means there will be plenty of time for the workforce to replenish in the intervening years between urban and rural compliance deadlines. And if, even after the delayed implementation timeline and good faith efforts, these facilities cannot staff to the minimum levels, hardship exemptions are available. 89 Fed. Reg. 40897-98. The record thus shows CMS amply considered and took meaningful steps to alleviate this potential challenge.

Fourth, Plaintiffs' argument that the Final Rule ignores differences among the States also fails. The Final Rule does not abrogate any existing state laws, nor does it nullify the "considered judgments of state lawmakers." Pls.' MSJ 38. As described *supra* Part B.3., the Final Rule merely sets a floor, but it does not displace the independent requirement that facilities provide staff to meet their particular residents' needs based on the facility assessment. That was the reality in all states prior to the Final Rule and will continue to be the reality. To the extent that states' standards are below the minimum CMS has determined to be necessary for health and safety, bringing facilities across all the states into

compliance with that minimum level of staffing is precisely the point. *See* 89 Fed. Reg. 40880 ("[W]idespread variability in existing minimum staffing standards across the United States . . . highlight the need for national minimum staffing standards[.]").

At bottom, the Final Rule represents a carefully considered balance of interests. As CMS explained, "[o]ur goal is to protect resident health and safety and ensure that facilities are considering the unique characteristics of their resident population in developing staffing plans, while balancing operational requirements and supporting access to care." *Id.* at 40883. While Plaintiffs may disagree with the balance chosen by CMS in the Final Rule, the APA does not permit a plaintiff or a court to "substitute its judgment for that of the agency." *State Farm*, 463 U.S. at 43. Because the CMS "examined 'the relevant data' and articulated 'a satisfactory explanation' for [its] decision, 'including a rational connection between the facts found and the choice made,'" Plaintiffs' arbitrary and capricious challenge fails. *Dep't of Comm. v. New York*, 588 U.S. 752, 773 (2019) (quoting *State Farm*, 463 U.S. at 43).

III. ANY RELIEF SHOULD BE APPROPRIATELY LIMITED

If the Court disagrees with Defendants' arguments, any relief should be no broader than necessary to remedy the demonstrated harms of these Plaintiffs. "A plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *Gill v. Whitford*, 585 U.S. 48, 73 (2018), and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Center, Inc.*, 512 U.S. 753, 765 (1994) (citation omitted).

Plaintiffs ask this Court to vacate and set aside both the 24/7 RN requirement and the HPRD requirements of the Final Rule under the APA. Pls.' MSJ 5. Defendants here preserve the argument that 5 U.S.C. § 706(2) does not authorize *any* particular form of relief; it merely directs a reviewing court to disregard "agency action, findings, and conclusions" that it finds unlawful when resolving an individual APA challenge. *See* Br. for Petitioners at 39-44, *United States v. Texas*, 599 U.S. 670 (2023)

(No. 22-58), 2022 WL 4278395, at *40-41. Moreover, traditional principles of equity are counter to awarding the sweeping relief of universal vacatur. *See Trump v. Hawaii*, 585 U.S. 667, 717 (2018) (Thomas, J., concurring) (explaining that English and early American "courts of equity" typically "did not provide relief beyond the parties to the case"). When Congress adopted the "unremarkable" "set aside" language in § 706(2), there is no reason to think it "meant to upset the bedrock practice of case-by-case judgments with respect to the parties in each case." *Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring); *see also California v. Texas*, 593 U.S. 659, 672 (2021) (explaining that remedies "ordinarily 'operate with respect to specific parties,'" rather than "'on legal rules in the abstract'" (citation omitted)).

Defendants nevertheless recognize that the Fifth Circuit has characterized vacatur as the "default" remedy under the APA. *Data Mkg. P'ship, LP v. U.S. Dep't of Labor*, 45 F.4th 846, 859-60 (5th Cir. 2022). But that default remedy is neither always required nor always appropriate, as courts in this district have recently recognized. *See, e.g., Nuziard v. Minority Bus. Dev. Agency*, 721 F. Supp. 3d 431, 499-502 (N.D. Tex. 2024), *appeal filed* No. 24-10603 (5th Cir. July 3, 2024) (declining to vacate agency regulations implementing a statutory provision the court found unconstitutional, and instead enjoining the agency from enforcing the challenged provisions).

In that regard, *first*, any injunction or vacatur of the Final Rule in this case should apply only to those aspects of the rule for which the Court finds Plaintiffs have met their burden for summary judgment relief. The Supreme Court has held a regulation severable where severance would "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." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (invalidating only the provision of a regulation that exceeded the agency's statutory authority). Severability clauses, such as the one in the Final Rule, 89 Fed. Reg. 40913, create a presumption that the validity of the entire regulation is not dependent on the validity of any specific unlawful provision

if that unlawful provision would not impair the function of the regulation as a whole. *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987). Plaintiffs' challenges in this case are limited to the 24/7 RN and HPRD requirements alone. *See* Pls.' MSJ 5; Am. Compl., Prayer for Relief at ¶¶ 1-4, ECF No. 26. All other requirements of the Final Rule—*see, e.g.*, 89 Fed. Reg. 40905-06 (enhanced facility assessment requirement); *id.* at 40914 ("Medicaid Institutional Payment Transparency Reporting Provision")—are not at issue in this litigation, and thus should not be disturbed.

Second, any relief should be limited, at most, to facilities operated by Plaintiffs and their members. "The Court's constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill*, 138 S. Ct. at 1933; *see also* 138 S. Ct. at 1933-34 (citing *Daimler Chrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006)); *Madsen*, 512 U.S. at 765. Indeed, Plaintiffs have no interest in whether non-member facilities are subject to the rule (and in fact, if their allegations concerning trends among health care workers are to be believed, they would gain a competitive advantage from relief being circumscribed to their facilities alone), nor standing to assert claims on behalf of facilities that Plaintiffs do not themselves operate or represent. Thus, Plaintiffs' claims would be fully redressed through relief prohibiting the Secretary from enforcing the challenged portions of the Final Rule against only the facilities operated or represented by Plaintiffs themselves.

Nationwide relief would be particularly harmful here given that another district court is currently considering similar challenges to the 24/7 RN and HPRD requirements of the Final Rule. *See* Pl.'s Mot. for Prelim. Inj. & Oral Argument, *Kansas v. Becerra*, No. 24-cv-110, ECF No. 30 (N.D. Iowa Oct. 22, 2024). Nationwide relief would render the district court's order in *Kansas*, as well as any additional orders that might follow from other courts, meaningless as a practical matter. It would also preclude appellate courts from testing Plaintiffs' claims against the Final Rule in other jurisdictions. Moreover, many States and facilities are not challenging the Final Rule at all. There is no reason why Plaintiffs' disagreements with it should govern the rest of the country. *See California v. Azar*, 911 F.3d

558, 583 (9th Cir. 2018) ("The detrimental consequences of a nationwide injunction are not limited to their effects on judicial decisionmaking. There are also the equities of non-parties who are deprived the right to litigate in other forums."); *see also* 911 F.3d at 582-84 (vacating nationwide injunction in facial APA challenge).

CONCLUSION

The Court should deny Plaintiffs' motion for summary judgment and grant judgment to Defendants.

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Respectfully submitted,

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