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

STATE OF KANSAS, 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. 1:24-cv-00110-LTS-KEM

MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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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 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 LTC 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 health and safety concerns and 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—20 States and 21 private organizations—seek to challenge CMS's 24/7 RN and HPRD requirements. They claim that these requirements exceed CMS's authority and conflict with or cast constitutional doubt on the Medicare and Medicaid statutes, and are arbitrary and capricious in violation of the Administrative Procedure Act ("APA"). *See generally*, Mem. in Supp. of Mot. for Prelim. Inj. ("PI Mot."), ECF No. 30-1. All 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 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, nor does it entitle them to the extraordinary remedy of a preliminary injunction. As a legal matter, Plaintiffs fail to demonstrate that their claims are likely to succeed on the merits, that they face any imminent and irreparable injury due to the requirements they challenge, or that the public interest favors preliminary injunctive relief. The Court should deny their motion for preliminary injunction.

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, and health care professionals that meet the statutory and regulatory requirements for participation. Participation in both programs is voluntary. 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).

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 [HHS] . . . who in turn exercises his authority through [CMS]"). 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 id.* § 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, 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 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) ("Institute of Medicine Study"), *available at* https://archive.ph/KFNCi).

Thus, FNHRA effectuated a major overhaul of the requirements for nursing home participation in the Medicare and Medicaid programs. Among other things, Congress established over

[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.

100 requirements 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 regularly 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 facility staff); *id.* § 483.70(o)(2) (work experience requirement for required 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 process, involving Congress and HHS alike, to gather the data necessary to support promulgation and future refinement of minimum staffing standards by CMS. *See, e.g.*, Institute of Medicine Study at 200-01 (recognizing that the agency 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 reevaluate minimum nurse 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* 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. *Id.* at viii ("[N]urse staffing levels are a 'critical factor' in determining nursing home quality of care."); *id.* at 1("nursing homes with higher staff-to-resident ratios provide better care" and "have also had greater success in addressing the COVID-19 pandemic"); *id.* at xiii ("[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."). *See also* 88 Fed. Reg. 61352, 61359-65 (Sept. 6, 2023) (further detailing the "systematic literature review," "qualitative analysis,"

"quantitative analysis," "cost and savings analysis," and "listening sessions" commissioned by CMS).

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").

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.*

Based on the findings of the 2022 Abt Study and other literature, *see, e.g.*, *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'"). CMS also proposed revising its existing facility assessment requirement, which acts to ensure that, in accordance with the statute, facilities "determine the necessary resources and staff that the facility requires to care for its residents, regardless of whether or not the facility is staffed at or above the new minimum staffing requirement." *Id.* at 61373. Specifically, CMS proposed to move the assessment requirement to a standalone section of its regulations and to specify the considerations that the assessment must account for, including the facility's resident population, resources, staff training needs, and facility and community-based risk assessment. *Id.* at 61373-74. In response to its notice of proposed rulemaking, CMS received over 46,000 public comments expressing a range of views. 89 Fed. Reg. 40883.

B. The Final Rule

Having now gathered previously-unavailable data and considered a wealth of new research and public comments, *see id.* at 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 and safety of residents. *Id.* at 40890.

Based on concerns raised during the rulemaking process about workforce challenges and costs, CMS announced plans for 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, added a 3.48 HPRD total nurse staffing standard, and finalized inclusive hardship exemptions. *Id.* at 40886, 40888. CMS's total cost estimates closely tracked the estimates in the Proposed Rule and benefits exceeded 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' motion challenges the Final Rule's 24/7 RN and HPRD requirements. *See* PI Mot. 2-3. 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 for 8-hours per day of the 24/7 RN requirement on a case-by-case basis.[2] Exemption eligibility is based on: (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 public 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]

LEGAL STANDARDS

"A preliminary injunction is an extraordinary and drastic remedy" that should "never [be] awarded as of right[.]" *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008) (citation omitted). A plaintiff is entitled to such an "extraordinary remedy" only "upon a clear showing" that it is "entitled to such

[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). Contrary to Plaintiffs' suggestion, PI Mot. 24, 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.

relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). To establish such entitlement, a plaintiff must demonstrate that (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest. *Id.* at 20. "No single factor is dispositive," but the "likelihood of success on the merits is the most significant." *Turtle Island Foods, SPC v. Thompson*, 992 F.3d 694, 699 (8th Cir. 2021) (citation 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(2). 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*). "Arbitrary and capricious is a highly deferential standard of review. We defer to agency action so long as 'an agency examine[d] the relevant data and articulate[d] a satisfactory explanation for its action.'" *Adventist Health Sys./SunBelt, Inc. v. HHS*, 17 F.4th 793, 803 (8th Cir. 2021) (quoting *Org. for Competitive Mkts. v. U.S. Dep't of Agric.*, 912 F.3d 455, 459 (8th Cir. 2018)).

ARGUMENT

I. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS BECAUSE THE FINAL RULE FITS SQUARELY WITHIN THE SECRETARY'S AUTHORITY TO PROTECT THE HEALTH AND SAFETY OF LTC FACILITY RESIDENTS AND DOES NOT CONFLICT WITH ANY PORTION OF THE STATUTE

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 id.* § 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 has also given 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 id.* §§ 1395i-3(d)(4)(B), (f)(1) (same).

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.'" *Id.* at 369 (quoting *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 280-81 (1969)). The Eighth Circuit adopted a similarly expansive reading of the exact "health and safety" statutory authorities at issue in this case just three years ago when it rejected an analogous APA challenge to CMS's 2016 nursing home arbitration rule, holding that CMS's "health and safety" authorities 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. HHS*, 14 F.4th 856, 870 (8th Cir. 2021) (citing 42 U.S.C. §§ 1395i-3(f)(1), 1396r(f)(1), 1395i-3(d)(4)(B), 1396r(d)(4)(B)), *cert. denied*, 143 S. Ct. 294 (2022).

The Eighth Circuit's expansive reading of CMS's health and safety rulemaking authorities, including, *inter alia*, 42 U.S.C. §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B), is all but dispositive of Plaintiffs' lack of statutory authority argument. *See Northport*, 14 F.4th at 870-73. There can be no genuine dispute that the Final Rule falls within the authority Congress has conferred upon the agency under this "capacious[]" standard. *Id.* 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) (requirements regarding vaccination of 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. *See* PI Mot. 19 (complaining that CMS used its statutory authority "to authorize staffing ratios that are nowhere to be found in the statute"); *see also id.* at 21 (same). 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, 94 (quoting 42 U.S.C. § 1395x(e)(9) and citing *id.* §§ 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. While Plaintiffs are quick to note that Congress "does not . . . hide elephants in mouseholes," PI Mot. 19 (quoting *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)), the statutory health and safety authorities at issue here are "less a mousehole and more a watering hole—exactly the sort of place we would expect to find this elephant." *Atl. Richfield Co. v. Christian*, 590 U.S. 1, 22 (2020). Plaintiffs' contrary arguments misapprehend the relevant statutes and mischaracterize the Final Rule.

A. The 24/7 RN Requirement Is Authorized By Statute And Not In Conflict With Congress's Statutory Requirements

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." *Nat'l 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, and does not conflict with it.

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 id.* 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 provided "authority for CMS to engage in rulemaking" via 42 U.S.C. §§ 1396r(d)(4)(B); 1395i-3(d)(4)(B)—the very provisions cited as authority for the challenged portions of the Final Rule. PI Mot. 20; *see* 89 Fed. Reg. 40879.

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. *Mourning*, 411 U.S. at 369. *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 Plaintiffs disagree with the Secretary's determination that 24/7 RN coverage is necessary for resident health and safety, that argument goes to whether Plaintiffs can prove CMS's decision was arbitrary or capricious (*see infra* 28-48), 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." PI Mot. 20, 23 (quoting 42 U.S.C.

§ 1396r(b)(4)(C)(i)).[4] 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).

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[4] Plaintiffs also argue that the 24/7 RN requirement conflicts with Congress's statutory waiver for the requirements of 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i), *see* PI Mot. 24, but this argument reflects a misreading of the Final Rule. The statutory waiver provides that "[t]o the extent [] clause (i) may be deemed to require that a skilled nursing facility engage the services of a registered professional nurse for more than 40 hours a week, the Secretary is authorized to waive such requirement" if certain conditions are met. 42 U.S.C. § 1395i-3(b)(4)(C)(ii); *accord id.* § 1396r(b)(4)(C)(ii). That process remains available under the Final Rule. As CMS clearly explained:

> Given that this rule finalizes an additional regulatory flexibility for facilities to receive an exemption of 8 hours per day of the 24/7 RN requirement, we want to clarify that facilities who may also meet the requirements for the statutory waivers as detailed at existing sections § 483.35(e) and (f) (finalized as paragraphs (f) and (g) in this rule) will still have the ability to choose which process they want to pursue to achieve regulatory flexibility from the 24/7 RN requirement.

89 Fed. Reg. 40899. Thus, the new regulatory exemption does not render the "statutory waiver provision null and void," as Plaintiffs claim. PI Mot. 24. The Final Rule permits facilities to choose whether to seek the statutory waiver (waiving all hours above 40 hours per week, 42 U.S.C. § 1395i-3(b)(4)(C)(ii)), and the regulatory exemption (waiving 8 hours per day). *See also* 89 Fed. Reg. 40878 (the Final Rule "does not purport to eliminate or modify the existing statutory waiver.").

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)(A). CMS'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.

In response, Plaintiffs turn away from the plain text of the statute, and rely instead on the section headings and subheadings of 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B) to make their case. *See* PI Mot. 20-21. But it is well established that "'the title of a statute . . . cannot limit the plain meaning

of the text. For interpretive purposes, [it is] of use only when [it] shed[s] light on some ambiguous word or phrase.'" *Pennsylvania Dep't of Corrs. v. Yeskey*, 524 U.S. 206, 212 (1998) (quoting *Trainmen v. Baltimore & Ohio R. Co.*, 331 U.S. 519, 528-529 (1947)). No ambiguity exists here because the meaning of the statutory text itself is plain: the Secretary has the authority to promulgate "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), *accord id.* § 1395i-3(d)(4)(B). *See also Northport*, 14 F.4th at 870 (holding that these provisions operate "capaciously"). And it is beyond dispute that staffing levels relate to resident health and safety.

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), *accord id.* § 1395i-3(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. *Id.* §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i).[5] "[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 And Not In Conflict With Congress's Statutory Requirements

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* 10-13, 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.

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* PI Mot. 20 (conceding that Congress provided "authority for CMS to engage in rulemaking"). Rather, they again argue that the Final Rule is impermissible because it purportedly conflicts with Congress's independent statutory

[5] That Congress *did* prohibit CMS from using its delegated authority 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), 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.").

requirements for LTC staffing—namely, the requirement that an LTC facility must provide nursing services "sufficient to meet the nursing needs of its residents." PI Mot. 21 (quoting 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i)).[6] But Plaintiffs' argument rests on a flawed premise: that "[i]nstead of accommodating the wide variation of resident needs in different states and communities, the Final Rule inflexibly mandates that each facility in each state meet an arbitrary numerical staffing threshold[,]" *id.* at 21-22. As explained in the Final Rule, however, CMS's HPRD requirements are not "inflexibl[e] mandates," *id.* 21:

> 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. *See also id.* at 40908; *infra* 38-40.

The Secretary's HPRD requirements thus comfortably coexist with Congress's independent "sufficient to meet the nursing needs of [] residents" requirement. 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i). Contrary to Plaintiffs' suggestion, PI Mot. 21-22, Congress's requirement that facilities 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

[6] Plaintiffs also argue that CMS lacks authority for the HPRD requirements because "they are not mentioned anywhere in the statute." PI Mot. 21. But as explained *supra* 10-13, the Supreme Court squarely rejected that exact argument when considering CMS's COVID vaccination rule, holding that the Secretary's authority "to promulgate . . . such 'requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution,'" encompasses 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 *id.* §§ 1395i–3(d)(4)(B), 1396r(d)(4)(B) as analogous).

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 qualitative standard," leaving CMS no room to further regulate a facility's infection control regime. PI Mot. 21. But the Supreme Court in *Missouri* squarely rejected that argument, explaining that the same "health and safety" authorities at issue here permitted CMS 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 requirements regarding vaccination of LTC staff and other healthcare workers 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, 12, 16 (citing further examples).

Because the textual basis for CMS's statutory authority is thus unambiguous, Plaintiffs' argument that "Congress weighed what staffing levels to require from LTC facilities" and did not set HPRD requirements of its own is beside the point. PI Mot. 22; *id.* at 18. 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 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 (cited at PI Mot. 25) is illustrative of this point. *See* Institute of Medicine Study at 200-01. The Supreme Court has correctly acknowledged that this study's conclusions on staffing formed the basis for Congress's landmark FNHRA. *See 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 ("[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, *the HCFA*[7] 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 ("Thompson Letter") 1 (Mar. 19, 2002), reprinted as appx. 1, *available at* https://perma.cc/4P6W-7LMH (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 LTC facility staffing rules "once a sufficient amount

[7] The Health Care Financing Administration ("HCFA") was renamed the Centers for Medicare & Medicaid Services in 2001. *See* HHS, *The New Centers for Medicare & Medicaid Services* (June 14, 2001).

[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* 28-31. 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.

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

Because Congress's delegation of health and safety rulemaking authority to CMS is unambiguous and has long been recognized to encompass the power to set requirements relating to LTC facility staffing, *see Missouri*, 595 U.S. at 90-94; *supra* 10-13, Plaintiffs' reliance on interpretive canons like the major questions doctrine is misplaced. Such canons of interpretation "may only be used 'where words are of obscure or doubtful meaning.'" *Iverson v. United States*, 973 F.3d 843, 853 (8th Cir. 2020) (citing *Russell Motor Car Co. v. United States*, 261 U.S. 514, 520 (1923)). Here, Plaintiffs do not dispute that establishing a minimum required floor for LTC facility 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). Where "health and safety" has "a character of its own" that plainly encompasses adequate nurse staffing levels, Plaintiffs' interpretative canons are thus inapplicable. *Russell Motor Car*, 261 U.S. at 519. And, in any event, Plaintiffs have shown no evidence

of "Congress' consistent judgment to deny [CMS] this power." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000); *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"). Plaintiffs can point to no statutory text that would indicate that Congress meant "health and safety" to mean anything other than its natural implication, which includes the protection of patients from the dangerous effects of inadequate staffing at Medicare- and Medicaid-funded LTC facilities.

For this reason, Plaintiffs' reliance on *Alabama Association of Realtors v. Department of Health & Human Services*, 594 U.S. 758 (2021) (cited at PI Mot. 17-18), is misplaced. The Court there rejected an eviction moratorium under a different statute, reasoning that a "downstream connection between eviction and the interstate spread of disease is markedly different from the direct targeting of disease that characterizes the measures identified in [that] statute." *Id.* at 764. The Secretary here is not regulating the "downstream" effects of the pandemic. Rather, the statutes directly instruct him to protect the health and safety of LTC facility residents while they receive care paid for by Medicare or Medicaid. Because the Secretary found that patients in these settings face health and safety concerns due to chronic understaffing, and that the challenged minimum staffing requirements are an effective means of protecting resident health and safety, he discharged his statutory duty by issuing the Final Rule. *See generally Merck & Co. v. U.S. Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537-38 (D.C. Cir. 2020) (distinguishing an invalid rule with only "a hoped-for trickle-down effect on the regulated programs" from a valid rule with "an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs").

Even if the Secretary's health and safety authorities were ambiguous (and they are not, *see Northport*, 14 F.4th at 870 (CMS's "health and safety" authorities operate "capaciously," and "are broadly worded to give HHS significant leeway in deciding how best to safeguard LTC residents' health and safety,")), 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). 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).[8]

For this reason, Plaintiffs' citation to *West Virginia v. EPA* is inapt. PI Mot. 18. In *West Virginia*, the Supreme Court emphasized that the agency had only recently located a "newfound power" in the "vague language" of an "ancillary provision[]" of the statute—one that "had rarely been used in the preceding decades." 597 U.S. at 724 (quotations omitted). Here, by contrast, CMS has for years repeatedly exercised its authority to promulgate additional requirements pertaining to LTC facility staffing and the health and safety of patients in any facility under CMS jurisdiction more broadly, as the Supreme Court itself recognized 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

[8] 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, *id.* at 502.

§§ 1395i–3(d)(4)(B), 1396r(d)(4)(B)). *See also supra* 5, 12, 16 (citing additional examples of previous CMS LTC facility staffing requirements).

Rejecting the same argument Plaintiffs make here, the Supreme Court in *Missouri* explained that despite its wide-ranging impact, CMS's vaccination rule was not "surprising" because "addressing infection problems in Medicare and Medicaid facilities is what [the Secretary of HHS] does." *Id.* at 95. And 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, *see infra* 32, 36-37, 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 exercise of "vague language in a long-extant statute" implicating the major questions doctrine. PI Mot. 18 (citation omitted).

Plaintiffs' economic significance argument fares no better—though the economic significance of an agency action cannot alone 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. The expected cost of the requirements Plaintiffs challenge—$4.3 billion annually on average over the next 10 years, 89 Fed. Reg. 40969, "not includ[ing] adjustments for any exemptions that [CMS] may provide, which could reduce the rule's cost," *id.* at 40955—is dwarfed by the recent cases applying the doctrine based on economic significance, which have involved hundreds of billions of dollars of impact. 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. *See Nebraska*, 600 U.S. at 483 ($430 billion impact); *West Virginia*, 597 U.S. at 715 ($1 trillion by 2040)). 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," *Missouri*, 595 U.S. 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* PI Mot. 18 (conceding that the Final Rule regulates nursing homes alone).

Nor does the Final Rule implicate the major questions doctrine merely by virtue of the fact that it impacts "powers reserved to the States." PI Mot. 19. The Medicare and Medicaid statutes were enacted under the Spending Clause, and the Secretary has a duty to ensure that federal funds are used as Congress directed, in particular, by protecting residents' health and safety in facilities funded by these programs. "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare, [and] to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare[.]" *Sabri v. United States*, 541 U.S. 600, 605 (2004). This power applies even when Congress legislates "in an area historically of state concern." *Id.* at 608 n.*. The rule does not intrude on state authority any more than do CMS's myriad long-standing rules conditioning federal funds on LTC facilities' commitment to obey other requirements of participation.

Congress has expressly delegated to CMS authority to "'fill up the details' of the statutory scheme" of nursing home regulation, *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 id.* § 1395i-3(d)(4)(B). 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 extraordinary 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).

D. The Final Rule Casts No Constitutional Doubt On The Statute

Plaintiffs also attempt to invoke the nondelegation doctrine to contend that Congress could not lawfully delegate to the Secretary the authority to protect the health and safety of Medicare and Medicaid patients. PI Mot. 22-23. But as Plaintiffs themselves acknowledge, *id.* at 23, a "statutory delegation is constitutional as long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." *Bhatti v. Fed. Hous. Fin. Agency*, 15 F.4th 848, 854 (8th Cir. 2021) (internal quotations and alterations omitted). This standard is not demanding. It is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *Am. Power & Light Co. v SEC*, 329 U.S. 90, 105 (1946).

For more than 80 years, the Supreme Court has consistently upheld "Congress' ability to delegate power under broad standards," *Misretta v. United States*, 488 U.S. 361, 373 (1989).[9] The Secretary's statutory authority to protect the health and safety of Medicare and Medicaid patients easily meets this minimal standard, as the cases cited in Plaintiffs' brief confirm. *See Gundy v. United States*,

[9] For instance, the Supreme Court has upheld statutes authorizing the Secretary of War to determine and recover "excessive profits" from military contractors, *Lichter v. United States*, 334 U.S. 742, 785-86 (1948) (quotation marks omitted); the Price Administrator to fix "fair and equitable" commodities prices, *Yakus v. United States*, 321 U.S. 414, 420 (1944); and the EPA to set national air-quality standards limiting pollution to the level required to "protect the public health," *Am. Trucking*, 531 U.S. at 472.

588 U.S. 128, 146 (2019) (plurality opinion) (noting that Supreme Court had previously upheld delegations "to regulate 'in the public interest'"; "set 'fair and equitable' prices and 'just and reasonable' rates"; and "issue whatever air quality standards are '*requisite to protect the public health*'" (emphasis added)) (cited at PI Mot. 23); *see also Missouri*, 595 U.S. at 90-95 (concluding that CMS's vaccination rule was a permissible exercise of the same "health and safety" authority challenged here).

II. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS OF THEIR ARBITRARY OR CAPRICIOUS CLAIM BECAUSE 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* PI Mot. 24-32. 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); *Adventist Health Sys.*, 17 F.4th at 803 ("We defer to agency action so long as 'an agency examine[d] the relevant data and articulate[d] a satisfactory explanation for its action.'") (citation 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,[10] 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.

[10] 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.

61356. And as CMS explained, "NAs" are the employees who "spend the most time providing care 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), *available at* https://doi.org/10.17226/26526 (cited at 88 Fed. Reg. 61371). Contrary to Plaintiffs' assertion (PI Mot. 12), the 2022 Abt Study confirmed this recommendation, leading CMS to propose the 24/7 RN requirement. *See* 2022 Abt Study at 12 ("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 span 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 several 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 accounts for reliance interests by maintaining facilities' staffing flexibility. Finally, compliance with the Final Rule is feasible based on the agency's fulsome consideration of the asserted compliance challenges. 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://perma.cc/XEY5-RABS ("2001 Abt Study") ("Strong evidence supports the relationship between increases in nurse staffing ratios and avoidance of critical quality of care problems."); Institute of Medicine Study at 101-03 ("Greater numbers of nurses have been associated with improved resident outcomes in research studies."); Harrington, Charlene, *et al.*, *Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2009 Through 2016*, KFF (Apr. 3, 2018), *available at* https://perma.cc/EY8N-TKG9 ("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."); CMS, *Staffing Data Submission Payroll Based Journal (PBJ)*, *available at*

https://perma.cc/6JJG-439U ("Staffing Data Submission PBJ") ("(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; *see* 80 Fed. Reg. 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."); Staffing Data Submission PBJ ("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*. PI Mot. 25. 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* 38-40. 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 selectively quote, PI Mot. 25) 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. 42168, 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.

In arguing that CMS has not justified "sharply departing" from its alleged prior position, Plaintiffs claim that the 2022 Abt Study is only "a single study" and "even that study did not justify" the rule. PI Mot. 26. This argument mischaracterizes the study and ignores both the decades of support for measures to increase staffing in LTC facilities described above and also the body of research CMS relied upon to set the standards. Contrary to Plaintiffs' assertion that the study "did not justify" the rule, PI Mot. 26, the 2022 Abt Study in fact found that increased nursing home staffing is critical for resident health and safety. 2022 Abt Study at viii ("[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"); *id.* at xiii ("[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 selectively quote from the 2022 Abt Study to support their preferred characterization, stating that the report did "not identif[y] a minimum staffing level." PI Mot. 26. But that sentence of the report in fact reads "*Past literature* has established strong evidence for a relationship between staffing and quality but has not identified a minimum staffing level to ensure safe and quality care." 2022 Abt Study at xiv (emphasis added). When read in context, Plaintiffs' selective quotation merely acknowledges 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. *Id.* at xi ("*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); *id.* at 11 ("*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* 31-34. But the 2022 Abt Study *added* to the existing literature and presented options for CMS to consider in setting the minimum staffing standard. *See* 2022 Abt Study at 114-16 (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. 88 Fed. Reg. 61359-65 (detailing the "systematic literature review," "qualitative analysis," "quantitative analysis," "cost and savings analysis," "PBJ System data," and "listening sessions" reviewed by CMS and Abt as support for the requirements of the Final Rule). And CMS relied on all of that research in promulgating the Final Rule. *See* 89 Fed. Reg. 40948.

In any event, Plaintiffs' argument reduces to a dispute over where to draw the line for a minimum staffing rule. *See* PI Mot. 13 (arguing that "the Abt Study does not substantiate those specific [HPRD] levels"). 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).

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. *See Adventist Health Sys.*, 17 F.4th at 803; *Org. for Competitive Mkts.*, 912 F.3d at 459; *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. 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)[11] represent just 0.3% of the U.S. population of 333,287,557 (in 2022).[12] 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.* 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). CMS also 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 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"

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

[12] 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.

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 Accounts For Reliance Interests By Maintaining Facilities' Staffing Flexibility

Plaintiffs argue that the Final Rule is arbitrary because CMS failed to consider reliance interests by imposing a "one-size-fits-all requirement." PI Mot. 26. But Plaintiffs' argument betrays a fundamental mischaracterization of the Final Rule. Plaintiffs describe the rule as "issuing staffing quotas," but the rule does no such thing. *Id.* at 25. The Final Rule does not dictate the correct staffing level for any particular facility, but rather, it sets the floor. In light of the 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* 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[.]"); White House, *FACT SHEET: Biden-Harris Administration Takes Steps to Crack Down on Nursing Homes that Endanger Resident Safety* (Sept. 1, 2023), *available at* https://perma.cc/99ZX-S64E ("White House Fact Sheet") ("[T]he numerical staffing levels are a floor—not a ceiling—for safe staffing."); *supra* 18-22.

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."); White House Fact Sheet ("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). The rule therefore continues to allow for "variations in circumstances," as Plaintiffs request. PI. Mot. 28. 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.

Relatedly, Plaintiffs claim that CMS failed to consider reliance interests by ignoring individual states' minimum staffing requirements, but this argument fails. To start, the Final Rule does not abrogate any existing state laws. And LTC facilities in states that already have minimum staffing requirements will either already meet—or be significantly closer to meeting—the staffing requirements of the Final Rule. As described above, 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 a facility assessment. That was the reality in all states prior to the Final Rule and will continue to be true. Facilities will still be required to have sufficient staff, accounting for each facility's "variations in circumstances" and that "reflect local conditions." PI Mot. 28. 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"); *id.* at 40886 ("this final rule . . . [does] not preempt the applicability of any State or local law providing a higher [staffing] standard. . . . To the extent Federal standards exceed State and local law minimum staffing standards, no Federal pre-emption is implicated because facilities complying with Federal law would also be in compliance with State or local law.").

Moreover, CMS expressly considered existing state standards during the rulemaking process, recognizing this potential reliance interest and addressing it in the Final Rule. 89 Fed. Reg. 40877, 40886, 40904, 40955, 40994; 88 Fed. Reg. 61353, 61363, 61374, 61426. That is all the APA requires. *See Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 32 (2020) (reliance interests "are but one factor to consider" and the agency "may determine, in the particular context before it, that other interests and policy concerns outweigh any reliance interests").

4. Compliance With The Final Rule Is Feasible Based On The Agency's Fulsome Consideration Of The Asserted Challenges

Plaintiffs claim that the Final Rule is arbitrary because of a failure to consider alleged compliance challenges, including a purported workforce shortage, implementation costs, and the limited availability of hardship exemptions. 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 Proj.*, 592 U.S. at 423).[13]

[13] LeadingAge—the parent organization of several Plaintiffs in this case—itself called for a 24/7 RN coverage requirement in recent years. *See* AHCA/NCAL, *Care For Our Seniors Act*, https://perma.cc/6AB4-LVPT, at 4. ("Research shows a positive association between RN hours and

Workforce Shortage. Plaintiffs claim that complying with the minimum staffing standards will be "almost impossible" due to a workforce shortage, PI Mot. 32, but in fact, for the majority of LTC facilities, compliance will not be unduly burdensome. 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 (HPRD). ASPE, *Nurse Staffing Estimates in US Nursing Homes, May 2024* (June 28, 2024) at 1, *available at* https://perma.cc/QN9U-P6PW. 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 upon the statistic that under the Final Rule, 79% of LTC facilities would have to increase staffing, PI Mot. 29-30, 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.[14] This statistic also does

overall quality. [The 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*, *available at* https://perma.cc/86GE-P32V.

[14] 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. 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

not account for facilities that may qualify for an exemption under the Final Rule as discussed *infra* 47-48.

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."); 2022 Abt Study at viii, xii, xx, xxi, 19, 35, 37; White House Fact Sheet; HRSA, *Workforce Projections* (Apr. 22, 2024), *available at* https://data.hrsa.gov/topics/health-workforce/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, 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 finding 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

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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.*

thus help prevent staff burnout, thereby reducing staff turnover[.]"); Trang, Brittany, *Is There a Nursing Shortage in The United States? Depends on Whom You Ask*, STAT (Oct. 16, 2023), *available at* https://perma.cc/H63R-ZQBG ("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. *See* White House Fact Sheet. 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 operates in addition to (not in place of) 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* 47-48.

In conjunction with their workforce concerns, Plaintiffs argue that the Final Rule "irrationally discounts the vital role of LPNs/LVNs" and "creates an incentive" to replace them with nurse aides. PI Mot. 29. But 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* 89 Fed. Reg. 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.* ("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.

The agency's fulsome responses to comments, significant grant funding initiative, delayed implementation timeline, and hardship exemptions provide ample evidence that CMS has seriously considered and addressed potential compliance challenges arising from the nursing workforce. *See Adventist Health Sys.*, 17 F.4th at 803 (decision not arbitrary so long as "an agency examine[d] the relevant data and articulate[d] a satisfactory explanation for its action.") (quotation omitted).

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; 2022 Abt Study at 114-19. 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.[15] In 2022, Medicaid spent $191.3 billion for care in freestanding nursing care facilities and continuing care retirement communities.[16] 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 figures 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

[15] 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).

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

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. at 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 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." *United States v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039, 1044 (5th Cir. 1984). 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 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 "does not do anything to alleviate" their concerns because it cannot be proactively sought and is too limited. PI Mot. 30. 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." PI Mot. 30. 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. 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.

Id. 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.

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 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 Com. v. New York*, 588 U.S. 752, 773 (2019) (citation omitted).

III. THE REMAINING INJUNCTION FACTORS REQUIRE DENIAL OF PLAINTIFFS' MOTION

For the reasons set forth above, Plaintiffs have failed to demonstrate a likelihood of success as to any of their claims. This Court may accordingly deny relief without evaluating the remaining preliminary injunction factors. *Winter*, 555 U.S. at 20. In any event, Plaintiffs also fail to demonstrate that they meet any of the remaining requirements for preliminary injunctive relief.

A. Plaintiffs Fail To Establish Imminent Irreparable Harm

"[F]ailure to show irreparable harm is, by itself, a sufficient ground upon which to deny a preliminary injunction." *Adam-Mellang v. Apartment Search, Inc.*, 96 F.3d 297, 299 (8th Cir. 1996) (*quoting Gelco Corp. v. Coniston Partners*, 811 F.2d 414, 418 (8th Cir. 1987)). The requirements Plaintiffs challenge by their motion for preliminary injunction pose them no imminent irreparable harm.

Plaintiffs substantively challenge only the 24/7 RN requirement and the HPRD requirements, *see* PI Mot. 17-37, neither of which will be implemented for several years. *See* 89 Fed. Reg. 40887 (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 earliest a subset of facilities could even feasibly be harmed by any of the challenged provisions is two years after the rule's publication. *Id.* at 40910 (for urban facilities, the 24/7 RN requirement goes into effect "2 years after the publication date of the final rule"). Even then, any violation of the requirements would not be documented until the annual survey following the effective date, and at that point, the facility could be granted a hardship exemption if it is eligible.

A requirement that Plaintiffs are not required to comply with for multiple years hardly amounts to imminent, irreparable harm. *See Wyoming v. U.S. Dep't of the Interior*, No. 2:16–CV–0280–SWS, 2017 WL 161428, at *11 (D. Wyo. Jan. 16, 2017) (denying motion for preliminary injunction where "any alleged expenses associated with 'immediate action to begin Rule implementation and compliance planning' are simply too uncertain and speculative to constitute irreparable harm."). The limited purpose of a preliminary injunction is to "preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). The merits of the 24/7 RN and HPRD requirements challenged by Plaintiffs here can certainly be resolved in under two years, particularly where Defendants have already stated their willingness to proceed directly to summary judgment at the earliest opportunity (an offer Plaintiffs rejected). *See* ECF No. 46. Plaintiffs'

request to preliminarily enjoin the 24/7 RN and HPRD requirements is both unnecessary and inappropriate in this context.

Even assuming, *arguendo*, that Plaintiffs are somehow imminently harmed by 24/7 RN and HPRD requirements that they do not have to comply with for years, the only harms they describe are purely economic, and not caused by the Final Rule at all. First, Plaintiffs allege "devastating financial strain" based on the purported cost of implementation, PI Mot. 32, but the Final Rule imposes no staffing requirements to implement for several years. Plaintiffs' purported desire to voluntarily accelerate their compliance with the 24/7 RN and HPRD requirements beyond what the rule itself requires is at most a self-inflicted injury, and does not amount to an irreparable harm for purposes of the preliminary injunction analysis. *See H&R Block Tax Servs. LLC v. Santiago*, No. 4:19-CV-00154, 2019 WL 1415466, at *4 (W.D. Mo. Mar. 28, 2019) (discounting alleged harm because it was "largely self-inflicted"); *Sierra Club v. U.S. Army Corps of Engineers*, 645 F.3d 978, 997 (8th Cir. 2011) (same); *see also Wyoming*, 2017 WL 161428, at *11. Second, Plaintiffs cite "workforce shortages" as a harm entitling them to an injunction. PI Mot. 32-33. But the alleged workforce shortage is not caused by the rule; Plaintiffs themselves admit that the workforce shortage they complain of here existed before the Final Rule and will continue even if the rule is enjoined. *See id.* at 28-30. Any alleged injury they will suffer from a high demand for nurses is therefore not caused by this rule and cannot justify preliminary relief. Finally, Plaintiffs allege "current compliance burden" as a harm justifying relief. *Id.* at 33. But this purported harm is merely a summary of the already alleged "financial strain" and "workforce shortages" rather than a distinct harm itself.

Although they claim to be harmed by it, PI Mot. 33, Plaintiffs' motion for preliminary injunction does not substantively challenge the enhanced facility assessment ("EFA") requirement of the Final Rule as arbitrary and capricious, contrary to law, or lacking statutory authority. *See generally* PI Mot. (mentioning the EFA requirement in the introduction, background, and harm discussions,

but not on merits). Because a preliminary injunction can only issue upon a showing of substantial likelihood of success on the merits, *see Winter*, 555 U.S. at 20, Plaintiffs cannot obtain an injunction against regulatory requirements they do not substantively contest. And even if Plaintiffs *had* substantively challenged the EFA requirement, they would not be facing imminent harm from it because the deadline to complete the EFA has already passed. 89 Fed. Reg. 40910 ("Phase 1 would require facilities to comply with the facility assessment requirements (§ 483.71) 60-days after the publication date of the final rule."). The facility assessment compliance date was August 8, 2024, *see* CMS Center for Clinical Standards and Quality, *Revised Guidance for Long-Term Care Facility Assessment Requirements* 1 (June 18, 2024), *available at* https://www.cms.gov/files/document/qso-24-13-nh.pdf, but Plaintiffs filed suit months later, after they would have already expended resources to comply with that portion of the Final Rule. Rather than demonstrating imminent irreparable harm, Plaintiffs would have done no more than allege a past violation of law, had they challenged the EFA requirement at all. But "[t]he purpose of a preliminary injunction is not to remedy past harm but to protect plaintiffs from irreparable injury that will surely result without their issuance." *Schrier v. Univ. of Colo.*, 427 F.3d 1253, 1267 (10th Cir. 2005).

Finally, even if the challenged requirements did require imminent action from Plaintiffs, their five-month delay in filing suit belies their assertion of imminent irreparable harm. It is well established that a "party requesting a preliminary injunction must generally show reasonable diligence." *Benisek v. Lamone*, 585 U.S. 155, 159 (2018). And nothing prevented Plaintiffs from raising their claims within the past five months. Indeed, the American Health Care Association, the Texas Health Care Association, and several Texas-based LTC facilities all filed suit challenging the Final Rule on the same grounds Plaintiffs raise here less than two weeks after promulgation of the Final Rule. *See Am. Health*

Care Ass'n v. Becerra, No. 24-cv-114-Z-BR (N.D. Tex.) (filed May 23, 2024).[17] The Eighth Circuit has held that a similar delay of approximately five months provides ample grounds to affirm denial of a motion for preliminary injunction. *See Phyllis Schlafly Revocable Tr. v. Cori*, 924 F.3d 1004, 1010, n.4 (8th Cir. 2019). The same result should obtain here—Plaintiffs' five-month delay in filing suit refutes any assertion that their alleged harms are imminent or irreparable.

B. Plaintiffs Fail To Establish That The Balance Of Equities And Public Interest Factors Favor The Requested Injunction

The balance of harms and the public interest "merge when the Government is the opposing party," *Nken v. Holder*, 556 U.S. 418, 435 (2009), and both factors also favor Defendants here. Measured against Plaintiffs' lack of imminent irreparable harm, Defendants and the public would suffer significantly were this Court to enjoin the Final Rule. Indeed, Congress has made 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 the Final Rule represents the fulfillment of that statutory duty. Enjoining its requirements would frustrate Congress's objectives, preventing CMS from "effectuating statutes enacted by representatives of [the] people," and causing the United States to "suffer[] a form of irreparable injury" as a result. *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (citation omitted).

Enjoining the Final Rule would also harm the public interest directly, by further exposing nursing home residents to the risks of inadequate nursing care due to chronic understaffing. *See supra* 4, 28-30. For residents and their loved ones, this means numerous additional lives affected by neglect, hospitalization, or even death. *See* 88 Fed. Reg. 61357. By comparison, any theoretical harm that Plaintiffs might experience absent a preliminary injunction is, as explained *supra* 49-52, both speculative and purely economic. Nowhere do Plaintiffs dispute CMS's evidence of the positive effects

[17] LeadingAge (the parent organization of many of the organizational Plaintiffs in this case), also joined that suit more than five months ago.

of increased staffing on resident health and safety. In fact, in discussing the public interest prong, Plaintiffs fail to acknowledge the welfare of nursing home residents at all. *See* PI Mot. 35. Rather, Plaintiffs argue that the Final Rule will cause them to "incur expenses necessary to prepare for [] implementation." *Id.* But as noted above, those purely economic costs pale in comparison to the health and safety of 1.2 million nursing home residents, and are in any event offset by CMS's decision to delay implementation of the challenged requirements by 2-5 years. *See supra* 49-50. Accordingly, the balance of the equities and the public interest weigh against Plaintiffs' requested relief.

IV. ANY RELIEF SHOULD BE LIMITED TO FACILITIES OPERATED BY THE PLAINTIFFS, AND ONLY TO ASPECTS OF THE FINAL RULE FOR WHICH THE COURT FINDS THAT PLAINTIFFS HAVE MET THE REQUIREMENTS FOR PRELIMINARY INJUNCTIVE RELIEF

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*, 138 S. Ct. 1916, 1934 (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 Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted).

In that regard, *first*, any injunction 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 preliminary injunctive 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 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 their motion for preliminary injunction are limited to the 24/7 RN and

HPRD requirements alone, *see* PI Mot. 2-3, so any injunction should be similarly limited to the portions of those requirements for which the Court finds that Plaintiffs have met the test for preliminary relief. While Plaintiffs argue that the enhanced facility assessment requirement imposes a financial burden on them, *see* PI Mot. 33-34, they mention the requirement only in their discussion of alleged irreparable harms. *See id.* Plaintiffs offer no argument as to why the enhanced facility assessment requirement is contrary to law, lacking in statutory authority, or arbitrary and capricious in violation of the APA. *See generally*, *id.* at 17-31 (challenging the 24/7 RN and HPRD requirements alone). All other requirements of the Final Rule, including, *inter alia*, the enhanced facility assessment requirement, 89 Fed. Reg. 40905-06, and the Medicaid Institutional Payment Transparency Reporting Provision, *id.* at 40914, are thus not at issue in Plaintiffs' motion and 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 id.* at 1934 (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 other States and 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 a preliminary injunction prohibiting CMS from "enforcing" the rule against facilities Plaintiffs operate.

Plaintiffs' only argument to the contrary is that "[l]ess than a nationwide injunction would require the organizational plaintiffs to monitor and report their membership rolls to determine which LTCs were members," PI Mot. 37. But maintaining a roster of membership is precisely what associational plaintiffs do by virtue of their associational status, and Plaintiffs already admitted to

maintaining such membership data in this case. *See* Am Compl. ¶¶ 21-40, ECF No. 37 (providing membership allegations for each of the organizational Plaintiffs). Indeed, the fact that the organizational Plaintiffs have already confessed to maintaining membership rolls is precisely what allows them to bring suit as associations on behalf of their members. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 344 (1977) (test for asserting standing on behalf of members). It thus imposes no burden on Plaintiffs to "monitor and report their membership rolls to determine which LTCs were members" for purpose of effectuating a limited preliminary injunction, should the Court determine that any relief is warranted at this stage. PI Mot. 37.

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 brought by LeadingAge—the parent organization to many of the organizational Plaintiffs here—among others. *See Am. Health Care Ass'n v. Becerra*, No. 24-cv-114-Z-BR (N.D. Tex.). Nationwide relief would render the district court's order in *Am. Health Care Ass'n*, 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."); *id.* at 582-84 (vacating nationwide injunction in facial APA challenge).

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for preliminary injunction should be denied.

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Respectfully submitted,

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