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

AMERICAN HEALTH CARE ASSOCIATION, et al.,

Plaintiffs,

v.

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

Defendants.

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

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Sources

INTRODUCTION

Defendants' Final Rule requires nursing homes that receive Medicare and Medicaid funding to maintain nurse staffing levels at or above minimum thresholds deemed necessary for the health, safety, and well-being of their residents by the Secretary of Health and Human Services. *See* Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40876 (May 10, 2024) (to be codified at 42 C.F.R. pts. 438, 442, 483) ("Final Rule"). Requirements like those at issue in this case are a standard exercise of the Secretary's congressionally delegated authority to condition nursing homes' participation in Medicare and Medicaid on compliance with requirements related to the health and safety of residents—authority that the Secretary has exercised in similar ways many times over the past four decades. Plaintiffs have consistently complained that the minimum staffing levels selected by the Secretary will require facilities that currently employ fewer staff than required by the rule to hire more nursing staff or risk losing access to federal funding if they do not receive an exemption or waiver. That is indeed the consequence of the rule, just as it is the consequence of many Medicare and Medicaid rules adopted to protect patients and the public. And Plaintiffs' combined response and reply brief, Pls.' Resp. to Defs.' Cross-Mot. for Summ. J., ECF No. 96 ("Pls.' Br."), does not dispute these minimum staffing requirements qualify as a measure to protect residents' "health and safety" within the plain meaning of those terms, and fails to demonstrate that the challenged requirements are otherwise arbitrary, capricious, or contrary to law.

The Secretary's statutory authority to promulgate the challenged requirements is both clear and broad, as the Supreme Court confirmed just two years ago when upholding his use of the exact same authority to promulgate, as a condition on Medicare and Medicaid funding, a requirement that facilities seeking such funding take steps to ensure that their health care workers be vaccinated. The statute's key provision provides authority to create new "requirements relating to the health and safety

of residents or relating to the physical facilities thereof as the Secretary may find necessary," beyond those requirements specified by statute alone. 42 U.S.C. § 1396r(d)(4)(B); *see also id.* § 1395i-3(d)(4)(B). Plaintiffs cannot credibly contest that the Final Rule's requirement that a facility have at least one Registered Nurse ("RN") "on site 24 hours per day and 7 days per week," and "provide, at a minimum, 3.48 total nurse staffing hours per resident per day ("HPRD") of nursing care, with 0.55 RN HPRD and 2.45 [Nurse Aide ("NA")] HPRD[,]" are plainly encompassed by that authority as reasonable health-and-safety-related measures. 89 Fed. Reg. 40877. Instead, they primarily argue that the challenged 24/7 RN and HPRD requirements lie at odds with Congress's other requirements for nursing homes' participation in the Medicare and Medicaid programs. But as explained in Defendants' opening brief and below, the regulatory and statutory requirements at issue do not conflict, and in the absence of actual inconsistency with 42 U.S.C. § 1396r(b)(4)(C)(i), Defendants' 24/7 RN and HPRD requirements should be upheld.

Plaintiffs' other challenges to the Final Rule fare no better. The major questions doctrine is not implicated in this case. And contrary to what Plaintiffs maintain, the need for the protections embodied in the Final Rule is well supported in the administrative record. The Court should, accordingly, enter judgment for Defendants.

ARGUMENT

I. THE 24/7 RN AND HPRD STAFFING REQUIREMENTS FIT SQUARELY WITHIN CMS'S STATUTORY AUTHORITY

In their opening brief, Defendants explained that Congress instructed the Secretary to administer the Medicare and Medicaid programs to ensure that nursing home residents' health and safety are protected, *see, e.g.*, 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B), and that the challenged 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"); Mem. of P. & A. in Supp. of Defs.' Cross-Mot. for Summ.

J. & Opp'n. to Pls.' Mot. for Summ. J. at 4-6, 10-21, ECF No. 80-1 ("Defs.' MSJ"). Plaintiffs' response does not demonstrate otherwise as to either the 24/7 RN requirement or the HPRD requirements. *See* Pls.' Br. at 4-16.

A. The 24/7 RN Requirement Neither Exceeds Nor Conflicts With CMS's Statutory Authority

Plaintiffs' combined response and reply, like their opening brief, advances the view that the Final Rule's 24/7 RN requirement exceeds CMS's health and safety rulemaking authority because Congress separately provided that federally funded nursing homes "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) (cited at Pls.' Br. at 4); *accord id.* § 1395i-3(b)(4)(C)(i). While the Supreme Court has instructed that "[o]rdinarily, where a specific provision conflicts with a general one, the specific governs[,]" *Edmond v. United States*, 520 U.S. 651, 657 (1997), there is no "conflict" between the challenged 24/7 RN requirement and the statutory requirement to employ an RN for *at least* 8 hours here, as Plaintiffs now admit, *see* Pls.' Br. at 7 ("of course a facility can (at least in theory) comply with both"). That concession is fatal to Plaintiffs' challenge, as they do not otherwise contest that Defendants' health and safety rulemaking authority encompasses the power to promulgate the 24/7 RN requirement, since RN staffing is plainly "relat[ed] to the health and safety of [nursing home] residents." 42 U.S.C. § 1396r(d)(4)(B); *id.* § 1395i-3(d)(4)(B). *See* Defs.' MSJ at 13-14; Pls.' Br. at 4-10.

Plaintiffs rely on *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*—which stated that "general language" in one part of a statute "will not be held to apply to a matter specifically dealt with in another part of the same enactment"—to argue that Congress's requirement that nursing homes maintain "at least 8" hours of RN coverage precludes CMS's ability to promulgate a 24/7 RN requirement using its separate health and safety authority. 566 U.S. 639, 645-46 (2012) (citation omitted) (cited at Pls.' Br. at 5). But the Supreme Court's application of that interpretative canon in *RadLAX* demonstrates its inapplicability here. The contested interpretation at issue in *RadLAX*

involved an actual and direct conflict between the "specific" and "general" provisions of the statute in question: the respondents' interpretation of the general clause would have "permit[ted] precisely what [the specific clause] proscribe[d.]" 566 U.S. at 645. But here, Plaintiffs correctly concede that facilities "can . . . comply with both" CMS's application of its health and safety authority and Congress's "at least 8" hour RN coverage requirement. *See* Pls.' Br. at 7; Defs.' MSJ at 15 ("After all, there can be no dispute that 24 hours is 'at least 8' hours."). It is a long-established rule of interpretation that when presented with two statutes, courts should "regard each as effective" absent "irreconcilable" conflict between them or "clear and manifest" intention to repeal. *Me. Cmty. Health Options v. United States*, 590 U.S. 296, 315 (2020) (citation omitted). No "irreconcilable" conflict exists between the Secretary's exercise of his statutory health and safety rulemaking authority and the "at least 8" hour requirement in this case, so both provisions must be regarded as effective under this rule of interpretation. *Id.*

Plaintiffs' attempt to avoid Defendants' argument by characterizing it as a "post hoc rationalization" is unavailing. *See* Pls.' Br. at 6. As Plaintiffs note, the agency disclaimed reliance on the "statutory 8/7 RN requirement as a source of authority" for the 24/7 RN requirement in its Final Rule. *Id.* (quoting 89 Fed. Reg. 40891). That position has not changed—CMS did not then, and does not now, invoke the statutory "at least 8" hour requirement as authority for its 24/7 RN requirement. Instead, Defendants have consistently argued that the Secretary has the "independent power to establish 'other requirements relating to the health and safety of residents'" pursuant to 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B), and that this authority is itself sufficient to support the 24/7 RN requirement. Defs.' MSJ at 15. *See* 89 Fed. Reg. 40890 ("The Secretary has concluded that these HPRD levels and RN onsite 24/7 requirements are necessary for resident health, safety, and well-being, under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act"); *Chiquita Brands Int'l Inc. v. SEC*, 805 F.3d 289,

299 (D.C. Cir. 2015) (the bar on post hoc rationalization "does not bar an agency's counsel from merely elaborating on the consistent stance the agency articulated below").

Defendants invoked the statutory "at least 8" hour RN requirement, and the words "*at least*" in particular, not as a source of rulemaking authority, but rather to rebut Plaintiffs' contention that the 24/7 RN requirement conflicts with this portion of the statute. *See, e.g.*, Mem. in Supp. of Pls.' Mot. for Summ. J. at 30, ECF No. 57-1 ("Pls.' MSJ") (arguing that the 24/7 RN requirement is "inconsistent with" the statutory requirement (quoting 42 U.S.C. § 1302(a))). It is no post hoc rationalization for Defendants to respond to Plaintiffs' argument that the rule is contrary to statute by referencing the language of the statute to explain why no conflict exists. *See Sierra Club v. FERC*, 827 F.3d 36, 48–49 (D.C. Cir. 2016) (the bar on post hoc rationalization "applies only to 'determinations specifically entrusted to an agency's expertise,' not 'legal principles.'" (citation omitted)).

For the same reason, Plaintiffs' unremarkable observation that the "at least 8" hour statutory RN provision imposes a requirement on "nursing homes," without "mention[ing] CMS," is beside the point. Pls.' Br. at 6-7. Again, Defendants do not argue otherwise—as explained in the Final Rule, the 24/7 RN requirement is an exercise of the Secretary's well-established health and safety rulemaking authority, not of any authority conferred on CMS by 42 U.S.C. § 1396r(b)(4)(C)(i) and § 1395i-3(b)(4)(C)(i). *See* 89 Fed. Reg. 40890-91 ("CMS is using separate authority as described above to establish these new requirements rather than the authorities found at sections 1819(b)(4)(C) and 1919(b)(4)(C) of the Act"). Defendants' reference to Congress's use of the words "at least" in its 8-hour RN requirement merely demonstrates that this exercise of CMS's separate health and safety authority does not conflict with the statute, as Plaintiffs have now conceded. *See* Pls.' Br. at 7 (acknowledging that a nursing home can "comply with both"); Defs.' MSJ at 15. As regards nursing home staffing, Congress made the choice to expressly require that facilities comply with any "requirements relating to the health and safety of residents or relating to the physical facilities thereof

as the Secretary may find necessary," on top of those requirements specifically set forth in the statute by Congress itself. 42 U.S.C. § 1396r(d)(4)(B); *see also id.* § 1395i-3(d)(4)(B); Defs.' MSJ at 10-13. And because the two requirements do not conflict, the 24/7 RN requirement does not "override Congress' choice." Pls.' Br. at 8.

Plaintiffs also argue that the 24/7 RN requirement "departs from the statutory text by replacing the requirement to 'use the services of' an RN, which encompasses administrative and supervisory roles, with a requirement to have an RN 'available to provide direct resident care.'" Pls.' Br. at 4 (quoting 89 Fed. Reg. 40997). But again, these portions of the 24/7 RN requirement and the statute do not conflict, as CMS explained in response to comments regarding whether a covered facility's Director of Nursing ("DON")—an RN acting in the type of "administrative and supervisory role[]" Plaintiffs contemplate, Pls.' Br. at 4—would be counted toward the Rule's requirement for 24/7 RN coverage. *See* 89 Fed. Reg. 40897 (noting that "[m]any commenters opposed the DON being counted towards the 24/7 RN requirement, as well as any other RN that is assigned to administrative duties."). In response, CMS explained that it was not adopting some commenters' preference that "only RNs providing direct resident care should be counted towards the requirement." *Id.* Instead, the Final Rule allows administrative and supervisory employees like the DON to "count towards [the 24/7] requirement[,]" "if the DON is a[n] RN and is available to provide direct resident care." *Id.* Accordingly, because a facility which "use[s] the services" of an RN in an "administrative and supervisory role[]" for 8 hours per day in accordance with the statute would still be permitted to count that employee toward the rule's 24/7 RN requirement, Pls.' Br. at 4, the Court should "regard each as effective," and uphold this aspect of the Final Rule, *Me. Cmty. Health Options*, 590 U.S. at 315 (citation omitted). *Cf.* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 66 (2012) ("[a]n interpretation that validates outweighs one that invalidates.").

Just as was the case for the other health and safety regulations cited in Defendants' opening brief, then, Defendants' 24/7 RN requirement is a permissible exercise of the Secretary's statutory health and safety authority and does not conflict with any other portion of the statute. *See* Defs.' MSJ at 5-6, 12, 15-16 (citing 42 C.F.R. §§ 483.60(a)(1), 483.70(e)(1), 483.70(o), 483.80(b), *inter alia*). Plaintiffs do not contest the validity of these comparator health and safety regulations, *see* Pls.' Br. at 8-9, n.1, and many have been cited approvingly by the Supreme Court as examples of permissible exercises of CMS's regulatory power, *see Biden v. Missouri*, 595 U.S. 87 (2022) (*per curiam*). For each of those regulations, Congress had similarly already spoken on the subject at issue via statute, by providing necessary but not sufficient standards for nursing homes to meet. *See, e.g.*, 42 U.S.C. §§ 1396r(b)(4), 1396r(b)(7), 1396r(d)(3)(A) (cited at Defs.' MSJ at 15-16). And in each case, CMS permissibly utilized its separate health and safety authority to impose conditions not inconsistent with Congress's statutory requirements, consistent with Congress's choice to condition nursing homes' eligibility for Medicare and Medicaid funding not only on those requirements which Congress itself had the foresight to establish, but also on "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); *see also id.* § 1395i-3(d)(4)(B). The 24/7 RN requirement is no different and should not be disturbed.

B. The HPRD Requirements Neither Exceed Nor Conflict With CMS's Statutory Authority

Just as Plaintiffs fail to demonstrate that the 24/7 RN requirement falls outside of CMS's "capacious[]," and "broadly worded" authority, which gives Defendants "significant leeway in deciding how best to safeguard [long-term care ("LTC") facility] residents' health and safety," so too do they fail to carry their burden as to the HPRD requirements. *Northport Health Servs. of Ark., LLC v. U.S. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021) (discussing 42 U.S.C. § 1395i-3); *see* Pls.' Br. at 10-16. Again, Defendants do not argue that their authority to establish minimum HPRD requirements stems from Congress's necessary but not sufficient requirement that a facility "must

provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents[.]" 42 U.S.C. § 1396r(b)(4)(C)(i); *accord id.* §1395i-3(b)(4)(C)(i). Rather, CMS used its separate health and safety authority to additionally require facilities to provide "a minimum, 3.48 total nurse staffing [HPRD] of nursing care, with 0.55 RN HPRD and 2.45 NA HPRD." 89 Fed. Reg. 40877; *see id.* at 40891("CMS is using separate authority as described above to establish these new requirements rather than the authorities found at sections 1819(b)(4)(C) and 1919(b)(4)(C)"). The statutory and regulatory requirements do not conflict, *see* Defs.' MSJ at 18-19, and Plaintiffs do not contest that RN, NA, and total nurse staffing levels are "relate[d] to the health and safety of residents." 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B).

At the heart of Plaintiffs' response is their mischaracterization of Congress's existing "sufficient to meet the nursing needs of its residents" requirement as a "qualitative, facility-specific statutory staffing standard," with implicit preclusive effect over any effort by CMS to further delimit a quantitative minimum staffing level deemed necessary for resident health and safety through regulation. Pls.' Br. at 10-13 (citation omitted). The text and context demonstrate, rather, that Congress was silent as to the question of quantitative minimum staffing standards, given the lack of available data at the time of the statute's enactment. *See, e.g.*, Defs.' MSJ at 19-21. In this way, Congress's "sufficient to meet the nursing needs" standard is analogous to its treatment of, *e.g.*, dietary services or infection control prior to CMS's promulgation of additional, quantitative standards for employment of qualified professionals in those areas. *Compare* 42 U.S.C. § 1396r(b)(4) (requiring 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"), *and* 42 U.S.C. § 1396r(d)(3)(A) (requiring facilities to "establish and maintain an infection control program") *with* 42 C.F.R. § 483.60(a)(1) (requiring employment of at least one "qualified dietitian or other clinically qualified nutrition professional" with specific qualifications), *and* 42 C.F.R. § 483.80(b) (requiring employment

of at least one "[i]nfection preventionist" with specialized training in "infection prevention and control."). Plaintiffs do not contest the validity of those exercises of CMS's health and safety authority—nor could they, *see Missouri*, 595 U.S. at 94 (citing 42 C.F.R. § 483.60(a)(1) approvingly)—and provide no credible grounds to distinguish those judicially-sanctioned minimum staffing rules from the HPRD requirements at issue here.

Plaintiffs claim in response, *ipse dixit*, that although the "dietitian" and "infection preventionist" examples above do indeed reflect congressional "silence," Congress's "sufficient to meet the nursing needs" standard does not, and instead reflects a binding and unwavering commitment to flexibility for facilities which must be read to preclude all future attempts at quantitative staffing regulation. Pls.' Br. at 13-15. But that distinction is entirely unsupported by the text of the statutory provisions, which sets forth similarly flexible statutory requirements in both instances. *Compare* 42 U.S.C. §§ 1396r(b)(4)(C)(i); 1395i-3(b)(4)(C)(i) ("sufficient to meet the nursing needs of its residents") *with id.* § 1396r(d)(3)(A) ("assure that the meals meet the daily nutritional and special dietary needs of each resident"). In both cases, Congress's existing statutory requirement does not preclude the agency from establishing additional quantitative requirements via its regulatory authority to protect resident health and safety, as the Supreme Court has confirmed. *See Missouri*, 595 U.S. at 90, 94 ("the Secretary has always justified these sorts of requirements by citing his authorities to protect patient health and safety" (citing 42 C.F.R. §§ 483.80, 483.60(a)(1)(ii))).

Plaintiffs attempt to distinguish *Biden v. Missouri* on similar grounds, arguing that it "in no way suggests that the agency's power to impose 'such other requirements relating to the health and safety of [nursing home] residents . . . as [it] may find necessary,' is so sweeping as to empower the agency to override specific requirements that Congress has already established." Pls.' Br. at 14 (alterations in original) (citation omitted). But that argument fails because CMS's HPRD requirements no more "override" Congress's existing requirements than did the dietitian and infection preventionist rules

cited approvingly in *Missouri*. 595 U.S. at 90, 94. Just as CMS permissibly required that facilities employ dietitians and infection preventionists where the statute would have otherwise left facilities free to develop their own practices for meeting residents' dietary and infection-control needs, *see* 42 U.S.C. §§ 1396r(b)(4), 1396r(d)(3)(A), CMS's HPRD requirements do not "override" Congress's command, but rather supplement it in accordance with the agency's determination of what is necessary to protect residents' health and safety, Pls.' Br. at 14. All Plaintiffs are left with on the question of quantitative staffing, then, is congressional silence, which "lacks 'persuasive significance' because 'several equally tenable inferences' may be drawn from such inaction, 'including the inference that the existing legislation already incorporated the offered change.'" *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (quoting *United States v. Wise*, 370 U.S. 405, 411 (1962)). Such is the case here. Congress's decision not to set minimum staffing requirements reflects the fact that this responsibility had been appropriately delegated to CMS, through its capacious power to set additional requirements for resident health and safety.

If there were any doubt remaining as to the validity of the challenged requirements, legislative history from the time of the statute's enactment confirms that Congress did not intend its "sufficient to meet the nursing needs" standard to foreclose CMS's ability to set quantitative staffing standards by regulation in the future. *See* Nat'l Library of Med., Inst. of Med., *Improving the Quality of Care in Nursing Homes* 200-01 (1986), available at https://archive.ph/KFNCi ("Institute of Medicine Study") ("[i]f convincing evidence becomes available that some approaches to staffing and training are distinctly superior . . . to others, the *HCFA*[1] will be in a position to incorporate the desirable approaches into its regulatory standards." (emphasis added)). Despite citing this study in their opening

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

brief, *see* Pls.' MSJ at 8, 36, Plaintiffs now seek to minimize it, characterizing it as an "offhand remark by a private, non-profit entity," Pls.' Br. at 16. That characterization is misleading. The Institute of Medicine (now known as the National Academy of Medicine[2]) is part of the National Academies of Sciences, Engineering, and Medicine—a congressionally chartered organization established by Congress for the express purpose of providing advice to the Government to aid in lawmaking and to provide reports to Congress. *See* 36 U.S.C. §§ 150302, 150303. The Institute's 1986 Report at issue here is widely recognized as the basis for the Federal Nursing Home Reform Act ("FNHRA"), and was cited by the Supreme Court to help explain the intent of the statute as recently as 2023. *See Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 181 (2023). But even assuming, *arguendo*, that the Institute of Medicine Study "says nothing about whether Congress intended to grant CMS the authority it now asserts," Pls.' Br. at 16, "the fact that a statute can be 'applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth[,]'" *Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212 (1998) (quoting *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499 (1985)). 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 and should be upheld.

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

Because the Final Rule's requirement that Medicare and Medicaid facilities maintain 24/7 RN coverage and specific HPRD nurse staffing levels is so readily understood as an exercise of the "health and safety" authority conferred on the Secretary, Plaintiffs turn again to the argument that the Court should impose on Congress a clear statement requirement demanding express reference to quantitative

[2] *See* National Academy of Medicine, *About Us*, https://nam.edu/about-the-nam/.

staffing levels in its grant of rulemaking authority. There is no basis for that departure from the statute's text.

Invoking the major questions doctrine, Plaintiffs insist that the 24/7 RN and HPRD requirements lack a sufficiently clear delegation of authority from Congress, even though the Supreme Court recently upheld a far more expansive and politically controversial exercise of the same authority when considering a challenge to CMS's health care workforce vaccination rule in *Biden v. Missouri*. 595 U.S. at 104, 108 (Alito, J., dissenting) (characterizing the vaccination rule as "undoubtedly significant," and affecting "more than 10 million healthcare workers"); Pls.' Br. at 16-22; Defs.' MSJ at 23-24. This case lacks the hallmarks of the major questions decisions that Plaintiffs invoke, all of which grounded their analysis in the text, structure, and context of the relevant statutes. Here, CMS is not asserting regulatory power that is "markedly different" from the type of authority that Congress expressly identified in the relevant provision, *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2488 (2021) (*per curiam*) (cited at Pls.' Br. at 20-22), or claiming "an unheralded power representing a transformative expansion in [its] regulatory authority" that Congress has "conspicuously and repeatedly declined to enact," *West Virginia v. EPA*, 597 U.S. 697, 723-24 (2022) (quotation marks omitted) (cited at Pls.' Br. at 17). Nor is this a case where an agency responsible for public health has attempted to regulate something far afield from its core expertise, such as "the landlord-tenant relationship." *Ala. Ass'n*, 141 S. Ct. at 2489. Instead, the federal agency primarily responsible for health care is setting health and safety requirements for nursing homes participating in federally funded health care programs, pursuant to express statutory authorization to do just that.

In response, Plaintiffs argue that "the Executive Branch has *never* enacted nationwide minimum staffing mandates for nursing homes in the six decades since Medicare and Medicaid began," Pls.' Br. at 20, but that is plainly incorrect. As Defendants explained in their opening brief, CMS has long utilized the same authorities at issue here to establish additional staff-related

requirements that LTC facilities wishing to participate in Medicare or Medicaid must meet, including those requiring employment of a "qualified dietitian or other clinically qualified nutrition professional," 42 C.F.R. § 483.60(a)(1), an "[i]nfection preventionist," *id.* § 483.80(b), and "those professionals necessary to carry out" various facility-administration requirements, *id.* § 483.70(e)(1), *inter alia*. *See* Defs.' MSJ at 5-6. The Secretary's exercise of that same authority to require Medicare and Medicaid-funded facilities to meet certain additional minimum staffing levels for nurses found necessary for resident health and safety in no way renders the relevant statutes "unrecognizable." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (citation omitted).

And contrary to Plaintiffs' suggestion that "Congress has *never* recognized [CMS's] power to" enact such staffing requirements, Pls.' Br. at 20, Congress plainly authorized the Secretary to adopt additional health and safety requirements he finds necessary precisely because it understood that it could not foresee all requirements that might prove necessary to protect residents in the future, even as to staffing, *see* Institute of Medicine Study at 200-01 (recognizing that "[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] will be in a position to incorporate the desirable approaches into its regulatory standards."); *supra* 10-11. Indeed, when adopting nearly identical health and safety rulemaking authority in the portion of the statute dealing with hospitals, Congress explained in its committee report that such language was used "because it would be inappropriate and unnecessary to include in the legislation all the precautions . . . which should be required of institutions to make them safe." H.R. Rep. No. 213, 89th Cong., 1st Sess. 25-26 (1965). *See* 42 U.S.C. § 1395x(e)(9). The Supreme Court has instructed that a statutory phrase "should ordinarily retain the same meaning wherever used in the same statute[.]" *Nat'l Aeronautics & Space Admin. v. Fed. Lab. Rels. Auth.*, 527 U.S. 229, 235 (1999); *see also Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1811 (2019). Congress's repetition of the same health and safety authority in the portion of the statute at issue here addressing LTC facilities

demonstrates its intent to delegate such authority to the Secretary. There is thus nothing "breathtaking," *Ala. Ass'n*, 141 S. Ct. at 2489, or "extravagant," *Util. Air*, 573 U.S. at 324, about the Secretary's determination that requiring facilities to meet minimum staffing levels with a demonstrated positive impact on resident outcomes was necessary for those residents' health and safety.

Plaintiffs also rely heavily on the asserted "political and economic significance" of the challenged requirements. Pls.' Br. at 17. But the Supreme Court has never suggested that the emergence of political controversy about a particular agency action triggers a clear-statement requirement. *See, e.g.*, *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380-2381 (2020) (analyzing whether HHS's rule requiring contraceptive coverage—which generated considerable political controversy—complied with the statutory text without any heightened-clarity requirement). The meaning of a statute does not change with the shifting winds of politics or public opinion, *cf. Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024) ("statutes, no matter how impenetrable, do—in fact, must—have a single, best meaning"), and opponents of an agency's policy cannot succeed in limiting the agency's authority merely by vocally opposing it. Indeed, courts regularly decide challenges to agency actions of major economic and political significance under the usual rules of statutory interpretation, without imposing heightened-specificity requirements. *See, e.g.*, *Collins v. Yellen*, 141 S. Ct. 1761, 1776 (2021); *Little Sisters*, 140 S. Ct. at 2380; *Dep't of Comm. v. New York*, 139 S. Ct. 2551, 2571-2572 (2019); *cf. Trump v. Hawaii*, 138 S. Ct. 2392, 2408 (2018).

Likewise, although the size and scope of the Medicare and Medicaid programs inevitably means that the Secretary's determinations in this field often involve billions of dollars, *see Azar*, 139 S. Ct. at 1808, courts have never treated that as a reason to demand heightened clarity in every Medicare or Medicaid case. Plaintiffs thus err in reading *Mayfield v. U.S. Department of Labor*, 117 F.4th 611 (5th Cir. 2024), and *Alabama Association of Realtors*, 594 U.S. at 764, to imply that the mere fact that a rule could necessitate "billions of dollars in spending" requires Congress to have specifically referred to

the precise regulatory measure in the statute authorizing the agency action in every case. Pls.' Br. at 20-21. Indeed, as the Fifth Circuit noted when *rejecting* application of the major questions doctrine in *Mayfield*, "no case has set the threshold for 'economic significance,'" and "the recent cases applying the doctrine based on economic significance have involved *hundreds* of billions of dollars of impact"—a far cry from the estimated $4.3 billion annual cost of the requirements Plaintiffs challenge here. 117 F.4th at 616 (emphasis added) (cited at Pls.' Br. at 16-21) (rejecting major questions doctrine assertion for rule affecting 1.2 million workers with $472 million impact the first year alone). *See also* 89 Fed. Reg. 40955 (noting that the $4.3 billion estimate cited by Plaintiffs does "not include adjustments for any exemptions that [CMS] may provide, which could reduce the rule's cost").

Finally, faced with recent Supreme Court precedent interpreting the *exact same* agency's exercise of the *exact same* statutory authority at issue here and upholding it without applying a clear statement rule, Plaintiffs assert that *Biden v. Missouri* nonetheless "says little" about the application of the major questions doctrine here. Pls.' Br. at 18-19. Not so. In Plaintiffs' view, *Missouri* matters little because "what CMS claimed the power to do there (impose vaccination requirements) is entirely different from what CMS claims the power to do here (impose rigid, nationwide minimum-staffing ratios)." *Id.* But by that logic, the other cases cited in Plaintiffs' brief provide even less guidance, as they considered a different exercise of power and a different federal agency, acting under a different statutory authority. *See, e.g.*, *West Virginia*, 597 U.S. 697 (evaluating the Environmental Protection Agency's use of the Clean Air Act to regulate power plants emissions); *Mayfield*, 117 F.4th 611 (evaluating the Department of Labor's use of Fair Labor Standards Act authority to regulate the minimum salary for overtime eligibility). Rather, as Plaintiffs acknowledge, what matters for purposes of determining whether the major questions doctrine applies in the first place is not the identical substance of the regulation, but the unprecedented size and transformative nature of the exercise of agency authority when viewed through the lens of the particular statutory provision at issue. *See* Pls.'

Br. at 17 (arguing that the major questions doctrine is triggered because of the "political and economic significance" of the action).

In this regard, the Supreme Court's rejection of a clear statement rule in *Biden v. Missouri* is highly instructive. There, the Supreme Court considered a CMS health and safety rule that was "undoubtedly significant," and allegedly "put more than 10 million healthcare workers to the choice of their jobs or an irreversible medical treatment" while implicating issues that the dissent contended "fall squarely within a State's police power," all without applying the major questions doctrine. 595 U.S. at 104, 108 (Alito, J., dissenting). Contrary to Plaintiffs' suggestion that "*Biden v. Missouri* never so much as mentioned the major questions doctrine," Pls.' Br. at 19, the dissent in fact echoed the same arguments Plaintiffs make here, citing the same cases upon which Plaintiffs rely in arguing that "[w]e expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance," *Missouri*, 595 U.S. at 104 (Alito, J., dissenting) (quoting *Ala. Ass'n*, 141 S. Ct. at 2489 (cited at Pls.' MSJ at 20-21)).

Plaintiffs do not dispute that the political and economic significance of the vaccination rule at issue in *Missouri*—which applied not only to nursing homes, but to the health care industry as a whole—exceeds that of the comparatively modest 24/7 RN and HPRD requirements challenged in this case. *See* Pls.' Br. at 16-22. And if that exercise of CMS's health and safety authority presented no major questions problem in *Missouri*, then the Court should not read the doctrine to apply to a less politically and economically significant exercise of that same authority here. *See* Defs.' MSJ at 23-24. The agency's decision to set additional requirements for nursing home staff is thus in no way "unprecedented" as a health and safety measure, and the major questions doctrine does not apply. *Ala. Ass'n*, 141 S. Ct. at 2489.

II. THE FINAL RULE REFLECTS CMS'S REASONED DECISIONMAKING

Plaintiffs fail to rebut CMS's clear statutory authority to issue the Final Rule, and their arbitrary and capricious arguments fare no better. Plaintiffs' characterization of the agency's prior position on minimum staffing requirements is flatly contradicted by the record. Enacting minimum nurse staffing requirements for the first time is not a reversal in position, and the agency thoroughly explained its rationale for adopting these regulations now. Plaintiffs' other arbitrary and capricious arguments boil down to reiteration of their concerns that compliance will be difficult—concerns that are sufficiently addressed in the Final Rule. Defendants' thorough, extensively researched explanation of its rationale for the Final Rule easily meets the deferential requirement that an agency articulate "a rational connection between the facts found and the choice made." *Dep't of Com. v. New York*, 588 U.S. 752, 773 (2019).

A. The Final Rule Is Consistent With CMS's Longstanding Position On Minimum Staffing Requirements

The Final Rule is consistent with longstanding agency policy and does not represent a change in course. Plaintiffs characterize the rule as a "departure[,]" Pls.' Br. at 23, simply because CMS had, up to this point, not yet instituted minimum nurse staffing requirements. But each time CMS declined to establish such requirements in the past, it did so because of a lack of reliable data necessary to determine where to set the minimum requirements and how to effectively enforce them, not because it was opposed to minimum requirements on principle. Plaintiffs' selective and acontextual quotations do not show otherwise.

1. CMS Has Never Rejected Minimum Staffing Requirements On Principle

Despite Plaintiffs' assertions to the contrary, CMS has consistently supported regulations to increase staffing in LTC facilities.

At the heart of Plaintiffs' argument is a mischaracterization of the challenged requirements. The Final Rule does not dictate the correct or optimal staffing level for any particular facility, but

rather, it sets the floor. Put differently, the Final Rule's minimum staffing requirements are a necessary but not sufficient condition to satisfy the conditions of participation for Medicare and Medicaid. *See, e.g.*, 81 Fed. Reg. 68688, 68755 (Oct. 4, 2016) ("[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."). Setting a *minimum* requirement and leaving each LTC facility to staff at or above the minimum in a manner "sufficient to meet the nursing needs of its residents" 42 U.S.C. §§ 1396r(b)(4)(C)(i)(I), 1395i-3(b)(4)(C)(i), is altogether different than prescribing for each facility what would be a correct or optimal staffing level. Plaintiffs' arguments conflate these two things. While the Final Rule only does the former (sets a minimum), much of Plaintiffs' response focuses on the strawman of the latter. That is not an immaterial distinction. Plaintiffs' mischaracterization directly undercuts their argument that the challenged requirements represent a "dramatic shift from longstanding agency policy[.]" Pls.' Br. at 22.

Plaintiffs' sparse and out-of-context quotations largely speak to the propriety of prescribing what would be a *correct or optimal* staffing ratio, not on the propriety of a minimum requirement. And when the agency has in the past occasionally recognized potential drawbacks specific to minimum staffing requirements, it has never rejected that policy on principle but has instead requested further study based on more reliable data. CMS has therefore remained steadfast in its support for regulations to increase staffing in LTC facilities.

1974 Rulemaking. In their discussion of the 1974 rulemaking, Plaintiffs mischaracterize the agency's position on minimum staffing requirements. In responding to a single public comment, the agency declined a recommendation to set "a specific ratio of nursing staff to patients." 39 Fed. Reg. 2238, 2239 (Jan. 17, 1974). Even if a single sentence from 1974 can be read to definitively establish the agency's prior position on the matter (and it cannot), this sentence only addresses the latter type of policy described above—prescribing optimal staffing ratios—which the agency did not do here.

The challenged rule only sets minimum requirements. The 1974 rule goes on to spend one sentence specifically discussing a potential drawback to setting minimum requirements—that facilities would strive only to meet those minimums. *See id.* ("A minimum ratio could result in all facilities striving only to reach that minimum and could result in other facilities hiring unneeded staff to satisfy an arbitrary ratio figure."). An agency's recognition of a potential downside to a policy choice does not constitute definitive rejection of that policy. Agencies recognize the potential benefits and associated burdens of policy choices that they make all the time; indeed, that is part and parcel of making a rational decision.

Furthermore, in crafting the Final Rule here, CMS addressed these potential drawbacks raised years ago. Responding to the risk of "facilities striving only to reach th[e] minimum[,]" CMS noted that "[t]he additional requirements in this rule to bolster facility assessments are intended to . . . guard against any attempts by LTC facilities to treat the minimum staffing standards included here as a ceiling, rather than a floor (baseline)." 89 Fed. Reg. 40883. In response to the potential that facilities may hire "unneeded staff to satisfy an arbitrary ratio," CMS noted that the staffing requirements are set at a minimum level to ensure that "all residents across all facilities will be at significantly lower risk of receiving unsafe and low quality care." *Id.* at 40892. Moreover, the 1974 rulemaking occurred more than a decade before enactment of FNHRA, which substantially revised the statutes governing the participation of nursing homes in the Medicare and Medicaid programs based on concerns about the treatment and condition of residents.

1986 Institute of Medicine Study. Plaintiffs selectively quote from the 1986 Institute of Medicine Study to argue that CMS previously rejected minimum staffing requirements, but that study expressly supports regulations to increase nursing home staffing. For example, within the section titled "Issues Requiring Further Study" is a subsection for "Staffing of Nursing Homes" that recommends undertaking a study "to develop a minimum staffing algorithm relating staffing to case mix[.]" Institute of Medicine Study at 44. *See also id.* at 190. In the very same section from which Plaintiffs' quotation

is plucked, the study states that if "more licensed nurses are required to provide proper care to the residents, the nursing home should be required to provide it." *Id.* at 102-03. It also notes that "[a]lthough there has not been extensive research on staffing patterns, there is little doubt that qualified nursing personnel are one of the most important factors affecting high quality of care." *Id.* at 101. The final sentence of the section underscores the study's support for minimum staffing requirements, stating that "[i]ncreasing staffing may cause some problems initially, but the committee believes that the benefits to the residents of increasing the ratio of better-trained staff far outweigh the costs of increased staffing." *Id.* at 103. While these excerpts fit with the study's underlying support for increased staffing, the lone sentence Plaintiffs use to support their position is followed by a critically omitted point: The study found that "[u]ntil 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." *Id.* at 102. Such data is now generally available, and empirical studies have been completed. Although the study declined at the time to recommend "prescribing simple staffing ratios," it repeatedly supports regulations that would increase staffing in LTC facilities. Any suggestion that this study demonstrates that CMS was previously opposed to minimum staffing requirements is simply unfounded.

2015-16 Rulemaking. In describing the agency's 2015-16 rulemaking, Plaintiffs yet again lean on their mischaracterization of the 2024 Final Rule. Plaintiffs cite to a section of the 2015 proposed rule discussing whether to establish regulations defining what constitutes "sufficient" staffing for LTC facilities. But as described above, CMS did not do that here. It only set a minimum.[3] And the agency

[3] In fact, the 2016 final rule parses the very conflation that Plaintiffs make here, explaining that:

> Such minimum staffing standards are not a precise statement of how many staff are required to fully meet the needs of each specific group of residents on each unit, nor are they a quality improvement tool to optimize quality in each LTC facility. Rather, a

underscored its openness to minimum staffing requirements through its request for further study on such minimums in the very same section of the 2015 proposed rule:

> We considered combining this approach with a minimum staffing requirement. Options included establishing minimum nurse hours per resident day, establishing minimum nurse to resident ratios, requiring that an RN be present in every facility either 24 hours a day or 16 hours a day, and requiring that an RN be on-call whenever an RN was not present in the facility. . . . We welcome comment on all of these options. . . . We also invite comment on the benefits of a mandatory 24 hour RN presence . . . [and] evidence of appropriate thresholds for minimum staffing requirements[.]

80 Fed. Reg. 42168, 42201 (July 16, 2015). CMS also noted that "States have found that requirements for increased staffing levels resulted in improved resident care outcomes and decreased deficiencies." *Id.* at 42202. Finally, CMS reiterated that it "will reconsider these options in light of future research, recommendations, and the availability of more valid and reliable payroll-based staffing data." *Id.* at 42242.

The 2016 final rule similarly supported the concept of minimum staffing requirements. Plaintiffs quote a sentence of the rule where CMS recognizes a potential drawback of minimum requirements, but they overlook the agency's very next sentence, which clarified that: "[CMS] continue[s] to believe that our proposed requirement is necessary to address concerns about inadequate staffing and resulting harm to residents." 81 Fed. Reg. 68754. Regarding a 24/7 RN requirement specifically, CMS did not "expressly reject" this requirement as Plaintiffs claim, Pls.' Br. at 24, but rather stated "we are not mandating a 24/7 RN presence in each facility *at this time*," citing "concerns about the validity of self-reported staffing data" and noting that "payroll based reporting . . . may give us a better picture[.]" 81 Fed. Reg. 68755 (emphasis added); *see also id.* (CMS "remain[s] convinced that additional data will be helpful in determining if and what such [minimum staffing]

> 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.

Id. (quotation omitted).

ratios should be."). CMS then noted that it "has begun mandatory, payroll-based collection of staffing information" and "believe[s] this information, once a sufficient amount is collected . . . could greatly assist us in re-evaluating this issue." *Id.* at 68756. Such data is now available, and it provides ample support for the challenged requirements of the Final Rule. *See* Defs.' MSJ at 30 ("The implementation of the Payroll Based Journal ('PBJ') system in 2016 has since provided more reliable data than was previously available." (citing 89 Fed. Reg. 40879-80)).

Despite this explicit support for exploring minimum staffing requirements, Plaintiffs claim that CMS "rejected rigid 'minimum staffing ratios' in favor of a more 'flexib[le]' approach that determines 'sufficient staff' by considering 'facility- and resident-specific factors[.]'" Pls.' Br. at 24. Setting aside that those quotations are taken from the agency's discussion of the facility assessment, not its discussion of minimum staffing requirements, again, the minimums at issue in this case do not supplant the independent statutory requirement to "provide nursing services 'sufficient to meet the nursing needs of [facilities'] residents.'" 42 U.S.C. §§ 1396r(b)(4)(C)(i)(I), 1395i–3(b)(4)(C)(i). That is the difference between the policy CMS actually chose and the straw man Plaintiffs argue against.

At most, CMS's approach to minimum staffing requirements in prior years could be considered cautious, given the lack of available data. The record shows that at every turn, the agency has uniformly acknowledged the need for increased staffing. And when it has considered minimum requirements in the past, it has occasionally addressed potential drawbacks while affirming their utility in addressing chronic understaffing. It has always maintained that it would need more reliable data to set and enforce any minimum requirements, which is why it had not done so until this Final Rule. Plaintiffs' characterization that CMS has "firmly rejected" minimum requirements as "counterproductive[,]" Pls.' Br. at 26, simply contradicts the record. The agency now has the necessary data and has taken the long-contemplated step of establishing minimum staffing requirements as necessary for the health and safety of nursing home residents.

2. CMS Need Not Acknowledge A Change In Policy Where It Has Not Changed Its Policy

Plaintiffs' argument that the agency has not adequately explained its change in position fails primarily because, as described above, CMS has not changed its position on minimum staffing. Rather, the Final Rule is a clear example of an agency adopting a policy in the first instance, not rescinding or reversing a prior policy. But even if the culmination of a years-long research effort to determine how best to increase staffing in LTC facilities could be seen as a change in policy, the Supreme Court has been clear that even in situations where the agency changes course, the APA does not require a heightened level of arbitrary and capricious review. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). An agency still must only articulate "a rational connection between the facts found and the choice made." *Dep't of Com.*, 588 U.S. at 773.

The Supreme Court's decision in *FCC v. Fox Television Stations, Inc.* is instructive. That case involved the FCC's indecency ban which prohibited profane language in broadcasts during certain hours. *Id.* at 506. The FCC's prior policy had been that isolated or fleeting use of certain expletives was not indecent. *Id.* at 507-08. But with this enforcement action, the FCC reversed course, determining that even fleeting expletives could be indecent. The broadcaster sued under the APA, among other claims, arguing that this change in position was arbitrary. *Id.* at 508-09. In its decision, the Supreme Court drew a distinction between an agency's prior nonaction versus an agency's recission or reversal of a prior action. *See id.* at 514-15. The Court upheld the FCC's decision, holding that even when an agency is rescinding prior action rather than establishing new regulations for the first time, it does not have to justify its decision by reasons more substantial than those required to adopt a policy in the first place. *Id.* at 515. ("[T]he agency need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate[.]") And when an agency is adopting a policy in the first instance, it need only "show that there are good reasons" for the new policy. *Id.*

Here, CMS is firmly in the "blank slate" posture, establishing minimum nurse staffing requirements for the first time, so acknowledgement of a "chang[ed] position" is not required. *Id.* A reasoned explanation *might* require more if CMS had established these minimum requirements before and then decided they were no longer needed, marking a reversal in position. But even if CMS were reversing its prior policy, express acknowledgement of the change is only a factor in the court's determination of whether a decision is well explained. *Id.* In the Final Rule, CMS fully explained its good reasons to establish minimum nurse staffing requirements now, after learning hard lessons from the COVID-19 pandemic and gaining access to new, more reliable data through the Payroll Based Journal system. Indeed, the Proposed and Final Rule are replete with references to the newly available PBJ data and research stemming from the COVID-19 pandemic. *See, e.g.*, 89 Fed. Reg. 40876-77, 40880, 40882-83, 40888-89, 40893, 40948, 40987.

3. CMS Thoroughly Explained Why It Adopted Minimum Staffing Requirements Now

Plaintiffs next argue that CMS's reasons for deciding to establish minimum staffing requirements now are unpersuasive.[4] They wonder how it is that the COVID-19 pandemic "should now warrant measures" that they believe the agency previously rejected. Pls.' Br. at 26. First, as described above, CMS never rejected minimum requirements on principle and has uniformly supported regulations to increase staffing. Second, CMS thoroughly explained in the Final Rule its facially rational determination that the hundreds of thousands of nursing home resident deaths from a global pandemic, at a level vastly disproportionate to the rest of the population, and subsequent research linking those deaths to chronic understaffing, provided a good reason to finally establish

[4] Notably, in arguing that CMS's reasons are not good enough, Plaintiffs inherently concede that CMS did give reasons for adopting the Final Rule, and so it is not "unexplained." *See* Pls.' Br. at 1, 25-27.

minimum staffing requirements. CMS repeatedly cited the lessons learned and new research stemming from the pandemic throughout the rulemaking process. *See supra* 24.

Furthermore, in every instance in which CMS previously considered minimum staffing requirements and declined to implement them, it cited the lack of reliable data needed to set and enforce any potential minimums as reason for doing so. *See, e.g.*, 45 Fed. Reg. 47371 (July 14, 1980); Institute of Medicine Study at 19, 101-03; Abt. Associates, Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes at 10, 17 (2001), *available at* https://www.justice.gov/sites/default/files/elderjustice/legacy/2015/07/12/Appropriateness_of_Minimum_Nurse_Staffing_Ratios_in_Nursing_Homes.pdf; Letter from Sec'y Thommy G. Thompson to Rep. Hastert 1 (Mar. 19, 2002), reprinted as Appendix 1, *available at* https://archive.ph/KQWPt; 80 Fed. Reg. 42200; 81 Fed. Reg. 68755-56. Plaintiffs' suggestion that this rationale is post hoc, *see* Pls.' Br. at 26, is perplexing, given that Defendants have cited this rationale for at least a quarter century. The PBJ system was implemented in 2016 and has since then provided the reliable data that was previously unavailable. 89 Fed. Reg. 40879-80. Critically, the PBJ data is auditable because it is based on payroll, and facilities are required to provide this data on a frequent and regular basis. *Id.* at 40889. Several years of data collection are now available, and this data was used by the very studies that informed the minimum staffing requirements in the Final Rule. Acquiring sufficient reliable data necessary for setting minimum requirements, data that was previously lacking, is a plainly rational justification for establishing these requirements now.

Ultimately, Plaintiffs' argument that the Final Rule is an unexplained change in policy fails because CMS's decision to establish minimum staffing requirements now that sufficient data is available and it has learned lessons from the COVID-19 pandemic is rational and thoroughly explained in the Final Rule.

B. Plaintiffs Fail To Show The Final Rule Is Unreasoned In Any Way

Setting minimum staffing requirements is a rational response to decades of research demonstrating the perils of chronic understaffing in nursing homes. Plaintiffs claim the rule is "unreasonable" because they see it as precluding variation in staffing between facilities and because of their concerns about alleged compliance challenges. Pls.' Br. at 27. But the minimums do not preclude—and the statute indeed *requires*—variation in staffing between facilities, according to what is "sufficient to meet the nursing needs of [their] residents." 42 U.S.C. §§ 1396r(b)(4)(C)(i)(I), 1395i–3(b)(4)(C)(i). The rule merely sets the minimum standard of nurse staffing that is necessary to meet the health and safety needs of residents. And the alleged compliance challenges are overstated and were sufficiently addressed in the rulemaking process.

1. The Final Rule Allows Staffing Variation Between LTC Facilities

Plaintiffs first argue the rule is unreasonable because of "variation among nursing homes' resident populations," Pls.' Br. at 27, and because of "variation among the States[,]" *id.* at 28. These arguments misunderstand the rule. As stated *supra* 17-18, 22, the rule does not displace the independent statutory requirement that a facility "provide nursing services 'sufficient to meet the nursing needs of its residents.'" 42 U.S.C. §§ 1396r(b)(4)(C)(i)(I), 1395i–3(b)(4)(C)(i). Based on a particular facility's case mix, acuity, and other factors, it may well need to staff above the minimum requirements, as the Final Rule recognized. *See* 89 Fed. Reg. 40883 (describing minimum requirements as a floor, not a ceiling for safe staffing); *Id.* at 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[.]").

Plaintiffs complain that the rule will lead to "overstaffing[.]" Pls.' Br. at 27. This is not so because CMS has 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"). But even if some facilities were to perceive themselves to be overstaffed a result of the Final Rule, the Secretary has determined that the overall health and safety benefits of the minimum staffing requirements outweigh the costs. *See* 89 Fed. Reg. 40878, 40970, 40949-50. And the rule cannot lead to "understaffing[,]" Pls.' Br. at 27, because the statutory "sufficient" staffing requirement remains in place. *See* 89 Fed. Reg. 40879; 42 U.S.C. §§ 1396r(b)(4)(C)(i)(I), 1395i–3(b)(4)(C)(i).

Plaintiffs argue that the Final Rule is "irreconcilable with the judgment of . . . state governments." Pls.' Br. at 29. But it is the Secretary, not state governments, who was tasked by Congress with issuing regulations "relating to the health and safety of residents" in federally funded nursing homes. The fact that the states can adjust their own Medicaid rates, *see* Pls.' Br. at 28, is not a basis to permit nursing homes to provide a level of staffing below what the Secretary has determined is necessary for the health and safety of residents. Of course, facilities are free to decline federal Medicare and Medicaid payments and thus not be subject to the Final Rule, but the Secretary is charged with ensuring federal funds are used only to pay for the purposes that Congress intended.

Plaintiffs also claim that the minimum staffing requirements cannot be necessary for resident health and safety because they allege that "CMS's own survey findings . . . indicate that 'roughly 95 percent of facilities' are 'providing sufficient nursing staff'" despite not meeting "one or more of the new requirements[.]" Pls.' Br. at 29. The source of this statistic is not clear, as Plaintiffs' record citation is to their own comment on the Proposed Rule. *See* AR_00057776. But even if this data is correct, facility assessments, though "an important complement to the minimum staffing requirements[,]" 89 Fed. Reg. 40906, are distinct from the minimum staffing requirements. And the Secretary has found the minimum requirements independently necessary to the health, safety, and well-being of nursing home residents. 89 Fed. Reg. 40877 ("Each of the minimum staffing requirements independently

supports resident health and safety and is evaluated separately."); *Id.* at 40908 ("The facility assessment . . . is a separate requirement . . . . Each requirement works independently to achieve the separate goals of a minimum nurse staffing requirement and an assessment of the resources that are required to care for the LTC facility's resident population."). Furthermore, a facility assessment is only a snapshot in time and does not necessarily provide a comprehensive picture of needed care, which is why CMS relies on additional information beyond the assessments, including PBJ data, to set the minimum staffing requirements.

Plaintiffs also invoke the 2022 Abt Study to argue that CMS has failed to "identify any optimal" point at which to set the minimum requirements. Pls.' Br. at 28. But an agency is not required to identify the "optimal" threshold when it regulates. 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. That approach is entirely consistent with the agency's obligation to reasoned decision-making under the APA. *See WorldCom, Inc. v. FCC*, 238 F.3d 449, 461-62 (D.C. Cir. 2001) (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."). The Secretary has clearly elucidated the standards and has thoroughly explained the extensive research relied upon and factors considered in setting them. *See, e.g.*, 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."); *id.* (explaining CMS's consideration and rejection of various alternatives).

2. Plaintiffs' Reiterated Compliance Concerns Do Not Undermine The Final Rule's Reasonableness

The remainder of Plaintiffs' arguments largely reiterate points raised in their opening brief that were already addressed in Defendants' Opposition and Cross-Motion, ECF No. 80-1. Plaintiffs' compliance concerns are overstated and were sufficiently addressed in the Final Rule. There are, however, a few additional points worth addressing.

First, Plaintiffs disregard the HHS/ASPE report detailing the significant number of facilities that already meet some or all of the minimum staffing requirements because it post-dates publication of the Rule. Pls.' Br. at 30. But the Final Rule itself cited the same CMS Care Compare underlying data (which includes PBJ data and census data, among other sources) that the ASPE report relied on. Furthermore, the point is not that CMS relied on this exact report, but that it did consider the data that shows most facilities already meet at least some of these minimum requirements. *See* 89 Fed. Reg. 40955-56 ("78% of LTC facilities had 24/7 RN coverage"); *id.* at 40957-58 (table of additional RNs needed in urban and rural areas); *id.* at 40967-69 (tables of estimated costs for HPRD requirements). The Final Rule acknowledges that the greatest area of need will be for additional NA hours. *Id.* 40976-80. 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.

Second, Plaintiffs fail to acknowledge the data the agency relied upon showing that the nursing workforce is improving, and that hundreds of thousands of trained nursing staff are available to return to the workforce if conditions are favorable, including facilities channeling their hidden profits into staff salaries instead. *See* Defs.' MSJ at 42-43. In doing so, Plaintiffs concede these points.

Third, and perhaps most fundamentally, Plaintiffs entirely brush aside the hardship exemption that is available to facilities that cannot meet the Final Rule's requirements despite good faith efforts to do so. Plaintiffs' arguments about alleged compliance challenges dissipate when the exemption is

considered. The Final Rule recognized that "a significant number of facilities are likely to meet the workforce availability criterion of the exemption," 89 Fed. Reg. 40953, and the other requirements to show good faith effort to hire and retain staff and document its financial commitment to doing so are fully within the facility's control, *id.* at 40877. The hardship exemption disposes of Plaintiffs' argument that compliance will be "simply impossible." Pls.' Br. at 29.

CMS conducted a thorough examination of the likely impact and potential challenges of minimum staffing requirements—including all the issues raised by Plaintiffs—and offered a reasoned explanation for its decision to adopt the minimums based on the record evidence. That is all the APA requires. The agency's decision is therefore firmly "within a zone of reasonableness," and should be upheld. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

III. ANY RELIEF SHOULD BE APPROPRIATELY LIMITED

No relief is warranted in this case because Plaintiffs have failed to establish that the challenged requirements exceed Defendants' statutory authority, or that they are arbitrary, capricious, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A), (C). In all events, however, Plaintiffs do not dispute that if this Court disagrees with Defendants' arguments, an injunction that prevents Defendants from enforcing the challenged portions of the Final Rule against Plaintiffs would fully remedy every injury they have alleged in this case. *See* Pls.' Br. at 33-35; Defs.' MSJ at 46-49. Nor could they: Plaintiffs have no interest in whether non-member facilities are subject to the Final Rule, nor standing to assert claims on behalf of facilities that Plaintiffs do not operate or represent. And it is similarly uncontested that any relief awarded should apply only to those aspects of the rule for which the Court finds Plaintiffs have met their burden for summary judgment relief. Plaintiffs themselves do not seek relief as to any portion of the Final Rule apart from the 24/7 RN and HPRD requirements and have demonstrated no entitlement to relief as to the portions of the rule they do not purport to challenge substantively. *See* Pls.' Br. at 33 (asking the Court "to vacate the 24/7 RN requirement and

all three HPRD requirements," but not any other part of the Final Rule); Defs.' MSJ at 47-48. Any relief in this case should therefore be appropriately limited.

For their part, Plaintiffs argue that because the Fifth Circuit has characterized vacatur as the "default" remedy under the APA, vacatur is "required" as to the 24/7 RN and HPRD requirements at issue here, citing *Texas Medical Ass'n v. HHS*, 110 F.4th 762 (5th Cir. 2024). Pls.' Br. at 33. That the Fifth Circuit in *Texas Medical* held that "universal vacatur [wa]s appropriate [t]here[]" does not mean that vacatur is the required remedy in the instant action, however. *Tex. Med. Ass'n*, 110 F.4th at 780. To the contrary, the Fifth Circuit recognized that remedies other than vacatur were available in *Texas Medical* itself. *See id.* at 779 (explaining that, in some circumstances, "remand *without vacatur* is available" (emphasis added)). The Fifth Circuit nonetheless held that universal vacatur was necessary in that specific case "to promote uniformity and predictability" when determining the amount an insured patient will pay for emergency services furnished by an out-of-network provider—"one of the Departments' primary justifications for the Final Rule[]" at issue there. *Id.* at 780 (quotations omitted). But Plaintiffs have failed to demonstrate that the same need for uniformity exists here.

Indeed, if universal vacatur were the mandatory remedy for every unlawful agency action, as Plaintiffs claim, Pls.' Br. at 34, the *en banc* Fifth Circuit plurality in *Cargill v. Garland* could not have remanded with the instruction to the district court that although "vacatur of an agency action is the default rule in this Circuit," the district court should consider whether "a more limited remedy is appropriate in these circumstances." 57 F.4th 447, 472 (5th Cir. 2023), *aff'd*, 602 U.S. 406 (2024). The *Cargill* plurality's remand instruction reflects the Supreme Court's teaching that a congressional authorization for courts to issue a remedy—such as vacatur under the APA (assuming the APA does authorize such a remedy)—"hardly suggests an absolute duty" to grant such relief "under any and all circumstances." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). *See also Nuziard v. Minority Bus. Dev. Agency*, 721 F. Supp. 3d 431, 501 (N.D. Tex. 2024) (refusing to vacate agency regulations implementing a

statutory provision that the court found unconstitutional, and instead enjoining enforcement of that provision).

Braidwood Management., Inc. v. Becerra, 104 F.4th 930 (5th Cir. 2024), *cert. granted*, (U.S. Jan. 10, 2025) (cited at Pls.' Br. at 33-35), does not require otherwise. The Fifth Circuit in *Braidwood* justified its decision to *withhold* universal relief primarily because the plaintiffs in that case did not bring an APA claim at all. *Braidwood Mgmt.*, 104 F.4th at 952. The Fifth Circuit did not consider whether vacatur was required when more limited relief can remedy a plaintiff's injury, as is the case here. And the APA by its plain terms adopts equitable limitations on this Court's remedial powers. 5 U.S.C. § 702 ("Nothing herein . . . affects other limitations on . . . the power or duty of the court to . . . deny relief on any other appropriate legal or equitable ground[.]"). *See also Hecht*, 321 U.S. at 329 (explaining "[t]he essence of equity jurisdiction has been the power . . . to do equity and to mold each decree to the necessities of the particular case"); *Trump v. Hawaii*, 585 U.S. 667, 716 (2018) (Thomas, J., concurring) ("Although courts of equity exercised remedial 'discretion,' that discretion allowed them to deny or tailor a remedy despite a demonstrated violation of a right, not to expand a remedy beyond its traditional scope."). Because all of Plaintiffs' alleged injuries are a result of being subject to the challenged staffing requirements, an injunction that prohibits application of those requirements to Plaintiffs' facilities would fully remedy their injuries without disruptive universal vacatur. Accordingly, if this Court disagrees with Defendants' arguments on the merits, it should do no more than enjoin application of the specific requirement or requirements found arbitrary and capricious or in excess of statutory authority as to the facilities Plaintiffs represent. *See* Defs.' MSJ at 48-49.

CONCLUSION

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

Dated: January 17, 2025

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Allison Walter
ALLISON M. WALTER
ANDREW J. RISING
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, D.C. 20005
Phone: (202) 616-8492
E-mail: allison.m.walter@usdoj.gov

Counsel for Defendants