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

STATE OF KANSAS, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., 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

DEFENDANTS' REPLY MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR JUDGMENT ON THE ADMINISTRATIVE RECORD

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INTRODUCTION

In 2024, the Centers for Medicare & Medicaid Services ("CMS") promulgated a rule ("Final Rule") establishing minimum nurse staffing requirements for nursing homes seeking Medicare or Medicaid funding. It did so relying on decades of nursing home staffing research and using a well-established "health and safety" rulemaking authority, the exercise of which was recently upheld by the Supreme Court. Defendants' opening brief, ECF No. 122-1 ("Defs.' Mot."), explained why the Court should uphold the Final Rule as a proper exercise of statutory authority that is neither contrary to law nor arbitrary or capricious in any respect. Plaintiffs' opposition, ECF No. 149 ("Pls.' Opp."), offers no persuasive argument to the contrary.

First, the Final Rule fits firmly within the agency's delegated rulemaking authority as it neither exceeds nor conflicts with the Medicare and Medicaid statutes. Plaintiffs fail to identify any actual conflict between the statutes and the portions of the Final Rule they challenge, and can point to no statutory provision that precludes CMS from establishing quantitative requirements for nursing home staffing generally using its broad rulemaking power. As to the facility assessment and Medicaid Reporting provisions in particular, Plaintiffs' arguments amount to no more than conclusory statements and legal conclusions, devoid of evidence or reasoning. And Plaintiffs cannot establish that the Final Rule implicates the major questions doctrine or casts constitutional doubt on the statutes.

Second, Plaintiffs' allegation that the Final Rule is arbitrary or capricious also falls flat. The regulatory history shows that CMS has long supported regulations to increase staffing in nursing homes, so the Final Rule does not constitute an unlawfully unexplained change in position. Furthermore, CMS thoroughly explained the decades of research relied upon to develop and promulgate the Final Rule, and articulated good reasons for doing so now based on the new availability of reliable data and the continued severity of chronic understaffing in the wake of the COVID-19 pandemic. The reliance interests and compliance challenges raised by Plaintiffs were thoroughly and

adequately addressed in the Final Rule. Contrary to Plaintiffs' suggestion, the Administrative Procedure Act ("APA") requires no more.

For these reasons, judgment should be granted for Defendants, and the Final Rule should not be disturbed. If the Court disagrees, relief should be limited to the aspects of the rule for which Plaintiffs have carried their burden and should extend no further than necessary to address the alleged harms to the Plaintiffs in this case.

BACKGROUND

This case arises out of a challenge to a Final Rule issued by the Centers for Medicare & Medicaid Services ("CMS"): *Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting*, 89 Fed. Reg. 40876 (May 10, 2024) (codified at 42 C.F.R. pts. 438, 442, 483) ("Final Rule"). The Final Rule requires that Medicare and Medicaid certified Long-Term Care ("LTC") facilities each have at least one Registered Nurse ("RN") "on site 24 hours per day and 7 days per week," (the "24/7 RN Requirement") 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" (the "HPRD Requirements"). *Id.* at 40877. It also consolidated and revised existing facility needs assessment requirements, moving the assessment requirements to a standalone section of CMS's regulations and specifying the scope of the assessment, *id.* at 40877 (referred to by Plaintiffs as the "Enhanced Facility Assessment" or "EFA"), and added a new Medicaid institutional payment transparency reporting provision, to gather information regarding the percentages of Medicaid payments being spent on compensation to direct care workers and support staff, *id.* at 40913-15 ("Medicaid Reporting Requirement").

In addition to this lawsuit, two other suits have been filed challenging the 24/7 RN and HPRD Requirements of the Final Rule. *See Am. Health Care Ass'n ("AHCA") v. Kennedy*, No. 2:24-cv-114-Z-BR (N.D. Tex. 2024); *Texas v. HHS*, No. 2:24-cv-00171-Z (N.D. Tex. 2024) (consolidated). In those

consolidated cases, the district court recently concluded that CMS exceeded its statutory authority in promulgating the 24/7 RN Requirement and the HPRD Requirements and vacated those requirements on a nationwide basis while severing the remaining portions of the Final Rule, without engaging with the parties' arguments as to whether the Final Rule is arbitrary or capricious. *See AHCA v. Kennedy*, No. 2:24-cv-114-Z-BR, 2025 WL 1032692 (N.D. Tex. Apr. 7, 2025). For the reasons articulated in their summary judgment brief and reply brief in that case, Defendants respectfully disagree with the scope of relief that the *AHCA* district court entered and its conclusion that the agency exceeded its statutory authority. *See* Defendants' Brief, *AHCA v. Kennedy*, No. 2:24-cv-114-Z-BR (N.D. Tex. Nov. 15, 2024), ECF No. 80-1; Defendants' Reply Brief, *AHCA v. Kennedy*, No. 2:24-cv-114-Z-BR (N.D. Tex. Jan. 17, 2025), ECF No. 99.

ARGUMENT

I. THE FINAL RULE FITS SQUARELY WITHIN CMS'S AUTHORITY TO PROTECT THE HEALTH, SAFETY, AND WELL-BEING OF NURSING HOME RESIDENTS

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 "requirements are necessary for resident health, safety, and well-being"); Defs.' Mot. at 11-33. Plaintiffs' response does not demonstrate otherwise as to any of the requirements contained within the Final Rule. *See* Pls.' Opp. at 2-21.

At the outset, although a district court judge in another circuit has entered an order that vacates the 24/7 RN and HPRD Requirements of the Final Rule nationwide, *see AHCA*, 2025 WL 1032692, that order should not guide the Court's decision here. The *AHCA* court erred in holding that the 24/7 RN and HPRD Requirements of the Final Rule exceeded the CMS's scope of authority. As to the 24/7 RN Requirement, the court failed to give proper consideration to the role that the words "at

least" play in the statutory scheme. And as to the HPRD Requirements, the *AHCA* decision failed to grapple with both the fact that CMS has permissibly filled up the details of the statutory scheme with respect to other qualitative requirements in the past, and the reasons why the HPRD Requirements are not a one-size-fits-all requirement even as they set a minimum baseline that applies irrespective of a particular facility's case-mix. Nor is this Court bound by the *AHCA* court's holding as to the appropriate scope of relief, which was grounded in Fifth Circuit precedent not binding on this Court. Indeed, one of the benefits of the "traditional system of lower courts issuing" party-specific relief is that it "encourages multiple judges and multiple circuits to weigh in only after careful deliberation, a process that permits the airing of competing views that aids th[e Supreme] Court's own decisionmaking process." *DHS v. New York*, 140 S. Ct. 599, 600 (2020) (mem.) (Gorsuch, J., concurring in the grant of a stay). Notwithstanding that a district court in the Northern District of Texas has vacated the 24/7 RN and HPRD Requirements, this Court should uphold the Final Rule in full for the reasons stated below and in Defendants' prior briefing.

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

Plaintiffs begin their response by noting that "Congress has expressly prohibited the Secretary of Health and Human Services ("HHS") from publishing rules and regulations that are 'inconsistent with' the [Medicare and Medicaid statutes]." Pls.' Opp. at 3 (citing 42 U.S.C. § 1302(a)). But nowhere in Plaintiffs' opposition do they explain how the 24/7 RN Requirement is actually "inconsistent with" the law. *Id.* To the contrary, there is no actual conflict between the challenged 24/7 RN Requirement and the statutory requirement to employ an RN for *at least* 8 hours per day, as demonstrated in Defendants' opening brief. *See* Defs.' Mot. at 16 ("After all, there can be no dispute that 24 hours is 'at least 8' hours" (quoting 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i))). Plaintiffs' response—that the phrase "at least" does not itself serve as a grant of rulemaking authority to CMS, Pls.' Opp. at 7-8—does not help their case. Indeed, Defendants do not argue otherwise; as explained in the Final

Rule, the 24/7 RN Requirement is an exercise of the Secretary's separate 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 per day RN requirement merely demonstrates that this exercise of CMS's separate health and safety authority does not conflict with the statute.

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). Because Defendants' exercise of their health and safety rulemaking authority under 42 U.S.C. §§ 1396r(d)(4)(B); 1395i-3(d)(4)(B), can plainly coexist with the "at least 8" hours per day RN coverage requirement set by Congress at 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i-3(b)(4)(C)(i), the Court should regard both as effective and uphold the 24/7 RN Requirement of the Final Rule. *See* Defs.' Opp. to Pls.' Mot. Summ. J. at 8, ECF No. 148 ("Defs.' Opp.") (citing *Me. Cmty. Health Options v. United States*, 590 U.S. 296, 315 (2020); Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 66 (2012)).

Nor does the 24/7 RN Requirement generate inconsistency by "nullif[ing] the statutory RN waiver." Pls.' Opp. at 8. Plaintiffs' argument on this point continues to misread the Final Rule by suggesting that facilities that seek a regulatory exemption of 8 hours per day of the 24/7 RN Requirement will be unable to also apply for the existing statutory waiver for all hours above 40 hours per week, 42 U.S.C. § 1395i-3(b)(4)(C)(ii). But the Final Rule "does not purport to eliminate or modify the existing statutory waiver," 89 Fed. Reg. 40878, and the existence of the new regulatory exemption does not "mean[] that an LTC facility will never be allowed to have less than 16 hours of nursing staff

per day[,]" as Plaintiffs allege. Pls.' Opp. at 8. Rather, the Final Rule permits facilities to seek *both* 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), if the applicable conditions for each are met. 89 Fed. Reg. 40899. CMS plainly explained as much in the Final Rule itself. *See id.* ("facilities who may also meet the requirements for the statutory waivers . . . will still have the ability to choose which process they want to pursue to achieve regulatory flexibility from the 24/7 RN requirement.").

Lacking any actual conflict between the 24/7 RN Requirement and statutory text, Plaintiffs turn instead to various interpretative canons in an attempt to conjure ambiguity where none otherwise exists. *See* Pls.' Opp. at 4-5 (invoking the statutory section subheadings and the major questions doctrine). But Plaintiffs' attempt to circumvent the plain language of the statute by reference to the subheading of the section housing CMS's rulemaking authority ignores that "[t]he 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 Corr. v. Yeskey*, 524 U.S. 206, 212 (1998) (quoting *Trainmen v. Baltimore & Ohio R. Co.*, 331 U.S. 519, 528-529 (1947)). Congress's express provision of the power to set "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary" contains no such ambiguity, and Plaintiffs do not argue otherwise. 42 U.S.C. § 1396r(d)(4)(B); *accord id.* § 1395i-3(d)(4)(B); *see also* Pls.' Opp. at 8 (resisting "any suggestion that the statutory language is ambiguous").

Plaintiffs' observation that neither section specifically "mentions any grant of authority to promulgate new staffing or hours requirements" is equally unpersuasive, because the standard for specificity Plaintiffs invoke lacks any basis in law. Pls.' Opp. at 5. Even under the major questions doctrine (which does not apply for the reasons set forth *infra* 11-14), "a broad grant of authority" that "plainly encompasses the [agency]'s actions . . . does not require an indication that *specific* activities are permitted." *Florida v. HHS*, 19 F.4th 1271, 1288 (11th Cir. 2021) (emphasis added). *See also Biden v.*

Nebraska, 600 U.S. 477, 511 (2023) (Barrett, J., concurring) (explaining that the major questions doctrine does not "require[] 'an unequivocal declaration' from Congress authorizing the *precise* agency action under review"). And it is black-letter law in the Eighth Circuit that CMS's "health and safety" authorities constitute such a broad grant of authority, leaving it "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), *cert. denied*, 143 S. Ct. 294 (2022). *See also Biden v. Missouri*, 595 U.S. 87, 94 (2022) *(per curiam)* ("the Secretary's role in administering Medicare and Medicaid goes far beyond that of a mere bookkeeper" and encompasses the power to impose requirements that relate to "healthcare workers themselves").

Plaintiffs' reference to the legislative and regulatory history surrounding CMS's regulation of nursing home staffing is also undercut by several key omissions. *See* Pls.' Opp. at 5-7. First, Plaintiffs neglect to respond *at all* to the Institute of Medicine's express recognition that CMS—and not Congress alone—possessed sufficient statutory authority to promulgate "minimum nursing staff requirements" for LTC facilities "into its regulatory standards" if and when "convincing evidence becomes available that some approaches to staffing and training are distinctly superior (in quality of care/life and cost) to others." Nat'l Library of Med., Inst. of Med., *Improving the Quality of Care in Nursing Homes* 200-01 (1986) ("Institute of Medicine Study") (cited at Defs.' Mot. at 24), https://archive.ph/KFNCi. Congress relied on this report heavily when crafting the very statutory provisions at issue in this case, and Plaintiffs do not dispute that its conclusions should be viewed as instructive of Congressional intent. *See Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 181 (2023). Nor is Plaintiffs' reference to prior Congressional inaction on the topic of a 24/7 RN Requirement convincing, Pls.' Opp. at 7. It "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. *See* Institute of Medicine Study at 200-01. And while they cite various examples of instances in which CMS has declined to pursue greater staffing regulation in the past due to a lack of sufficient data, Pls.' Opp. at 6-7, Plaintiffs fail to grapple with the fact that CMS's own longstanding position accords with the Institute of Medicine's understanding of its authority. *See* 81 Fed. Reg. 68688, 68756 (Oct. 4, 2016) (recognizing that CMS could reevaluate LTC facility staffing rules "once a sufficient amount [of data] is collected and analyzed"). *See also Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2265 (2024) ("exercising independent judgment is consistent with the 'respect' historically given to Executive Branch interpretations").

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

Plaintiffs' argument as to the HPRD Requirements is even weaker than its opposition to the 24/7 RN Requirement. CMS's statutory authority to promulgate "requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary" is equally clear as to both provisions, 42 U.S.C. § 1396r(d)(4)(B); *id.* § 1395i-3(d)(4)(B), and in the case of the HPRD Requirements, it is undeniable that the Final Rule is not contrary to or inconsistent with the statute, because the statute does not contain any preexisting HPRD requirements at all.

Instead, Plaintiffs mischaracterize Congress's existing "sufficient to meet the nursing needs of [its] residents" requirement as a "qualitative requirement[]" 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.' Opp. at 8-10. But text and context demonstrate, rather, that Congress was simply silent as to the question of quantitative minimum staffing standards because of the lack of available data at the time of the statute's enactment. *See supra* 7-8; Defs.' Mot. at 22-24. 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)(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, CMS lawfully supplemented Congress's existing *qualitative* standards with additional evidence-based *quantitative* requirements found necessary for the health and safety of residents, as Congress intended. *See* 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); 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, *Missouri*, 595 U.S. at 94 (citing 42 C.F.R. § 483.60(a)(1) with approval)—and Plaintiffs provide no credible grounds to distinguish those minimum staffing rules from the HPRD Requirements at issue here.

Through subsection (d)(4)(B), Congress established a general rule permitting CMS to set additional "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). That general rule plainly encompasses the power to require the employment of specific quantities of LTC facility staff, as CMS's prior judicially-approved staffing regulations demonstrate. *See, e.g.*, 42 C.F.R. §§ 483.60(a)(1), 483.80(b). As Plaintiffs concede, "if Congress establishes a general rule and does not exclude some specific cases, then the general rule applies." Pls.' Opp. at 12. Such is the case as to CMS's health and safety authority and the HPRD Requirements. But even assuming, *arguendo*, that Congress did not "intend[] to give CMS rulemaking authority on this issue," *id.*; *but see* Institute of Medicine Study at 200-01 (recognizing that the agency had sufficient authority to incorporate "minimum nursing staff requirements" for nursing homes "into its regulatory standards"), "the fact that a statute can be 'applied in situations not expressly anticipated by Congress does not

demonstrate ambiguity. It demonstrates breadth[,]'" *Yeskey*, 524 U.S. at 212 (quoting *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499 (1985)). Because the HPRD Requirements 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. Plaintiffs' Opposition Confirms That The Enhanced Facility Assessment And Medicaid Reporting Requirements Fit Within CMS's Statutory Authority

Plaintiffs fail to respond to Defendants' argument demonstrating why the EFA and Medicaid Reporting Requirements neither exceed nor conflict with CMS's statutory authority. *Compare* Defs.' Mot. at 25-27 *with* Pls.' Opp. at 2-21. That alone is reason enough to grant judgment to Defendants as to these elements of the Final Rule. *See Mark v. Ault*, 498 F.3d 775, 786 (8th Cir. 2007) (failure to raise or address an argument constitutes abandonment).

At most, Plaintiffs reference the EFA and Medicaid Reporting Requirements in passing, by asserting in their discussion of the major questions doctrine that "clear authorization for imposing minimum staffing requirements and the related assessment and reporting requirements does not exist," Pls.' Opp. at 17; *see infra* 11-14, and in arguing that Plaintiffs met their Rule 8 burden as to these requirements. Pls.' Opp. at 37-38. But they offer no actual argument to refute Defendants' showing that the EFA and Medicaid Reporting provisions are lawful exercises of statutory authority. Instead, Plaintiffs merely rest on their argument that the Final Rule is not severable (*but see infra* 27-31), and on the fact that their "prayer for relief specifically seeks a declaration that the EFA exceeds CMS's statutory authority and is arbitrary, capricious, or otherwise not in accordance with the law and an order vacating and setting aside the EFA and permanently enjoining Defendants from taking any action to enforce that requirement." Pls.' Opp. at 37. *Accord* Compl. at 61-62, ECF No. 1 (containing no such request as to the Medicaid Reporting Requirements). But such legal conclusions, "naked assertions devoid of further factual enhancement," and "formulaic recitation[s] of the elements of a cause of action" are plainly insufficient to state a claim, let alone to refute the reasons why judgment

should be granted in Defendants' favor. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Accordingly, for the unrebutted reasons stated in Defendants' opening brief, the EFA and Medicaid Reporting Requirements should not be disturbed. *See* Defs.' Mot. at 25-27.

D. The Final Rule Does Not Trigger Or Violate The Major Questions Doctrine

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 in *Missouri*, 595 U.S. 87. *See* Pls.' Opp. at 13-19; Defs.' Mot. at 27-32. Plaintiffs' failure to grapple with *Missouri* is fatal to their attempt to invoke the major questions doctrine. In *Missouri*, 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). Indeed, the dissent invoked the same arguments for economic, political, social, and federalism-related significance Plaintiffs echo here, while 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," *id.* at 104 (Alito, J., dissenting) (quoting *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (cited at Pls.' Opp. at 4, 10, 14)). Yet the Supreme Court upheld the indisputably significant rule at issue without applying Plaintiffs' clear statement rule, concluding that it was "not [] surprising" that CMS would use the same authority at issue here "to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients' health and safety." *Id.* at 90, 95. In this regard, the Supreme Court's rejection of a clear statement rule in *Missouri* is highly instructive, and Plaintiffs offer no rebuttal to it on the question of whether the major questions doctrine applies in the first place. *See* Pls.' Opp. at 14-16.

Missouri thus confirms that the Final Rule does not trigger or violate the major questions doctrine. Plaintiffs' argument to the contrary—that mere economic or political significance alone is sufficient to trigger the doctrine, Pls.' Opp. at 14-16—ignores the non-application of the doctrine in *Missouri*. Indeed, courts regularly decide challenges to agency actions of major economic and social significance under the usual rules of statutory interpretation, without imposing heightened-specificity requirements. *See, e.g., Collins v. Yellen*, 594 U.S. 220, 237-38 (2021); *Little Sisters of the Poor Saints Peter & Paul Home v. Penn.*, 591 U.S. 657, 675-76 (2020); *Dep't of Comm. v. New York*, 588 U.S. 752, 776-77 (2019); *cf. Trump v. Hawaii*, 585 U.S. 667, 683-84 (2018).

Even if the major questions doctrine did apply, the Final Rule does not violate it because none of the indicia referenced by Plaintiffs are appliable here. *See* Pls.' Opp. at 17 (citing *West Virginia v. EPA*, 597 U.S. 697, 746-48 (2022) (Gorsuch, J., concurring)). The absence of the first factor cited by Plaintiffs, "whether the agency relies on 'oblique or elliptical language' or 'seeks to hide elephants in mouseholes,'" *id.* (cleaned up), is resolved by reference to controlling precedent on the scope of the authorities at issue. The Eighth Circuit has already made clear that CMS's health and safety rulemaking authority is no mousehole—rather, CMS's authorities operate "capaciously," and "are broadly worded to give HHS significant leeway in deciding how best to safeguard LTC residents' health and safety." *Northport*, 14 F.4th at 870. *See also* Defs.' Opp. at 9 ("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.'" (quoting *Atl. Richfield Co. v. Christian*, 590 U.S. 1, 22 (2020))); *Missouri*, 595 U.S. at 94 ("the Secretary's role in administering Medicare and Medicaid goes far beyond that of a mere bookkeeper" and encompasses the power to impose requirements related to "healthcare workers themselves"); *id.* at 93 (concluding the rule challenged "fits neatly within the language of the statute.").

Plaintiffs' second argument, that CMS has "deploy[ed] an old statute focused on one problem to solve a new and different problem," Pls.' Opp. at 17 (citation omitted), is also unpersuasive.

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."). 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, 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.

Third and finally, Plaintiffs argue that "CMS has never imposed minimum staffing mandates, or asserted its ability to do so on the basis of its 'health and safety authorities.'" Pls.' Opp. at 18. 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 staffing-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, e.g.,* Defs.' Mot. at 12-13. In each case, CMS lawfully exercised its health and safety authority to require facilities to employ a minimum number of specific types of staff. By Plaintiffs' own logic, these prior exercises of the same authority at issue here thus demonstrate that "such power was actually conferred" for purposes of the major questions doctrine. Pls.' Opp. at 18 (quoting *West Virginia*, 597 U.S. at 724).

E. Plaintiffs' Opposition Confirms That The Final Rule Casts No Constitutional Doubt On CMS's Authorizing Statute

In their opening brief, Defendants explained that CMS's statutory authority to promulgate rules nursing homes must follow in order to receive Medicare or Medicaid funding is predicated on the agency's adherence to an adequate "intelligible principle" set forth by Congress: that the rules CMS seeks to enact pursuant to this authority must be "relat[ed] to the health and safety of residents or [] to the physical facilities thereof." Defs.' Mot. at 33 (quoting 42 U.S.C. § 1396r(d)(4)(B), *accord id.* § 1395i-3(d)(4)(B)); *see also* Defs.' Opp. at 11-13. Rather than grappling with that intelligible principle, Plaintiffs simply pretend it does not exist. *See* Pls.' Opp. at 20 (wrongly asserting that CMS "never gets around to describing what that intelligible principle is for the Medicaid and Medicare statutory delegations it relies on"). Plaintiffs' argument fails because a requirement that CMS's rules be "relat[ed] to the health and safety of residents or [] to the physical facilities thereof" is a sufficient intelligible principle for purposes of the canon of constitutional avoidance, as the Supreme Court has confirmed by upholding similarly broad delegations repeatedly over the past century. 42 U.S.C. § 1396r(d)(4)(B); *see* Defs.' Mot. at 32-33, n. 11 (citing cases).

The health and safety intelligible principle set forth by Congress here is indeed "broad but not boundless." *Saxton v. Fed. Hous. Fin. Auth.*, 901 F.3d 954, 960 (8th Cir. 2018) (Stras., J., concurring) (cited at Pls.' Opp. at 20). If CMS were to promulgate a rule found to be unrelated to resident health and safety or nursing homes' physical facilities under this authority, it would indeed exceed Congress's

authorization. But that is not the case here, as Plaintiffs do not dispute that nursing home staffing levels are plainly related to resident health and safety. *See* 89 Fed. Reg. 40890 (finding that the challenged "requirements are necessary for resident health, safety, and well-being"). The intelligible principle at issue is no broader than the one upheld by the Supreme Court in *Whitman v. Am. Trucking*, where Congress similarly authorized an agency to regulate to the level it deemed required to "protect the public health." 531 U.S. 457, 472 (2001) (cited at Pls.' Opp. at 4, 5). *See also Gundy v. United States*, 588 U.S. 128, 146 (2019) (plurality opinion) (noting that Supreme Court has 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'" (citations omitted)).[1] Plaintiffs do not even attempt to grapple with this adverse controlling precedent in their opposition brief. *See generally* Pls.' Opp. at 19-21. Because a requirement that delegated authority be exercised in a manner "relat[ed] to the health and safety of residents or [] to the physical facilities thereof" is an adequate intelligible principle, the Court should reject Plaintiffs' argument that the Final Rule casts constitutional doubt on CMS's authorizing statute.

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

CMS has for decades consistently supported regulations to increase staffing in LTC facilities. The regulatory history shows that CMS has never rejected minimum staffing requirements on the merits, and has instead reiterated time and again the need for more reliable data upon which to set and enforce such requirements. But even if establishing minimum LTC nurse staffing requirements in the first instance could be considered a "sharp departure" in policy, which it cannot, CMS fully

[1] And again, where the Supreme Court voiced no objection to CMS's exercise of the same "health and safety" authority at issue when reviewing the agency's promulgation of a nationwide healthcare worker vaccination rule, it makes little sense to conclude that the same authority now constitutes a glaring violation of the nondelegation doctrine, as Plaintiffs allege. *See Missouri*, 595 U.S. at 90-95.

explained its reasons for establishing these requirements now—the necessary data is now available, and research stemming from the COVID-19 pandemic laid bare the sweeping extent of the understaffing problem. The agency has more than met the APA's deferential 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 (citation omitted).

A. CMS Has Never Rejected The Concept Of Minimum Staffing Requirements

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. at 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."). 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 straw man of the latter. That is not an immaterial distinction. Plaintiffs' mischaracterization directly undercuts their argument that the challenged requirements represent a "sharp departure from past practice[.]" Pls.' Opp. at 22.

Plaintiffs' sparse and out-of-context quotations of regulatory history largely speak to the propriety of prescribing what would be a *correct or optimal* staffing ratio, not to 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 but has instead noted the need for further study based on more reliable data. CMS has therefore remained steadfast in its support for regulations to increase staffing in LTC facilities. Defendants have thoroughly addressed Plaintiffs' misunderstanding of the regulatory history from 1974 through 2016 in their opening and opposition briefs, *see* Defs.' Mot. at 40-42 and Defs.' Opp. at 17-19, and will not reiterate those arguments here, except to emphasize that the regulatory history confirms CMS's consistently held position that regulations to increase staffing in LTC facilities would yield improved quality care and better health and safety outcomes for residents. Despite this explicit support for exploring minimum staffing requirements, Plaintiffs claim that CMS has "consistently rejected" minimum requirements in favor of a "flexible staffing mandate." Pls.' Opp. at 23, 28. But, again, LTC facilities retain flexibility because 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 "consistently rejected" minimum requirements as a matter of policy, Pls.' Opp. at 23, 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.

B. 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 departed from 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 set minimum staffing levels 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 (citation omitted).

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. 556 U.S. 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 the challenged enforcement action, the FCC reversed course, determining that even fleeting expletives could be indecent. The broadcaster sued under the APA, arguing, *inter alia*, 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 rescission 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 adopts 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 ("PBJ") 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.

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

Plaintiffs next argue that CMS's reasons for establishing minimum staffing requirements now are unpersuasive.[2] They wonder how it is that research stemming from the COVID-19 pandemic could support the rule when "people who [a]re elderly, already in poor health, or living in group settings" are more likely to die from COVID anyway, and because "the COVID-19 emergency formally ended." Pls.' Opp. at 26-27. Plaintiffs have entirely missed the point.

First, as described above and in Defendants' prior briefing, 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,

[2] Notably, in arguing that CMS's reasons are not good enough, Plaintiffs implicitly concede that CMS did give reasons for adopting the Final Rule, and so it is not unexplained. Pls.' Opp. at 22-25.

provided a good reason to finally establish minimum staffing requirements. CMS cited a 2020 study involving all of Connecticut's 215 nursing facilities that found that just 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. Plaintiffs' brushing aside the deaths of hundreds of thousands of nursing home residents just because they were "elderly, already in poor health, or living in group settings" ignores the point for which the Final Rule cites this research—increased staffing would have led to fewer deaths. This lesson bears importance not only for the COVID-19 virus itself, but also for other viruses or illnesses that could again have an outsized impact on LTC facilities if they remain chronically understaffed. CMS repeatedly cited the lessons learned and new research stemming from the pandemic throughout the rulemaking. *See supra* 19.

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), 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 Tommy G. Thompson to Rep. Hastert 1 (Mar. 19, 2002), reprinted as Appendix 1, https://archive.ph/KQWPt; 80 Fed. Reg. 42168, 42200 (July 16, 2015); 81 Fed. Reg. 68755-56. 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 of 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.

In arguing that "CMS identifies no reasonable justification" for the rule, Plaintiffs reiterate the allegations from their Complaint in an attempt to undermine the 2022 Abt Study. Pls.' Opp. at 25-26; Abt Associates, *Nursing Home Staffing Study Comprehensive Report* (2022), https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf. Defendants fully addressed these inaccurate allegations in their opening brief, Defs.' Mot. at 42-44. As CMS explained in the rule, "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." 88 Fed. Reg. 61357. And in any event, the Abt Study is not the only basis for the Final Rule. *See id.* at 61359-65 (detailing the "systematic literature review," "qualitative analysis," "quantitative analysis[,]" "[c]ost and [s]avings [a]nalysis," "PBJ System data," and "listening sessions" reviewed by CMS and Abt as support for the requirements of the Final Rule). The Abt Study itself referenced the voluminous existing literature tying increased staffing levels to improved patient outcomes. *See, e.g.*, 2022 Abt Study at 8-14.

To the extent Plaintiffs take issue with the specific staffing levels chosen by CMS, that argument reduces to a dispute over where to draw the line. An agency is not required to identify the "optimal threshold with pinpoint precision" threshold when it regulates. *See WorldCom, Inc. v. FCC*, 238 F.3d 449, 461-62 (D.C. Cir. 2001). As CMS explained, the body of research, including 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 of reasoned decision-making under the APA. *WorldCom, Inc.*, 238 F.3d at 461-62 (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).

D. 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 "failed to account for reliance interests" because Plaintiffs see the rule as precluding variation in staffing between facilities and because of Plaintiffs' concerns about alleged compliance challenges. Pls.' Opp. at 27, 30. 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 argue the rule is unreasonable because of "variations in circumstances within the different states" and "local conditions." Pls.' Opp. at 29. This argument misunderstands the rule. As stated *supra* 16-17, 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[.]"). LTC facilities therefore retain flexibility to "implement[] staffing requirements tailored to" the needs of their residents. Pls.' Opp. at 28. These facilities simply cannot (without a waiver or exemption) staff below the floor that CMS found is necessary for the health and safety of residents.

Relatedly, Plaintiffs argue that the Final Rule "ignores . . . state governments" because the rule's requirements exceed the minimum requirements of many states. Pls.' Opp. 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 the rates paid to Medicaid providers in their states, *see* Pls.' Opp. at 29, 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.

Finally, Plaintiffs argue the Final Rule is arbitrary because it "inflexibly mandate[s]" increasing certain "types of staffing[.]" Pls.' Opp. at 29. But CMS's decision to focus the rule on increasing RN and NA staffing levels specifically, in addition to total nurse staffing levels, was firmly based in research showing that increased staffing of RNs and NAs had a significant impact on health and safety outcomes of residents while increased staffing of LPN/LVNs had negligible impact. *Compare* 89 Fed. Reg. 40881 (RN and NA HPRD "have a strong association with safety and quality care"), *with id.* ("LPN/LVN hours per resident day, at any level, do not appear to have any consistent association

with safety and quality of care."), *and id.* at 40893 (There is "insufficient research evidence" to support establishing a minimum standard for LPN/LVNs.). While Plaintiffs may disagree with the policy choice made by the agency here, focusing the agency's efforts on increasing the types of nurse staffing that research shows garner the most benefit for the health and safety of residents is hardly arbitrary.

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

The remainder of Plaintiffs' arguments largely reiterate allegations raised in their Complaint that were already addressed in Defendants' opening and opposition briefs, ECF Nos. 122, 148. *See, e.g.*, Defs.' Mot. at 50-55 (workforce availability concerns); *id.* at 55-57 (implementation costs); *id.* at 57-58 (availability of hardship exemptions); *see also* Defs.' Opp. at 22-24. 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.' Opp. at 31; ASPE, *Nurse Staffing Estimates in US Nursing Homes, May 2024* (June 28, 2024), https://perma.cc/QN9U-P6PW. 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, if not most of, the rule's 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.* at 40976-80. But NA certification 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.' Mot. at 52. In doing so, Plaintiffs concede these points. Calling the data CMS relied upon "wishful thinking" is hardly a counterargument. *See* Pls.' Opp. at 33.

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 a facility's financial commitment to doing so are fully within the facility's control, *id.* at 40877. The hardship exemption disposes of Plaintiffs' argument that "many LTCs will not be able to comply with the Rule[.]" Pls.' Opp. at 32.

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).

E. Plaintiffs Fail To Show That Other Provisions Of The Final Rule Are Arbitrary Or Capricious

Plaintiffs' opposition brief confirms their failure to establish that the EFA or Medicaid Reporting requirements are arbitrary or capricious. As explained in Defendants' prior briefing, Plaintiffs fail to even meet their Rule 8 burden with regard to the EFA and Medicaid Reporting requirements. *See* Defs.' Mot. at 36-37, Defs.' Opp. at 22 n.6. In opposition, Plaintiffs state that they believe "those two requirements are an inseparable part of the Rule," Pls.' Opp. at 37, so the same

arguments apply. But simply attempting to retroactively fix pleading deficiencies through hypothetically copy and pasting arguments does not meet the burden of Rule 8. *See Thomas v. United Steelworkers Loc. 1938*, 743 F.3d 1134, 1140 (8th Cir. 2014) (citing *S. Walk at Broadlands Homeowner's Ass'n v. OpenBand at Broadlands, LLC*, 713 F.3d 175, 184 (4th Cir. 2013) ("It is well-established that parties cannot amend their complaints through briefing or oral advocacy.")); *see also Anderson v. Donahoe*, 699 F.3d 989, 997 (7th Cir. 2012) ("[A] plaintiff may not amend his complaint through arguments in his brief in opposition to a motion for summary judgment." (citation omitted)); *Am. Fed'n of State, Cnty. & Mun. Emps. Council 79 v. Scott*, 717 F.3d 851, 863 (11th Cir. 2013) ("A plaintiff may not amend her complaint through argument in a brief opposing summary judgment or one advocating summary judgment." (citation omitted)).

Moreover, the Rule is plainly severable for the reasons set forth in Defendants' opening brief and those below. *See* Defs.' Mot. at 60-61; Defs.' Opp. at 27-28; *infra* 27-31. Indeed, the EFA and Medicaid Reporting requirements serve distinct purposes from the 24/7 RN and HPRD Requirements. 89 Fed. Reg. 40913 ("the Medicaid reporting provisions of this final rule . . . operate independently of mandated levels of nurse staffing"); *id.* at 40908 ("The facility assessment requirement as set forth at § 483.71 is a separate requirement that is designed to ensure that each LTC facility has assessed its resident population to determine the resources, including direct care staff, their competencies, and skill sets, the facility needs to provide the required resident care.").

The few paragraphs of the Complaint cited by Plaintiffs in an attempt to argue that they meet their burden as to the EFA and Medicaid Reporting requirements refer to the Background section describing the EFA, which inherently does not advance legal arguments, *see* Compl. at 38-39, and the same conclusory statements addressed in Defendants' prior briefing that the EFA "imposes unreasonable administrative burdens" and "subjects [facilities] to vague requirements" without saying

how or why, *see* Compl. at 60-61. *See* Defs.' Mot. at 36-37, Defs.' Opp. at 22 n.6. These citations do nothing to further Plaintiffs' arguments here.

But even if Plaintiffs had pled enough to meet the Rule 8 burden, which they have not, the EFA and Medicaid Reporting Requirements are adequately explained in the Final Rule. CMS explained that the Medicaid Reporting Requirement collects information about the allocation of Medicaid funding that goes toward compensation for LTC direct care and support staff, which is "important for CMS and the public in helping determine whether Medicaid service payments are economic and efficient, as well as adequate to support sufficient access for beneficiaries to high quality care." 89 Fed. Reg. 40913-15. The EFA largely reorganizes the existing facility assessment requirements in a standalone section of the regulations and makes some modifications "to ensure that facilities have an efficient process" for documenting and assessing staff and resources in order "to provide ongoing care for its population that is based on the specific needs of its residents." *Id.* at 40877. CMS thoroughly considered the costs of all aspects of the Final Rule, including these requirements. *See id.* at 40878 (discussing total costs); *id.* at 40937-39 (discussing costs and administrative burden of EFA); *id.* at 40943-47 (tables summarizing the administrative and cost burdens for states of the Medicaid Reporting Requirement). And the EFA and Medicaid Reporting requirements themselves impose no additional staffing requirements, so Plaintiffs' reference to reliance interests and workforce shortages are inapt here. The agency's well-explained rationale and fulsome consideration of the burdens of these provisions easily meets the deferential standard that an agency act "within a zone of reasonableness." *See Missouri*, 595 U.S. at 96 (quoting *Prometheus Radio Project*, 592 U.S. at 423).

III. ANY RELIEF SHOULD EXTEND NO FURTHER THAN THE PROVISIONS OF THE FINAL RULE DEEMED UNLAWFUL AND THE PARTIES TO THIS CASE

For the reasons set forth above, no relief is warranted and judgment should be entered in favor of Defendants because the Final Rule is lawful in its entirety. Even assuming, *arguendo*, this Court finds in Plaintiffs' favor as to either the 24/7 RN Requirement or the HPRD Requirements, however, it

should do no more than issue declaratory relief as to the specific provision deemed unlawful. *See Anatol Zukerman & Charles Krause Reporting, LLC v. U.S. Postal Serv.*, 64 F.4th 1354, 1366-67 (D.C. Cir. 2023).

Although Plaintiffs note that the Eighth Circuit has described vacatur as the "default remedy" in APA cases, Pls.' Opp. at 39 (quoting *Missouri v. Trump*, 128 F.4th 979, 997 (8th Cir. 2025)), vacatur would be inappropriate and unnecessary here, *see* Defs.' Opp. at 24-26. *See Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (explaining that relief "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs"). And contrary to Plaintiffs' suggestion that vacatur is a required remedy whenever a court reaches the merits of an APA claim, *see* Pls.' Opp. at 39-40, it is well-settled that Congressional authorization for courts to issue a remedy such as vacatur under the APA (assuming the APA authorizes 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, e.g., 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 found unconstitutional on summary judgment, and instead enjoining enforcement of that provision); *N. New Mexico Stockman's Ass'n v. U.S. Fish & Wildlife Serv.*, 494 F. Supp. 3d 850, 1041 (D.N.M. 2020), *aff'd*, 30 F.4th 1210 (10th Cir. 2022) ("The district court may vacate the entire [rule], or it may fashion a narrower form of injunctive relief based on equitable arguments."); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("If the record before the agency does not support the agency action . . . the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation.").

Moreover, even if vacatur were an appropriate remedy, any vacatur should apply only to the portions of the Final Rule held to be unlawful, since equitable relief must be limited to the unlawful conduct that produced Plaintiffs' injury. *See Labrador v. Poe*, 144 S. Ct. 921, 923 (2024) (Mem.) (Gorsuch, J. concurring) (explaining that "sweeping relief" entered by district court was error because "the plaintiffs had failed to 'engage' with other provisions of [the state's] law that [did not] presently

affect them"); Defs.' Mot. at 59-61. Plaintiffs wrongly suggest that the Court should nevertheless vacate the Final Rule in its entirety, on the grounds that Defendants have failed to rebut an alleged presumption of non-severability. *See* Pls.' Opp. at 42 (contending that the Final Rule's express severability clause "do[es] not meet CMS's burden to show which parts of the Rule, if any, can be severed from the rest."). But this argument flips the burden—courts are bound by "a strong presumption of severability," reflecting an obligation to "salvage rather than destroy" an otherwise lawful statute or regulation. *Barr v. Am. Ass'n of Pol. Consultants, Inc.*, 591 U.S. 610, 625-26 (2020). And that presumption is all the stronger here, given the Final Rule's express severability clause. *See id.* at 624; 89 Fed. Reg. 40913.

In all events, Defendants' opening brief demonstrated that each provision of the Final Rule is severable from the remainder, because 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) (cited at Defs.' Mot. at 60). Plaintiff's argument to the contrary amounts to an assertion that each element of the Final Rule is important to the agency. *See* Pls.' Opp. at 41 (arguing that "[t]he EFA is an 'important complement' to the staffing mandates," and that "[t]he state transparency reporting is similarly integral to the Rule's combined policy"). But that is not the test for severability; the mere fact that an element of the Final Rule has value does not mean that it cannot "function sensibly without the stricken provision." *MD/DC/DE Broads. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001).

Plaintiffs do not appear to contest that "any of the individual minimum staffing requirements can operate independently of the other staffing requirements." Pls.' Opp. at 42. Accordingly, if the Court were to find, *e.g.*, that CMS had adequate statutory authority to promulgate the HPRD Requirements but not the 24/7 RN Requirement, it need not and should not vacate both. *See* 89 Fed.

Reg. 40913 ("the specific HPRD and 24 hour, 7 day a week RN staffing requirements . . . could independently make improvements in the number of staff present at a LTC facility—the continuity of any one of the numeric standards would be helpful, and they do not require enforcement of the others to improve conditions at LTC facilities.").

Because the EFA and Medicaid Reporting requirements are also capable of functioning without one or both of the staffing requirements, they should not be vacated regardless of Plaintiffs' success on the merits. *See* Defs.' Mot. at 60; Pls.' Opp. at 42 (conceding that the Final Rule explains how "the Medicaid transparency reporting requirement can operate independently of the staffing requirements." (citing 89 Fed. Reg. at 40913)). Plaintiffs' assertion that "[t]here is no mention of the EFA's survival if the staffing mandates, by themselves, are declared unlawful," is incorrect. Pls.' Opp. at 42. The EFA Requirement merely modifies an *existing* facility assessment requirement that has for years operated without the 24/7 RN and HPRD Requirements, and would easily continue to function sensibly without one or both of those provisions if the staffing requirements were enjoined, as CMS explained. *See* 88 Fed. Reg. 61373; 89 Fed. Reg. 40908 (explaining that the staffing and assessment requirements are "work[ing] 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 [nursing home]'s resident population"). Indeed, the EFA requirements are sensibly functioning independently of the staffing requirements *right now*. *See* Order Denying Mot. Prelim. Inj. at 6, ECF No. 95 (noting that "[e]ach requirement of the Final Rule has a different implementation timeline," and that the "EFA requirement took effect on August 8, 2024, for all facilities.").

Plaintiffs' *ipse dixit* assertion that the EFA and Medicaid Reporting requirements would not "have been adopted without the staffing mandates" also fails in the face of CMS's clear statement of intent in the text of the Final Rule. Pls.' Opp. at 41. *See* 89 Fed. Reg. 40913; 88 Fed. Reg. 61381, 61384; *Barr*, 591 U.S. at 624 (when determining intent, "courts hew closely to the text of severability or

nonseverability clauses"). Notably, even while vacating the 24/7 RN and HPRD Requirements, the district court in *AHCA* expressly determined that "'severance and invalidation of [the challenged requirements] will not impair the function of [Medicare and Medicaid participation conditions] as a whole[,]'" and that "'there is no indication that the regulation would not have been passed but for' the 'inclusion' of the offending provisions." *AHCA*, 2025 WL 1032692 at *24 (quoting *K Mart Corp.*, 486 U.S. at 294). Assuming, *arguendo*, that this Court determines that any relief as to the 24/7 RN or HPRD Requirements is warranted, it should similarly sever the remaining lawful portions of the Final Rule.

CONCLUSION

For the foregoing reasons, the Court should enter judgment for Defendants.

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