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' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

Defendants' Final Rule will require 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 ("HHS"). *See 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"). 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 assert 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. But Plaintiffs' Motion for Summary Judgment, ECF No. 118-1 ("Pls.' MSJ"), does not dispute these minimum staffing requirements qualify as measures to protect residents' "health and safety" within the plain meaning of those statutory 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 a requirement that facilities seeking Medicare or Medicaid funding develop and implement policies and procedures to ensure that their health care workers be vaccinated for COVID-19. The statute's key provision provides Defendants the authority to promulgate "such other requirements relating to the health and safety of residents or relating to the physical facilities

thereof as the Secretary may find necessary[,]" 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 requirements 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," 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 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 the statutes, Defendants' 24/7 RN and HPRD requirements should be upheld.

Plaintiffs' other challenges to the Final Rule fare no better. They do not substantively challenge the Facility Assessment or Medicaid Institutional Payment Transparency Reporting provisions on any grounds. The major questions doctrine and canon of constitutional avoidance are not implicated in this case. And contrary to Plaintiffs' suggestion, the need for the staffing requirements embodied in the Final Rule is well supported in the administrative record. The Court should deny Plaintiffs' motion for summary judgment.

BACKGROUND

The Centers for Medicare & Medicaid Services' ("CMS's") Final Rule protects the health and safety of nursing home residents through two independent requirements on LTC facilities' participation in the Medicare and Medicaid programs: (1) by requiring that covered facilities have an RN "onsite 24 hours per day, for 7 days a week[,]" 89 Fed. Reg. 40877, 40997 (the "24/7 RN requirement"); and (2) by requiring that facilities maintain at least 0.55 HPRD of RN staffing, 2.45

HPRD of NA staffing, and 3.48 HPRD total nurse staffing, 89 Fed. Reg. 40877, 40996 (the "HPRD requirements"). The Final Rule 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, 89 Fed. Reg. 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, 89 Fed. Reg. 40913-15 ("Medicaid Reporting Requirement"). Additional background information regarding the Final Rule and CMS's regulation of nursing home staffing is provided in Defendants' Motion for Judgment on the Administrative Record, ECF No. 122 ("Defs.' Mot.") at 3-10.

LEGAL STANDARDS

Under the Administrative Procedure Act ("APA"), an agency action may not be set aside unless it is "in excess of statutory jurisdiction, authority, or limitations," "arbitrary," "capricious," or "otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(A), (C). "Ordinarily, motions for summary judgment are not appropriate in actions for judicial review based on an administrative record[.]" N.D. Ia. L.R. 56(h). *See also Thomas v. U.S. EPA*, No. 06-CV-115-LRR, 2007 WL 2127881, at *1 (N.D. Iowa July 23, 2007) (requiring submission of "briefs on the merits" for resolution of APA claims under Local Rule 56(h) in lieu of motions for summary judgment (citing *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1579-80 (10th Cir. 1994))). In such cases, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (*per curiam*). "Arbitrary and capricious is a highly deferential standard of review. We defer to agency action so long as 'an agency examine[d] the relevant data and articulate[d] a satisfactory explanation for its action.'" *Adventist Health Sys./SunBelt, Inc. v. HHS*, 17 F.4th 793, 803 (8th Cir. 2021) (quoting *Org. for Competitive Mkts. v. U.S. Dep't of Agric.*, 912

F.3d 455, 459 (8th Cir. 2018)).

ARGUMENT

I. THE FINAL RULE IS LAWFUL

At the outset, Plaintiffs correctly recognize that when a statute "delegates discretionary authority to an agency," as is the case here, "the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limitations." Pls.' MSJ at 16 (citing *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 395 (2024)). But Plaintiffs omit that "[t]he court fulfills that role by recognizing constitutional delegations, 'fixing the boundaries of the delegated authority,' and ensuring the agency has engaged in 'reasoned decisionmaking' within those boundaries[.]" *Loper Bright,* 603 U.S. at 395 (cleaned up) (citations omitted).[1] In other words, once the Court has independently judged that the statute delegates discretionary authority to the agency, its review of the agency's substantive exercise of that discretion is limited to policing the outer boundaries of the delegation and ensuring that the agency's decision was neither arbitrary nor capricious. *See Kisor v. Wilkie*, 588 U.S. 558, 632 (2019) (Kavanaugh, J., concurring) ("courts allow an agency to reasonably exercise its discretion to choose among the options allowed by the text of the rule. But that is more *State Farm* than *Auer*" (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983))). "To stay out of discretionary policymaking left to the political branches, judges need only fulfill their obligations under the APA to independently identify and respect such delegations of authority, police the outer statutory boundaries of those delegations, and ensure that agencies exercise their discretion consistent with the APA." *Loper Bright*, 603 U.S. at 404.

[1] Plaintiffs also omit the Supreme Court's instruction that "courts may—as they have from the start—seek aid from the interpretations of those responsible for implementing particular statutes" when considering claims under the APA, and that "exercising independent judgment is consistent with the 'respect' historically given to Executive Branch interpretations[.]" *Loper Bright*, 603 U.S. at 394, 399.

The statutes at issue here plainly contain an express delegation of rulemaking authority enabling CMS to promulgate "requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary[,]" 42 U.S.C. § 1396r(d)(4)(B); *accord id.* § 1395i-3(d)(4)(B). That much is uncontested in this case. It is black letter law in the Eighth Circuit that CMS's "health and safety" authorities operate "capaciously," and "are broadly worded to give HHS significant leeway in deciding how best to safeguard LTC residents' health and safety." *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 870 (8th Cir. 2021) (citing 42 U.S.C. §§ 1395i-3(f)(1), 1396r(f)(1), 1395i-3(d)(4)(B), 1396r(d)(4)(B)), *cert. denied*, 143 S. Ct. 294 (2022). The Supreme Court has also expressly recognized that terms like "appropriate and necessary" and for the "protection of public health" serve as signals that Congress has expressly delegated discretion to the agency, thereby limiting the court's role to policing the outer boundaries of the delegation and conducting arbitrary and capricious review. *See Loper Bright*, 603 U.S. at 395 n.6 (citations omitted).

Accordingly, Plaintiffs' motion confirms that the Court's review of the regulation should be confined to ensuring that the minimum staffing requirements are reasonably "relat[ed] to the health and safety of residents or relat[ed] to the physical facilities thereof[,]" and that the requirements are neither arbitrary nor capricious. 42 U.S.C. § 1396r(d)(4)(B); *accord id.* § 1395i-3(d)(4)(B); *Loper Bright*, 603 U.S. at 404 (cited at Pls.' MSJ at 16). Because Plaintiffs fail to demonstrate that the minimum staffing requirements are unrelated to resident health and safety, contrary to law, or arbitrary or capricious, their motion for summary judgment should be denied.

A. The Requirements Of The Final Rule Fit Squarely Within CMS's Statutory Authority And Are Not Contrary To Law

Plaintiffs first argue that the Final Rule "contradicts the statute and exceeds CMS's limited statutory authority[.]" Pls.' MSJ at 16. But they identify no actual conflict between the terms of the statute and CMS's Final Rule, and fail to demonstrate that the agency's broad power to establish requirements relating to resident health and safety implicitly excludes the power to set quantitative

requirements for nursing home staffing. To the contrary, and as noted in Defendants' opening brief, CMS has for years utilized the same health and safety rulemaking authority at issue here to require facilities to maintain a minimum number of certain staff. *See* Defs.' Mot. at 5-6, 17-18, 22-23 (citing 42 C.F.R. § 483.60(a)(1) and 42 C.F.R. § 483.80(b)(4), *inter alia*, both of which were identified as proper exercises of CMS's statutory authority by the Supreme Court in *Biden v. Missouri*, 595 U.S. 87, 91, 94 (2022) (*per curiam*)). The staffing requirements challenged here are no different; they should not be disturbed. And Plaintiffs offer no argument that any other part of the Final Rule, such as the EFA or Medicaid Reporting provisions, are themselves unlawful in any way. *See* Pls.' MSJ at 15-23; *Holder v. Illinois Dep't of Corr.*, 751 F.3d 486, 493 (7th Cir. 2014) (as corrected Nov. 2, 2015) ("When a party selects among arguments as a matter of strategy, he also waives those arguments he decided not to present.").

1. The 24/7 RN Requirement neither exceeds nor conflicts with CMS's statutory authority.

Plaintiffs' motion for summary judgment 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)(II) (cited at Pls.' MSJ. at 17); *accord id.* § 1395i-3(b)(4)(C)(i). But there is no conflict between the challenged 24/7 RN requirement and the statutory requirement to employ an RN for *at least* 8 hours. *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 effectively concede as much in their motion: instead of identifying an actual conflict between the Rule and the statute, they argue only that "[t]here is no specific statutory provision that authorizes [the 24/7 RN requirement]." Pls.' MSJ at 17. But Plaintiffs do not credibly 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.' Mot. at 15.

The only other "conflict" Plaintiffs purport to identify regarding the 24/7 RN requirement stems not from the requirement itself, but from the Rule's hardship exemption, which Plaintiffs argue "nullifies th[e] statutory waiver" because the regulatory exemption "provide[s] only an 8-hour per day exemption to the 24-hour required staffing." Pls.' MSJ at 17 (citing 89 Fed. Reg. 40953). This argument reflects a misreading of the regulation. The statutory waiver provides that, "[t]o the extent that clause (i) may be deemed to require that a skilled nursing facility engage the services of a registered professional nurse for more than 40 hours a week, the Secretary is authorized to waive such requirement" if certain conditions are met. 42 U.S.C. § 1395i-3(b)(4)(C)(ii); *accord id.* § 1396r(b)(4)(C)(ii). That process remains available under the Final Rule. As CMS clearly explained:

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

89 Fed. Reg. 40899. Thus, the 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.' MSJ at 17. 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. The Final Rule "does not purport to eliminate or modify the existing statutory waiver." *Id.* at 40878.

Plaintiffs also 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 implicitly 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.' MSJ at 19). 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. Here, regulated facilities can comply with both CMS's application of its health and safety authority and Congress's "at least 8" hour RN coverage requirement, so there is no role for the canon in this case. *See* Defs.' Mot. at 16; *RadLAX*, 566 U.S. at 645-46 (noting that the canon avoids "the superfluity of a specific provision that is swallowed by the general one"). 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 statutory requirement in this case, so both provisions must be regarded as effective under this rule of interpretation. *Id. Cf.* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 66 (2012) ("[a]n interpretation that validates outweighs one that invalidates.").

As to the remainder of their statutory authority argument, Plaintiffs ignore the text of the statute and instead invoke the major questions doctrine (addressed *infra* Section I.C.) and the section headings and subheadings of 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B), in an attempt to avoid the plain meaning of the text itself. *See* Pls.' MSJ at 18-19. But "the title of a statute . . . cannot limit the plain meaning of the text. For interpretive purposes, [it is] of use only when [it] shed[s] light on some ambiguous word or phrase." *Pennsylvania Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212 (1998) (quoting *Trainmen v. Baltimore & Ohio R. Co.*, 331 U.S. 519, 528-529 (1947)). No ambiguity exists here because

the meaning of the statutory text is clear: the Secretary has the authority to promulgate "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." 42 U.S.C. § 1396r(d)(4)(B); *accord id.* § 1395i-3(d)(4)(B). By empowering CMS to promulgate "such other requirements" relating to the health and safety of residents as the Secretary deems necessary, *id.*, Congress plainly authorized the agency to establish conditions on facilities' participation in Medicare and Medicaid beyond that which would otherwise be required by statute alone. *Id. See also Northport*, 14 F.4th at 870 (holding that these provisions operate "capaciously"). That is precisely what the Secretary has done by promulgating the requirements at issue in this case. While Plaintiffs are quick to note that Congress "does not . . . hide elephants in mouseholes," Pls.' MSJ 18-19 (quoting *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)), the statutory health and safety authorities at issue here are "less a mousehole and more a watering hole—exactly the sort of place we would expect to find this elephant." *Atl. Richfield Co. v. Christian*, 590 U.S. 1, 22 (2020); *see 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 that relate to "healthcare workers themselves[,]" even when such requirements go beyond those otherwise specified by Congress).

2. The HPRD Requirements neither exceed nor conflict with CMS's statutory authority.

Just as Plaintiffs fail to demonstrate that the 24/7 RN requirement conflicts with or falls outside of CMS's statutory authority, so too do they fail to carry their burden as to the HPRD requirements. *See* Pls.' MSJ at 16-19; *supra* 6-9. Again, Plaintiffs effectively concede a lack of conflict in their opening brief. Instead of identifying an actual conflict between the HPRD requirements and the statute, they argue only that "[t]here are no staffing ratios in the statute." Pls.' MSJ at 17. At best, this argument goes to CMS's statutory authority alone, not to any conflict between the rule and the statute. Even then, all Plaintiffs are left with on the question of "staffing ratios" is at most

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. The absence of a quantitative minimum staffing ratio in the statute reflects the fact that this responsibility had been appropriately delegated to CMS, through Congress's grant of capacious power to set additional requirements for resident health and safety. *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"); Nat'l Acad. Press, Comm. on Nursing Home Regulation, Inst. of Med., *Improving the Quality of Care in Nursing Homes* 200-01 (1986), https://perma.cc/8GG8-GVY8 ("Institute of Medicine Study") (recognizing that CMS's predecessor had authority to incorporate "minimum nursing staff requirements" for nursing homes "into its regulatory standards" if "convincing evidence becomes available").[2] 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 bottom, Plaintiffs ignore Congress's choice to expressly require facilities to 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). And because the statutory and regulatory requirements can both operate together, the HPRD requirements do not

[2] Indeed, Congress itself confirmed CMS's power to exceed existing requirements via promulgation of stricter regulations through rulemaking shortly after passage of the Federal Nursing Home Reform Act ("FNHRA"). *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101–508, 104 Stat. 1388, 1388-50 (directing that "[a]ny regulations promulgated and applied by the Secretary . . . after the date of the enactment of [FNHRA] with respect to services described in clauses (ii), (iv), and (v) of section 1919(b)(4)(A) of the Social Security Act shall include requirements for providers of such services that are *at least as strict* as the requirements applicable to providers of such services prior to the enactment of [FNHRA]" (emphasis added)).

"conflict[] with Congress's decision." Pls.' MSJ at 17. To the contrary, Plaintiffs' reading of the statute, under which Congress alone may "determine[] the only appropriate standards to enforce nationwide[,]" *id.*, would nullify the Secretary's well-established rulemaking authority contrary to legislative intent. *See Missouri*, 595 U.S. at 90, 94 (citing 42 U.S.C. §§ 1395i–3(d)(4)(B), 1396r(d)(4)(B)).

Just as was the case for the other health and safety regulations cited in Defendants' opening brief, then, Defendants' HPRD requirements are a permissible exercise of the Secretary's statutory health and safety authority and do not conflict with any other portion of the statute. *See* Defs.' Mot. at 5-6, 17-18, 22-23 (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, and many have been cited approvingly by the Supreme Court as examples of permissible exercises of CMS's regulatory power, *see Missouri*, 595 U.S. at 91, 94. 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.' Mot. at 17-18). And in each case, CMS permissibly utilized its separate health and safety authority to impose additional conditions not inconsistent with the existing statutory requirements, in accordance with Congress's choice to condition nursing homes' eligibility for Medicare and Medicaid funding not only on those statutory 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 HPRD requirements are no different and should not be disturbed.

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

Having failed to demonstrate that the Final Rule is contrary to law or without statutory authority, Plaintiffs turn to the canon of constitutional avoidance. Plaintiffs argue that Congress's instruction that rules promulgated by CMS be "relat[ed] to the health and safety of residents or [] to

the physical facilities thereof" is an insufficient intelligible principle for purposes of the nondelegation doctrine. 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B); *see* Pls.' MSJ at 19-20. Not so, as the cases cited in their brief demonstrate.

For nearly a century, the Supreme Court has consistently upheld "Congress'[s] ability to delegate power under broad standards[,]" *Misretta v. United States*, 488 U.S. 361, 373 (1989) (cited at Pls.' MSJ at 20). Under the nondelegation doctrine, a statutory delegation is constitutional "as long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." *See Bhatti v. Fed. Hous. Fin. Agency*, 15 F.4th 848, 854 (8th Cir. 2021) (citation omitted) (cleaned up). This standard is not demanding. It is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *Am. Power & Light Co. v SEC*, 329 U.S. 90, 105 (1946). The Supreme Court has invoked the nondelegation doctrine to invalidate a federal law only twice, and not in more than 90 years. *See Nat'l Cable Television Ass'n v. United States*, 415 U.S. 352, 353 (1974) (Marshall, J., concurring and dissenting) (calling the doctrine "moribund").

The Secretary's statutory authority to protect the health and safety of Medicare and Medicaid patients easily meets the intelligible principle standard, as confirmed by the Supreme Court's decision upholding CMS's exercise of the same authority to promulgate a nationwide vaccination rule in *Biden v. Missouri*, 595 U.S. at 90-95. As noted in *Gundy v. United States* (cited at Pls.' MSJ at 20), the 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*[.]'" 588 U.S. 128, 146 (2019) (citations omitted) (emphasis added).[3] Because Congress

[3] Similarly, the Supreme Court has upheld statutes authorizing the Secretary of War to determine and recover "excessive profits" from military contractors, *Lichter v. United States*, 334 U.S. 742, 785-86 (1948) (citation omitted); the Price Administrator to fix "fair and equitable" commodities prices, *Yakus*

plainly supplied a comparable intelligible principle to govern the Secretary's exercise of his health and safety rulemaking authority here, *see* 42 U.S.C. § 1396r(d)(4)(B) (requiring that such rules "relat[e] to the health and safety of residents or [] to the physical facilities thereof"), *accord id.* § 1395i-3(d)(4)(B), the constitutional avoidance canon does not apply.

C. The Final Rule Does Not Implicate Or Violate 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 agency's "health and safety" authority, Plaintiffs resort to the argument that the Court should impose on Congress a clear statement requirement demanding express reference to quantitative staffing levels in its grant of rulemaking power. *See* Pls.' MSJ at 20-23. There is no basis for that departure from the statute's text. *See Missouri*, 595 U.S. at 90, 95 (it is "not [] surprising" that CMS would use this authority "to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients' health and safety."). Where health and safety has "a character of its own" that plainly encompasses adequate nurse staffing levels, Plaintiffs' interpretative canons are inapplicable. *Russell Motor Car Co. v. United States*, 261 U.S. 514, 519 (1923); *see Iverson v. United States*, 973 F.3d 843, 853 (8th Cir. 2020) (Such canons "may only be used 'where words are of obscure or doubtful meaning'"). Nevertheless, Plaintiffs invoke the major questions doctrine and 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 vaccination rule in *Biden v. Missouri*. *See* 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.' MSJ at 20-23; Defs.' Mot. at 27-32.

---

v. United States, 321 U.S. 414, 420 (1944); and the EPA to set national air-quality standards limiting pollution to the level required to "protect the public health," *Am. Trucking*, 531 U.S. at 472.

Plaintiffs first argue that the Final Rule triggers the major questions doctrine because its alleged cost, "social consequences[,]" and "upending of state regulation of LTCs have vast economic and political significance." Pls.' MSJ at 21. But 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*, 594 U.S. 758, 764 (2021) (*per curiam*) (cited at Pls.' MSJ at 18, 21), or claiming a "highly consequential power *beyond what Congress could reasonably be understood to have granted*." *West Virginia v. EPA*, 597 U.S. 697, 723-24 (2022) (emphasis added) (cited at Pls.' MSJ at 21-23). 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*, 594 U.S. at 764, or one where the agency action reflects "a fundamental revision of the statute, changing it from one sort of scheme of regulation into an entirely different kind[.]" *Biden v. Nebraska*, 600 U.S. 477, 502 (2023) (cleaned up) (cited at Pls.' MSJ at 21). Instead, the federal agency primarily responsible for health care has set health and safety requirements for nursing homes participating in federally funded health care programs, pursuant to express statutory authorization to do just that. *See Merck & Co. v. HHS*, 962 F.3d 531, 537-38 (D.C. Cir. 2020) (distinguishing an invalid rule with only "a hoped-for trickle-down effect on the regulated programs" from a valid rule with "an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs"). And Plaintiffs have shown no evidence of "Congress'[s] consistent judgment to deny [CMS] this power." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000) (cited at Pls.' MSJ at 21).

The expected cost of the Final Rule—$4.3 billion annually on average over the next 10 years, 89 Fed. Reg. 40969, "not includ[ing] adjustments for any exemptions that [CMS] may provide, which could reduce the rule's cost[,]" *id.* at 40955—is also dwarfed by the recent cases applying the doctrine

based on economic significance, which have involved hundreds of billions of dollars of impact. The gap between the economic impact in cases where the doctrine applies and this case is thus too large to warrant applying the major questions doctrine here based on economic significance. *See Nebraska*, 600 U.S. at 483 ($430 billion impact); *West Virginia*, 597 U.S. at 715 ($1 trillion by 2040)).[4]

Nor does the Final Rule implicate the major questions doctrine merely because it impacts "state regulation of LTCs[.]" Pls.' MSJ at 21. The Medicare and Medicaid statutes were enacted under the Spending Clause, and the Secretary has a duty to ensure that federal funds are used as Congress directed, in particular, by protecting residents' health and safety in facilities funded by these programs. "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare, [and] . . . to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare[.]" *Sabri v. United States*, 541 U.S. 600, 605 (2004). This power applies even when Congress legislates "in an area historically of state concern." *Id.* at 608 n.*. The mere fact that federal regulations promulgated pursuant to statutory authority preempt conflicting state laws as a matter of federal supremacy, *see* U.S. Const., Art. IV, Cl. 2, does not implicate the major questions doctrine. 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 assuming, *arguendo*, that the major questions doctrine did apply, Plaintiffs' argument that "Congress did not authorize the Rule," Pls.' MSJ at 22-23, is unavailing. As explained above, *supra* 4-

[4] 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 v. Allina Health Services*, 587 U.S. 566, 569 (2019). But courts have never treated that as a reason to demand heightened clarity in every Medicare or Medicaid case.

11, Congress plainly authorized the agency to establish conditions on facilities' participation in Medicare and Medicaid beyond that which would otherwise be required by statute alone. *See* 42 U.S.C. § 1396r(d)(4)(B); *accord id.* § 1395i-3(d)(4)(B). The doctrine's requirement for "clear congressional authorization" of agency action requires no more specificity. *See Nebraska*, 600 U.S. at 511 (Barrett, J., concurring) (explaining that the major questions doctrine does not "require[] 'an unequivocal declaration' from Congress authorizing the *precise* agency action under review"); *Florida v. HHS*, 19 F.4th 1271, 1288 (11th Cir. 2021) (major questions doctrine did not apply because "a broad grant of authority" that "plainly encompasses the [agency's] actions . . . does not require an indication that specific activities are permitted"). And again, if it poses no major-questions problem for CMS to rely on its "health and safety" authorities to promulgate vaccination requirements that allegedly "put more than 10 million healthcare workers to the choice of their jobs or an irreversible medical treatment" while implicating issues that the dissent contended "fall squarely within a State's police power," *Missouri*, 595 U.S. at 104, 108 (Alito, J., dissenting), it is *a fortiori* permissible for CMS to use the same authority to promulgate the Final Rule—which by Plaintiffs' admission would affect only a small portion of the healthcare industry and have a total workforce impact only a fraction of the size found permissible in *Missouri*. *See* Am. Compl. ¶ 217, ECF No. 37 (conceding that the Final Rule regulates "the nursing home industry" alone).[5]

[5] Plaintiffs' observation that the statutes at issue are "decades-old" also works against their argument because CMS has long utilized the same authorities at issue here to establish staffing requirements that facilities wishing to participate in Medicare or Medicaid must meet. *See supra* 6, 11 (citing 42 C.F.R. § 483.60(a)(1); *id.* § 483.80(b); *id.* § 483.70(e)(1)). As the Institute of Medicine recognized at the time of the statutes' enactment: "[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." Institute of Medicine Study at 200-01. *See also* H.R. Rep. No. 213, 89th Cong., 1st Sess. 25-26 (1965) (explaining that identical health and safety rulemaking authority was included in the portion of the statute dealing with hospitals "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.").

D. The Final Rule Is Neither Arbitrary Nor Capricious

Plaintiffs fail to controvert 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. Further, CMS sufficiently considered reliance on states' minimum standards, as well as Plaintiffs' concerns about workforce availability and compliance costs. 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).

1. The Final Rule is not an unexplained departure from past practice.

The Final Rule is consistent with longstanding agency policy and does not represent a change in course. Plaintiffs characterize the rule as a "sharp[] depart[ure] from 50 years of consistent practice" Pls.' MSJ at 25-26, simply because CMS had, up to this point, not yet instituted minimum nurse staffing requirements. But when 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. Lacking data needed to set and enforce minimum staffing requirements is not the same as rejecting these requirements as a matter of policy. Plaintiffs' acontextual citations to the agency's prior rulemaking do not show otherwise.

For instance, Plaintiffs argue that the Social Security Administration ("SSA") rejected minimum staffing requirements in 1974 because, in responding to a single public comment, the agency declined a recommendation to set "a specific ratio of nursing staff to patients." Skilled Nursing Facilities, 39 Fed. Reg. 2238, 2239 (Jan. 17, 1974); Pls.' MSJ at 25. But a single sentence cannot be read

to definitively establish the agency's prior position on minimum staffing requirements. And even if it could, that sentence only addresses whether the agency should set a rule prescribing the optimal staffing ratios for each facility, which CMS did not do here. The challenged rule only sets minimums—a "broadly applicable national floor (baseline) at which residents are at a significantly lower risk of receiving unsafe and low-quality care." 89 Fed. Reg. 40882; Defs.' Mot. at 40-41. Moreover, the 1974 rulemaking invoked by Plaintiffs 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, and granted HHS new powers to regulate in the interest of resident health and safety. *See* Defs.' Mot. at 4-6.

Plaintiffs' characterization of CMS's 1980 rulemaking is also misleading. They assert that CMS "declined to propose" minimum staffing requirements. Pls.' MSJ at 25. But they fail to note that CMS did so for the express reason that it did not have enough data at that time to know "how much staffing will be required" and that it "plan[ned] to undertake a study" about the impact of states' minimum staffing requirements. Conditions of Participation for Skilled Nursing and Intermediate Care Facilities, 45 Fed. Reg. 47368, 47371-72 (July 14, 1980). And again, this rulemaking occurred years before FNHRA drastically changed the legal landscape governing LTC facilities' participation in Medicare and Medicaid by granting HHS new authority to set requirements relating to resident health and safety.

Plaintiffs also misconstrue the 1986 Institute of Medicine Study. *See* Pls.' MSJ at 25; Institute of Medicine Study at 2. That study expressly supports regulations to increase nursing home staffing, stating that "the benefits to the residents of increasing the ratio of better-trained staff far outweigh the costs of increased staffing." Institute of Medicine Study at 103. The study also recommends further studies "to develop a minimum staffing algorithm relating staffing to case mix[.]" *Id.* at 44, 190. The study also critically noted that the reason for declining to recommend minimum staffing requirements at that time was because "[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 available, as CMS explained. *See* 89 Fed. Reg. 40880; Defs.' Mot. at 46-47.

Similarly, Plaintiffs' reference to a 2002 letter to Congress from the HHS Secretary is specious. They assert that the Secretary did not "recommend[] the imposition of minimum-staffing ratios[,]" *see* Pls.' MSJ at 25, but they again omit that the Secretary's stated reason for declining to implement minimum staffing requirements at that time was his "serious reservations about the reliability of staffing data at the nursing home level." Letter from Sec'y Tommy G. Thompson to Rep. Hastert 1 (Mar. 19, 2002), reprinted as Appendix 1, https://aspe.hhs.gov/reports/state-experiences-minimum-nursing-staff-ratios-nursing-facilities-findings-case-studies-eight-states-1#append1 ("Thompson Letter").

Once more, Plaintiffs' mention of the agency's 2016 rulemaking leaves out important information. They say, "CMS again rejected requests to adopt minimum-staffing rules," *see* Pls.' MSJ at 25, but in fact the rule states that "[CMS] continue[s] to believe that our proposed [staffing] requirement is necessary to address concerns about inadequate staffing and resulting harm to residents." Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688, 68754 (Oct. 4, 2016). The agency noted that "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[.]" *Id.* at 68755 (emphasis added); *see also id.* (CMS "remain[s] convinced that additional data will be helpful in determining if and what such [minimum staffing] 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.

Plaintiffs ask, "[w]hat happened to all of a sudden depart?" Pls.' MSJ at 25. But the premise of Plaintiffs' question is incorrect. The record shows that at every turn, the agency has uniformly acknowledged the need for increased staffing. And when CMS considered minimum staffing requirements in the past, it 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 promulgation of the Final Rule. 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.

But even if CMS's decision to finally institute minimum staffing requirements after carefully and deliberately gathering decades of research on the issue could fairly be characterized as a reversal in position (it cannot), the agency clearly explained its reasons for taking this action now: the COVID-19 pandemic revealed the urgency and necessity of taking action now to combat chronic understaffing in nursing homes, and reliable data upon which to set the requirements is now available. *See* 89 Fed. Reg. 40880; Defs.' Mot. at 46-47. Plaintiffs' characterization of the Abt Study does not show otherwise. *See* Defs.' Mot. at 42-45. And further, CMS did not base its rule solely on the Abt Study. *See* Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 88 Fed. Reg. 61352, 61359-65 (Sept. 6, 2023) (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).

2. CMS considered reliance interests.

The record belies Plaintiffs' argument that CMS failed to consider reliance interests because of variation between the states and because some states have set their own standards. First and foremost, the Final Rule maintains LTC facilities' flexibility to staff at varying levels based on their resident population and acuity. *See* Defs.' Mot. at 47-50. That is because the Final Rule merely sets *minimum* requirements—it does not prescribe the sufficient staffing level for each facility nor does it

supplant the independent statutory requirement that LTC facilities provide staffing "sufficient to meet the nursing needs of [their] residents[.]" 42 U.S.C. §§ 1396r(b)(4)(C)(i), 1395i–3(b)(4)(C)(i). The Final Rule simply sets a floor that, based on decades of research, CMS determined is necessary for health and safety of residents because it is a staffing level "at which residents are at a significantly lower risk of receiving unsafe and low-quality care." 89 Fed. Reg. 40882. The agency acknowledged that many or even most facilities may need to staff above the minimum requirements to meet the needs of their specific residents. *See 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[.]"). And in cases where the minimum staffing requirements are not feasible, exemptions are available. 42 C.F.R. § 483.35(h). Clearly then, flexibility remains for facilities to "implement[] staffing requirements tailored to" the needs of their residents. Pls.' MSJ at 26. 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.

Further, CMS expressly considered existing state standards. *See, e.g.*, 89 Fed. Reg. 40880, 40877, 40886, 40904, 40955, 40994; 88 Fed. Reg. 61353, 61363, 61374, 61426. The agency determined that, to the extent those state standards are lower, they are insufficient to meet the health and safety needs of LTC residents. *See* 89 Fed. Reg. 40880 ("[W]idespread variability in existing minimum staffing standards across the United States . . . highlight the need for national minimum staffing standards[.]"). Bringing nursing homes into compliance with the "national floor (baseline) at which residents are at a significantly lower risk of receiving unsafe and low-quality care" is precisely the point. 89 Fed. Reg. 40882. It has long been the case that, in order to receive federal funding for Medicare and Medicaid, LTC facilities must meet the conditions of participation of the Medicare and Medicaid programs, including any new regulations promulgated by CMS under those programs. *See, e.g.,* 42 U.S.C. §§ 1395cc, 1396a(a)(78). And beyond that, CMS's fulsome consideration of any asserted reliance

interest is evidenced by the fact that the Final Rule includes staggered implementation deadlines and hardship exemptions to give facilities flexibility to come into compliance. *Id.* at 40885-88. All the APA requires is that an agency "consider" reliance interests as "but one factor[,]" acknowledging that the agency "may determine, in the particular context before it, that other interests and policy concerns outweigh any reliance interests." *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 32 (2020). Having considered these interests and found that the health and safety of nursing home residents outweighs nursing homes' reliance on insufficient state law minimum staffing requirements, CMS clearly met the deferential standard set by the APA here.

3. CMS did not fail to consider important aspects of the problem.

Contrary to Plaintiffs' assertion, CMS adequately considered both workforce availability and the cost of compliance with the Final Rule during the rulemaking process, and determined the Final Rule's requirements are feasible.[6]

The record shows that CMS seriously grappled with the workforce challenges. *See* 89 Fed. Reg. 40885 ("We acknowledge the workforce challenges in LTC facilities."); Abt Associates, *Nursing Home Staffing Study*, Comprehensive Report (June 2023) ("Abt Study"), Administrative Record ("AR") AR_00069990, 00069994, 00070002-03, 00070023, 00070039-41, HRSA, Health Workforce, *Workforce*

[6] Plaintiffs make no argument in their Motion for Summary Judgment that the EFA requirement is arbitrary or capricious beyond stating in cursory fashion that "the EFAs are arbitrary and unduly burdensome" without explanation of how or why. *See* Pls.' MSJ at 28. As this Court has already held, "such conclusory arguments do not come close to meeting the required showing" for success on the merits. Order on Pls.' Mot. for Prelim. Inj. at 17 n.8, ECF No. 95; *see also Holder*, 751 F.3d at 493 ("When a party selects among arguments as a matter of strategy, he also waives those arguments he decided not to present."); *Lorenzen v. GKN Armstrong Wheels, Inc.*, 345 F. Supp. 2d 977, 986 (N.D. Iowa 2004) (finding that a party "failed to meet its initial burden on its motion for summary judgment of informing the district court of the basis for its motion and identifying those portions of the record which show lack of a genuine issue" because it "provided only . . . conclusory assertions") (citation omitted). Plaintiffs have thus waived any challenge to the EFA requirement. In any event, the EFA provision consists mostly of material consolidated from existing regulations, and the rationale for the new material was sufficiently explained in the Final Rule so it should be upheld even if Plaintiffs had adequately challenged this requirement. *See* Defs.' Mot. at 37.

Projections (Apr. 22, 2024), AR_00069880-69884. *See also* Defs.' Mot. at 50-58. Moreover, 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. 89 Fed. Reg. 40885, 40880; U.S. Bureau of Labor Statistics, *All Employees, Skilled Nursing Care Facilities*, [CES6562310001], retrieved from FRED, Federal Reserve Bank of St. Louis, https://fred.stlouisfed.org/series/CES6562310001; AR_00069400. And rather than "irrationally discount[ing] the vital role of LPNs/LVNs," *see* Pls.' MSJ at 29, CMS made the eminently rational decision to focus its rule on RNs and NAs because the data showed that RNs and NAs have the biggest impact on the health and safety of nursing home residents while increased staffing of LPNs/LVNs was found to have negligible impact. *See* 89 Fed. Reg. 40881, 40893.

CMS also carefully considered the cost of the Final Rule during its decisionmaking process, and determined that the costs are not prohibitive. 89 Fed. Reg. 40878, 40970, 40949-50; AR_00069996; 2022 Abt Study at AR_00070118-123. Plaintiffs ignore the fact that the cost of the Final Rule is a fraction of the government funding paid by Medicare and Medicaid to LTC facilities each year and that the additional costs will be factored into Medicare and Medicaid reimbursement. *See* Defs.' Mot. at 55-56.

Critically, Plaintiffs entirely brush aside the hardship exemption that will be available to facilities that cannot meet the Final Rule's requirements despite good faith efforts to do so. *See* 89 Fed. Reg. 40897-98; AR_00069366-81; Defs.' Mot. at 57-58. 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," Defs.' Mot. at 58, and the exemption's other requirements to show good faith effort to hire and retain staff and document a financial commitment to doing so are fully within a facility's control, 89 Fed. Reg.

40877. The availability of hardship exemptions disposes of Plaintiffs' argument that compliance will be "unattainable[.]" Pls.' MSJ 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).

II. PLAINTIFFS' REQUESTED RELIEF IS OVERBROAD

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 contrary to law. 5 U.S.C. § 706(2)(A), (C). But even if this Court disagrees with Defendants' merits arguments, the relief requested by Plaintiffs is overbroad. Significant portions of the Final Rule have not been challenged substantively and thus should not be held unlawful. *See supra* 6. Even as to the challenged provisions, "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury[,]" *Gill v. Whitford*, 585 U.S. 48, 73 (2018), and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs[,]" *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted). Because each provision of the Final Rule is designed to stand on its own, *see* Defs.' Mot. at 59-60 (citing 89 Fed. Reg. 40913), the Court should limit any remedy to declaratory or injunctive relief as to the portions of the rule held to be unlawful and the parties to this action alone. *See id.* at 59-64.

A. Form Of Relief

First, Plaintiffs argue that the Court should grant them a permanent injunction, declaratory relief, and vacatur as to the Final Rule. *See* Pls.' MSJ at 32-33. Defendants do not dispute that when an agency action is found to be unlawful, the Court has the power to issue declaratory relief and enjoin

enforcement of any offending provisions as to the parties in the case, subject to the traditional constraints on equitable relief. *See Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944) (explaining "[t]he essence of equity jurisdiction has been the power . . . to do equity and to mould each decree to the necessities of the particular case"); *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (equitable relief "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs"); *Trump v. Hawaii*, 585 U.S. 667, 716-17 (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."). In this case, declaratory relief would adequately define the legal rights of the parties and establish any unlawfulness, preventing any alleged harm. *See Anatol Zukerman & Charles Krause Reporting, LLC v. U.S. Postal Serv.*, 64 F.4th 1354, 1366-67 (D.C. Cir. 2023). And if the Court chooses to implement an injunction, one limited to preventing enforcement of any unlawful provisions of the rule against Plaintiffs themselves would also fully resolve any harm shown by Plaintiffs. *See Direct Mktg. Ass'n v. Brohl*, 575 U.S. 1, 13 (2015); *Garland v. Aleman Gonzalez*, 596 U.S. 543, 550 (2022). Those traditional equitable remedies are more than sufficient to address the harms alleged by Plaintiffs, and Plaintiffs do not argue otherwise. *See* Pls.' MSJ at 32-33.

Vacatur of the Final Rule, by contrast, is unwarranted and would defy the principle that remedies "ordinarily 'operate with respect to specific parties[,]'" *California v. Texas*, 593 U.S. 659, 672 (2021) (citation omitted), and the rule that equitable relief "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs[,]" *Califano*, 442 U.S. at 702. While the Eighth Circuit has observed that "[u]pon ultimate success in an Administrative Procedure Act challenge, the default remedy is to set aside or vacate[,]" *Missouri v. Trump*, 128 F.4th 979, 996-97 (8th Cir. 2025) (citation omitted), Defendants here preserve the argument that the APA itself does not authorize *any* particular form of relief; it merely directs a reviewing court to disregard "agency action,

findings, and conclusions" that it finds unlawful when resolving an individual APA challenge. 5 U.S.C. § 706(2). *See* Br. for Petitioners at 39-44, *United States v. Texas*, No. 22-58, 2022 WL 4278395, at *40-41 (Sept. 12, 2022). When Congress adopted the "unremarkable" "set aside" language in § 706(2), there is no reason to think it "meant to upset the bedrock practice of case-by-case judgments with respect to the parties in each case[.]" *Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring).

Plaintiffs cite several cases and law review articles for the proposition that the APA nevertheless "authorizes vacatur of agency rules[,]" Pls.' MSJ at 32-33 (quoting *Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 144 S. Ct. 2440, 2460 (2024) (Kavanaugh, J., concurring)), but it is well settled that vacatur is not a required or appropriate remedy in *every* APA case. *See, e.g., U.S. Steel Corp. v. EPA*, 649 F.2d 572, 577 (8th Cir. 1981) (declining to vacate and instead "leav[ing] these designations in effect pending completion of further administrative proceedings in accordance with the APA"); Defs.' Mot. at 61-62. 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*, 321 U.S. at 329; *see 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, and instead enjoining enforcement of that provision). Vacatur is unnecessary and unwarranted here because injunctive and declaratory relief as to the parties would fully remedy any injury Plaintiffs have alleged. *See 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. The reviewing court is not generally empowered to conduct a de novo inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.")

B. Scope Of Relief

Next, Plaintiffs argue that "[t]he entire Rule is unlawful and should be vacated in its entirety[,]" despite forfeiting their substantive challenge to any portion of the Final Rule apart from the 24/7 RN and HPRD staffing requirements. Pls.' MSJ at 33; *see supra* 6. As explained in Defendants' opening brief, Plaintiffs lack standing to seek relief with respect to provisions they do not contend are unlawful, *California*, 593 U.S. at 680, and 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' request for wholesale vacatur thus comes down to whether the portions of the Final Rule challenged by Plaintiffs are severable. If they are, any relief must be limited (at most) to portions of the rule that have actually been held unlawful. *See, e.g., Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 328-29 (2006) ("We prefer, for example, to enjoin only the unconstitutional applications of a statute while leaving other applications in force").

There is no question that the Final Rule is fully severable here, because CMS made clear that each portion of the final rule can function independently, and that it would have adopted each portion on its own. *See* Defs.' Mot. at 59-61. To that end, Plaintiffs' characterization of the Final Rule's detailed severability clause as mere "boilerplate," Pls.' MSJ at 33, is demonstrably false. As CMS explained, "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*." 89 Fed. Reg. 40913 (emphasis added). Likewise, "the Medicaid reporting provisions of this final rule regarding the percent of payments spent on compensation for direct care and support staff workforce operate independently of mandated levels of nurse staffing[.]" *Id.* The same is true of

the facility assessment requirements, which merely modify 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. *See* 88 Fed. Reg. 61373; 89 Fed. Reg. 40908 (explaining that the staffing requirements and the 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"). Because each portion of the Rule "could function sensibly without the stricken provision[,]" the requirements for severability are met. *MD/DC/DE Broads. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001); *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (similar).

The agency's intent is similarly clear: CMS expressly confirmed that "to the extent a court may enjoin any part of the rule, [CMS] intends that other provisions or parts of provisions should remain in effect." 89 Fed. Reg. 40913. *See also* 88 Fed. Reg. 61381, 61384 (similar). Plaintiffs' *ipse dixit* assertion that the EFA and Medicaid Reporting Requirements "would not have been adopted on [their] own" fails in the face of this clear statement of agency intent. Pls.' MSJ at 34-35. *See Barr v. Am. Ass'n of Pol. Consultants, Inc.*, 591 U.S. 610, 624 (2020) (when determining intent, "courts hew closely to the text of severability or nonseverability clauses"); *Barr*, 591 U.S. at 625-26 (courts are bound by "a strong presumption of severability[,]" reflecting the obligation to "salvage rather than destroy" an otherwise lawful regulation); *Advantage Media, LLC v. City of Eden Prairie*, 456 F.3d 793, 800 (8th Cir. 2006) (crediting broad severability clause).

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion for summary judgment.

Dated: April 3, 2025

Respectfully submitted,

YAAKOV M. ROTH
Acting Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Andrew J. Rising
ANDREW J. RISING
ALLISON M. WALTER
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW, Rm. 12520
Washington, D.C. 20005
Phone: (202) 514-0265
E-mail: andrew.j.rising@usdoj.gov

Counsel for Defendants

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' LOCAL RULE 56(b)(2) RESPONSE
TO PLAINTIFFS' STATEMENT OF MATERIAL FACTS

Pursuant to Rule 56(b)(2) of the Local Rules of the United States District Court for the Northern District of Iowa, Defendants respectfully submit this response to Plaintiffs' statement of material facts in support of Plaintiffs' motion for summary judgment, ECF No. 118-2.

Defendants note that this response is solely designed to respond to Plaintiffs' statement of material facts by identifying which of the factual grounds for Plaintiffs' motion are disputed rather than undisputed as Plaintiffs suggest. In light of Defendants' separate motion for judgment on the administrative record, the use of the word "disputed" should not be construed to mean that Defendants believe that there are genuine issues of fact that would necessitate a trial. Rather, such language simply means that Defendants dispute Plaintiffs' statement regarding that matter. Defendants maintain their position that there are no genuine issues of material fact with respect to the grounds entitling Defendants to judgment on the administrative record as a matter of law.

In that regard, Defendants make this response without waiving their position that where, as here, Plaintiffs seek Administrative Procedure Act ("APA") review of agency action, Local Rule 56(h) governs and factual findings concerning the merits are not warranted because "under the APA, the

district court 'sits as an appellate tribunal' and the entire case on review is a question of law." *Border States Indus., Inc. v. USCIS*, 751 F. Supp. 3d 956, 964 (D. Neb. 2024) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)); *see also Thomas v. EPA*, No. 06-CV-115-LRR, 2007 WL 2127881, at *1 (N.D. Iowa July 23, 2007) (applying L.R. 56(h)). "By confining judicial review to the administrative record, the APA precludes the reviewing court from conducting a *de novo* trial and substituting its opinion for that of the Agency." *Voyageurs Nat'l. Park. Ass'n v. Norton*, 381 F.3d 759, 766 (8th Cir. 2004) (emphasis added) (citing *United States v. Morgan*, 313 U.S. 409, 422 (1941)). The Court accordingly does not "engage in lengthy fact finding," *Pharm. Research & Mfrs. of Am. v. FTC*, 44 F. Supp. 3d 95, 111 (D.D.C. 2014), because "[g]enerally speaking, district courts reviewing agency action under the APA's arbitrary and capricious standard do not resolve factual issues, but operate instead as appellate courts resolving legal questions." *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996) (citation omitted).

Defendants also note that significant portions of Plaintiffs' statement of material facts consist of argument and recitation or characterization of various legal authorities, which are not appropriately understood as facts. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (citation omitted) ("As to materiality, the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude . . . entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted."). Defendants respond to Plaintiffs' legal arguments and characterizations of legal authority in their opening brief and memorandum in opposition to Plaintiffs' motion.

The format of this document is as follows. The text of the facts originally alleged in Plaintiffs' statement is set forth at the beginning of each paragraph, along with Plaintiffs' section headings where applicable. Defendants' reproduction of the facts and section headings originally alleged in Plaintiffs'

statement does not itself constitute an admission of any facts contained therein. The balance of each numbered paragraph contains Defendants' response as to that particular alleged fact.

* * *

A. Congress enacts statutes that specify staffing requirements for LTC facilities

1. In 1965, Congress established the Medicare and Medicaid programs by amending the Social Security Act. *See* Pub. L. No. 89-97, 79 Stat. 286 (July 30, 1965).

RESPONSE: Undisputed.

2. Nursing homes that participate in Medicare must comply with the statutory requirements for "skilled nursing facilities" ("SNFs"), 42 U.S.C. § 1395i-3, while those participating in Medicaid must meet similar requirements for "nursing facilities" ("NFs"), 42 U.S.C. § 1396r.

RESPONSE: Undisputed.

3. The statutory requirements for both SNFs and NFs are largely parallel. These facilities are often collectively referred to as "long-term care" ("LTC") facilities, as they are herein.

RESPONSE: Undisputed.

4. CMS has issued consolidated regulations applicable to all SNFs and NFs (collectively referred to as "LTCs") participating in Medicare and/or Medicaid. E.g., 42 C.F.R. § 483.1.

RESPONSE: Undisputed.

5. Both statutes require LTC facilities to utilize the services of a registered professional nurse for "at least 8 consecutive hours a day, 7 days a week," and to provide 24-hour licensed nursing services that are "sufficient to meet the nursing needs of their residents." 42 U.S.C. § 1395i-3(b)(4)(C)(i) (Medicaid); 42 U.S.C. § 1396r(b)(4)(C)(i)(I)-(II) (Medicaid).

RESPONSE: Undisputed, but incomplete. Both statutes also require facilities to meet, *inter alia*, "such other requirements relating to the health and safety [and well-being] of residents . . . as the Secretary may find necessary." 42 U.S.C. §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B).

6. There are no staffing quotas within the statutes. *See*, *e.g.*, 42 U.S.C. § 1395i-3(b)(4)(C)(i) (Medicaid); 42 U.S.C. § 1396r(b)(4)(C)(i)(I)-(II) (Medicaid).

RESPONSE: This statement implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. The legal conclusion is disputed for the reasons explained in Defendants' briefing. Both statutes require facilities to meet "such other requirements relating to the health and safety [and well-being] of residents . . . as [the Secretary] may find necessary," *Id.* §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B), which provides authority for the challenged Final Rule.

7. Under the Medicare statute, the Secretary is authorized to waive the requirement for LTC facilities to employ an RN for more than 40 hours per week if: (1) the facility is "located in a rural area and the supply of skilled nursing services is not sufficient to meet the needs" of local residents; (2) "the facility has one full-time [RN] who is regularly on duty at [the LTC] for 40 hours [per] week"; (3) the LTC facility has patients whose physicians have indicated that they do not require an RN or physician for 48 hours, or it has arranged for an RN or physician to provide necessary services when the full-time RN is not on duty; (4) "the Secretary provides notice of the waiver to the State long-term care ombudsman …"; and (5) the facility that is granted the waiver notifies residents and their families of the waiver. *See generally* 42 U.S.C. § 1395i-3(b)(4)(C)(ii)(I)-(V).

RESPONSE: Undisputed.

8. Under the Medicaid statute, a state may waive the staffing requirements for an LTC facility if: (1) the LTC facility demonstrates that, despite diligent efforts, it was unable to recruit appropriate personnel; (2) granting a waiver will not endanger the health or safety of the LTC facility's

residents; (3) during times when an RN is unavailable, an RN or physician must be able to respond to calls from the LTC facility; (4) the state agency notifies the state long term care ombudsman of the waiver; and (5) the LTC facility informs its residents and family of the waiver. *See* 42 U.S.C. § 1396r(b)(4)(C)(ii)(I)-(V). Such waivers are subject to annual review by the State and the Secretary. See 42 U.S.C. § 1396r(b)(4)(C) ("Required nursing care").

RESPONSE: Undisputed.

9. If a state is found to regularly grant waivers without facilities making diligent efforts to meet staffing requirements, the Secretary "shall assume and exercise the authority of the State to grant waivers." *Id.*

RESPONSE: Undisputed.

B. <u>Congress did not to impose inflexible staffing mandates</u>

10. After Congress amended the Social Security Act to declare that all LTC facilities participating in Medicare or Medicaid provide "24-hour nurse service[s] which is sufficient" to meet patient needs, including employing at least one registered professional nurse full-time, Pub. L. No. 92-603, § 278, 86 Stat. 1329, 1424-27 (1972), it also introduced nurse-staffing waiver provisions for rural facilities under specific conditions, *see id.* § 267, 86 Stat. at 1450.

RESPONSE: Undisputed.

11. The Department of Health, Education and Welfare (predecessor of HHS), through its Social Security Administration ("SSA") proposed regulations in 1973 that aligned with these statutory requirements. *See* 38 Fed. Reg. 18,620 (July 12, 1973).

RESPONSE: Undisputed.

12. During the notice-and-comment period for the 1973 regulations, the SSA received comments urging it to deviate from Congress's flexible (qualitative) approach for a staffing

requirement that all nursing homes implement a rigid (quantitative) nurse-to-patient ratio. *See* 39 Fed. Reg. 2,238, 2,239 (Jan. 17, 1974).

RESPONSE: Undisputed.

13. The SSA rejected such a uniform approach, citing the variability in facility needs and the potential negative impacts of arbitrary staffing quotas. *Id.*

RESPONSE: Undisputed, but misleading. SSA's recognition of a potential downside to a policy choice did not constitute definitive rejection of that policy on the merits. The agency chose at that time to rely on quarterly staffing reports to monitor the adequacy of staffing. 39 Fed. Reg. at 2239.

14. SSA reasoned that "the variation from facility to facility in the composition of its nursing staff, physical layout, patient needs and the services necessary to meet those needs precludes setting [a specific ratio]." *Id.*

RESPONSE: Undisputed, but misleading. SSA's recognition of a potential downside to a policy choice did not constitute definitive rejection of that policy on the merits. The agency chose at that time to rely on quarterly staffing reports to monitor the adequacy of staffing. *Id.*

15. In 1980, HHS took over the administration of Medicare and Medicaid services but the standard on staffing remained the same. *See* 45 Fed. Reg. 47,368 (July 14, 1980).

RESPONSE: Undisputed.

16. It proposed a "general revision" of the regulation governing the participation of LTC facilities in Medicare and Medicaid. *See id.*

RESPONSE: Undisputed.

17. HHS declined to implement any specific staffing ratios. *Id.* at 47371; *see also id.* at 47387.

RESPONSE: Undisputed, but incomplete. HHS noted that it "[did] not have enough conclusive evidence to support requiring any specific numerical standards" at that time and "plann[ed] to

undertake a study" about the impact of states' minimum staffing requirements. 45 Fed. Reg. at 47,371-72.

18. In 1987, Congress—and not HHS—redefined nursing home categories and imposed uniform staffing requirements on LTC facilities under Medicare and Medicaid by requiring a registered nurse on duty for at least eight hours per day, seven days a week. See Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4201(a), 101 Stat. 1330-161; *accord id.* § 4211(a), 101 Stat. 1330-186 (Dec. 22, 1987).

RESPONSE: Undisputed, but incomplete and misleading. The 1986 Institute of Medicine report relied on by Congress when crafting the Federal Nursing Home Reform Act expressly recognized that although then-available data was inadequate, the Executive Branch—not Congress alone—possessed sufficient authority to set "minimum nursing staff requirements" for LTC facilities if and when such data "becomes available." Nat'l Library of Med., Inst. of Med., *Improving the Quality of Care in Nursing Homes* 200-01 (1986) ("Institute of Medicine Study"), https://archive.ph/KFNCi ("[i]f convincing evidence becomes available that some approaches to staffing and training are distinctly superior (in quality of care/life and cost) to others, the HCFA will be in a position to incorporate the desirable approaches into its regulatory standards."). In addition to the statutory minimum, Congress explicitly authorized the Secretary to require facilities to meet "such other requirements relating to the health and safety [and well-being] of residents . . . as the Secretary may find necessary." 42 U.S.C. §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B).

19. Congress included waiver provisions and commissioned studies to analyze staffing requirements—in particular "the appropriateness of establishing minimum caregiver to resident ratios." *See* Pub. L. No. 101-508, §§ 4008(h), 4801(a), 104 Stat. 1338 (1990)).

RESPONSE: Undisputed.

20. Congress implemented no mandatory ratios or staffing requirements, and CMS continuously administered the staffing standards established by Congress without incident. *See* 42 C.F.R. § 483.35(a)-(b) (2016).

RESPONSE: The assertion that Congress implemented no "staffing requirements" implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. The legal conclusion is disputed for the reasons explained in Defendants' briefing. Congress required facilities to meet "such other requirements relating to the health and safety [and well-being] of residents . . . as the Secretary may find necessary[,]" 42 U.S.C. §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B), which provides authority for the challenged Final Rule.

21. In 2016, CMS once again dismissed the push for mandatory staffing ratios in LTC facilities and for the 24/7 RN requirement. *See* 81 Fed. Reg. 68,688, 68,754-56 (Oct. 4, 2016).

RESPONSE: Disputed insofar as CMS did not reject minimum staffing requirements on principle, but for lack of sufficient reliable data. *See* 81 Fed. Reg. at 68,755-56.

22. It concluded that a "one-size-fits-all approach" to staffing was not only "inappropriate[,]" but also that "mandatory ratios" and a "24/7 RN presence" were concerning. *Id.* at 68,754-56, 68,758; *see also* 80 Fed. Reg. 42,168, 42,201 (July 16, 2015) (emphasizing the importance of taking resident acuity levels into account").

RESPONSE: Disputed. CMS clarified that the agency "continue[s] to believe that our proposed requirement is necessary to address concerns about inadequate staffing and resulting harm to residents[,]" 81 Fed. Reg. at 68,754, and noted that it was "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 [CMS] a better picture[,]" *id.* at 68,755 (emphasis added). Defendants also dispute the characterization of a minimum staffing "ratio" as a "one-size-fits-all

approach." A minimum staffing "ratio" itself guarantees that the required number of staff will vary based on number of residents, and as such, cannot be characterized as "one-size-fits-all."

23. Specifically, CMS expressed concerns about mandatory ratios and the 24/7 requirement because "LTC facilities [vary] in their structure and in their resident populations." *Id.*

RESPONSE: Undisputed, but misleading. CMS's recognition that LTC facilities vary did not constitute rejection of minimum staffing requirements on the merits. *See* 81 Fed. Reg. at 68,755-56.

24. CMS determined that the "focus" of its regulations "should be on the skill sets and specific competencies of assigned staff to provide the nursing care that a resident needs rather than a static number of staff or hours of nursing care." 80 Fed. Reg. at 42,201.

RESPONSE: Undisputed, but misleading. CMS did consider the "the skill sets and specific competencies of assigned staff" in establishing the minimum staffing requirements in the Final Rule. *See, e.g.*, Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40,876, 40,881, 40,893 (May 10, 2024).

25. And "establishing a specific number of staff or hours of nursing care could result in staffing to that number rather than to the needs of the resident population." *Id.*

RESPONSE: Undisputed, but misleading. CMS's recognition of potential benefits and associated burdens of potential policy choices did not constitute rejection of minimum staffing requirements on the merits. *See* 81 Fed. Reg. at 68,755-56.

26. CMS also found that having a 24/7 RN requirement "could negatively impact the development of innovative care options, particular[ly] in smaller, more home-like settings," and that "geographic disparity in supply could make such a mandate particularly challenging in some rural and underserved areas." 81 Fed. Reg. at 68,755.

RESPONSE: Undisputed, but misleading. CMS's recognition of potential benefits and associated burdens of potential policy choices did not constitute rejection of minimum staffing requirements on the merits. *See id.* at 68,755-56.

27. As CMS acknowledged, there is "widespread variability in existing minimum staffing standards" adopted by 38 States and the District of Columbia. 89 Fed. Reg. at 40,880.

RESPONSE: Undisputed.

28. CMS found that obvious when it succinctly explained its rejection of the one-size-fits-all staffing requirement: "The care needs of each of these populations are different. Facilities range in size from the very small to the very large. The capabilities of these facilities are [] different." *Id.* at 68755.

RESPONSE: Disputed. CMS's recognition that LTC facilities vary did not constitute rejection of minimum staffing requirements on the merits. Moreover, CMS expressly noted in the 2016 Rule that it needed more data to set minimum staffing requirements, stating that "CMS has begun mandatory, payroll-based collection of staffing information from long-term care facilities," along with other data because CMS "believe[s] this information, once a sufficient amount is collected and analyzed, could greatly assist us in re-evaluating this issue[,]" 81 Fed. Reg. at 68,756.

C. <u>CMS issues the Rule that departs from past practice</u>

29. In February 2022, the Biden-Harris Administration departed from decades of practice to establish a "reform" that would "establish a minimum nursing home staffing requirement." White House, FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes (Feb. 28, 2022) ("White House Fact Sheet").[1]

[1] The White House, FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes (Feb. 28, 2022), available at https://tinyurl.com/bddcshn4.

RESPONSE: Disputed. Characterization of the reform as "depart[ing] from decades of practice" is a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. The legal conclusion is disputed for the reasons explained in Defendants' briefing.

30. The administration directed CMS to conduct a research study to determine the level and type of staffing needed to accomplish this directive. *Id.*

RESPONSE: Disputed. The February 28, 2022 White House Fact Sheet stated that "CMS will conduct a new research study to determine the level and type of staffing needed *to ensure safe and quality care* and will issue proposed rules within one year." White House Fact Sheet (emphasis added).

The Abt Study

31. CMS contracted with a private firm, Abt Associates, to perform a "mixed-methods Nursing Home Staffing Study" as a party of CMS's goal of identifying a minimum staffing requirement. Abt Associates, Nursing Home Staffing Study: Comprehensive Report (June 2023) ("Abt Study") at viii, available https://tinyurl.com/b2ehy528.

RESPONSE: Undisputed.

32. The Biden-Harris Administration's goal was to issue proposed rules establishing minimum staffing requirements by February 2023. See White House Fact Sheet.

RESPONSE: Undisputed.

33. Therefore, the Abt Study was, "conducted on a compressed timeframe" with data collected between June of 2022 through December of 2022. Abt Study at xix.

RESPONSE: Undisputed, but incomplete and misleading. As the Abt Study explains, "[t]he short duration [also] reflects the time-sensitive nature of the study[,]" and "[t]he mixed-methods approach was intended to compensate for the limited timeframe[.]" Abt Study at xix.

34. The study was completed and published in June 2023. *Id.* at i.

RESPONSE: Undisputed.

35. Consistent with the decades of prior practice, the Abt Study did "not identif[y] a minimum staffing level to ensure safe and quality care." Abt Study at 115.

RESPONSE: Disputed. The characterization of this statement as "[c]onsistent with the decades of prior practice" implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. Moreover, this paragraph misleadingly quotes the Abt Study's characterization of *past* literature as a conclusion of the study itself. The portion misquoted states in full only that "[*p*]*ast literature* has established strong evidence for a relationship between staffing and quality but has not identified a minimum staffing level to ensure safe and quality care." Abt Study at 115 (emphasis added).

36. Instead, it found that if a minimum staffing level was imposed, "[n]ursing homes [would] face barriers to hiring, primarily [with] workforce shortages and competition from staffing agencies." *Id.* at xi; *see also, e.g., id.* at xii, xiv, 19, 31-32, 115.

RESPONSE: Disputed. This paragraph adopts the inaccurate characterization of the Abt Study addressed in response to paragraph 35, *see supra* ¶ 35. This paragraph also misquotes the Abt Study by inaccurately reframing its observation that "[n]ursing homes face many barriers to hiring, primarily workforce shortages and competition from staffing agencies[,]" Abt Study at 115, as a conclusion that nursing homes *would* face such barriers only *if* a minimum staffing level was imposed.

37. It concluded that a federal minimum staffing requirement would require between 43 and 90 percent of nursing homes to add more staff; could cost the nursing home industry up to $6.8 billion in compliance costs each year; and would increase annual total salaries per nursing home from as low as $316,000 to $693,000 in order to comply. *Id.* at 113-14.

RESPONSE: Disputed. The portion of the Abt Study cited in this paragraph stated that "Quantitative analyses found that between *42* and 90 percent of nursing homes would need to increase staffing under a federal minimum staffing requirement, depending on the requirement level and

design." Abt Study at 113 (emphasis added). The $6.8 billion maximum cost figure likewise was limited only to "a requirement that included minimum staffing levels for all four nurse staff types (RN, LPN, nurse aide, and total nurse staff)[.]" *Id.* at 114. And the Abt Study's observation regarding the estimated increased salary costs referenced in this paragraph was applicable only "among nursing homes needing to increase staffing[,]" not among all nursing homes as Plaintiffs imply. *Id.*

38. In addition, there were several relevant findings that the Abt Study did not make:

a. The Abt Study did not conclude that a minimum staffing requirement would result in definitive benefits. The Abt Study provides data for only "potential minimum staffing requirement benefits" and for "potential barriers to and unintended consequences of [an] implementation." Abt Study at 121 (emphasis added).

RESPONSE: Disputed. The Abt Study expressly stated as "Key Takeaways" that "[n]ursing homes with higher staffing levels tend to have better performance, regardless of the outcome measure or standard for acceptable quality and safety used in the analyses[,]" that "[t]here is a strong positive relationship between quality and nurse aide staffing at high staffing levels[,]" and that "[r]esults of these analyses suggest a potential role for minimum staffing requirements." *Id.* at 39.

b. The Abt Study did not conclude that a federally mandated minimum staffing requirement would actually provide better healthcare outcomes for nursing home residents. Rather, the reviewed literature "underscored" that there was no "clear eviden[tiary] basis for setting a minimum staffing level." *Id.* at xi.

RESPONSE: Disputed. The Abt Study expressly stated as one of its "Key Takeaways" that "[n]ursing homes with higher staffing levels tend to have better performance, regardless of the outcome measure or standard for acceptable quality and safety used in the analyses[,]" that "[t]here is a strong positive relationship between quality and nurse aide staffing at high staffing levels[,]" and that "[r]esults of these analyses suggest a potential role for minimum staffing requirements." *Id.* at 39.

c. The Abt Study did not find the implementation of a federally mandated minimum staffing requirement to be feasible without considering factors such as variations in resident acuity, ongoing staffing shortages, compliance costs, and the diverse circumstances affecting quality patient care. *Id.* at 32. Rather, there was no "specific evidence" that a minimum nursing staff level could be feasibly implemented. *Id.* at 111.

RESPONSE: Disputed. This paragraph plainly mischaracterizes the findings of the Abt Study by attributing the statements of some interview respondents as a "finding" of the Study itself. The Study stated that *some* interview respondents believed that these factors "should be considered when developing a minimum staffing requirement[,]" *id.* at 32, and that the *past* studies reviewed for the literature review did not "present[] a specific evidence-based minimum staffing level[,]" *id.* at 111. In any event, CMS did consider those factors in its rulemaking. *See*, *e.g.*, 89 Fed. Reg. at 40,878, 40,880, 40,883, 40,885, 40,908-09, 40,949-50, 40,970.

39. CMS has rejected staffing mandates in the past. *See*, *e.g.*, 39 Fed. Reg. 2,238, 2,239 (Jan. 17, 1974) (explaining that variation in patients' needs is a valid basis to reject setting a specific staff-to-patient ratio); 45 Fed. Reg. 47,368, 47,371 (July 14, 1980) (rejecting nursing staff ratios or minimum number of nursing hours per patient day because of the lack of conclusive evidence supporting a minimum staffing requirement); 52 Fed. Reg. 38,583, 38,586 (Oct. 16, 1987) (explaining that a 24-hour nursing requirement would be impractical and that a nurse staffing requirement should be sensitive to the "patient mix") ; 80 Fed. Reg. 42,168, 42,201 (July 16, 2015) ("the focus should be on the skill sets and specific competencies of assigned staff to provide the nursing care a resident needs rather than a static number of staff or hours of nursing care that does not consider resident characteristics such as stability, intensity and acuity and staffing abilities including professional characteristics, skill sets and staff mix."); 81 Fed. Reg. 68,688, 68755 (Oct. 4, 2016) ("[w]e do not agree that we should establish minimum staffing ratios at this time . . . [t]his is a complex issue and we do

not agree that a 'one-size-fits-all' approach is best . . . [o]ur approach would require that facilities take into account the number of residents in the facility, those residents' acuity and diagnosis.").

RESPONSE: Disputed insofar as CMS did not reject minimum staffing requirements on the merits, but for lack of sufficient reliable data. *See, e.g.*, 39 Fed. Reg. at 2239; 45 Fed. Reg. at 47,372; 81 Fed. Reg. at 68,755-56.

40. The Abt Study never came to a definitive conclusion that supported a national, one-size-fits-all approach to minimum staffing requirements but also had its own shortcomings.

RESPONSE: Disputed as to the characterization of the Abt Study as not offering a conclusion that supported federal minimum staffing requirements. The Abt Study expressly stated as "Key Takeaways" that "[n]ursing homes with higher staffing levels tend to have better performance, regardless of the outcome measure or standard for acceptable quality and safety used in the analyses[,]" that "[t]here is a strong positive relationship between quality and nurse aide staffing at high staffing levels[,]" and that "[r]esults of these analyses suggest a potential role for minimum staffing requirements." Abt Study at 39. Defendants also dispute the implication that the Final Rule reflects a "one-size-fits-all approach." *See supra* ¶ 22 Response.

41. The study acknowledged but ultimately ignored several potential unintended consequences of a national minimum staffing requirement, including: (1) the possibility that nursing homes might be unable to achieve the staffing levels; (2) LTC facilities could be limited in resident admissions because of staff-to-patient ratios; and (3) nursing homes might even close down entirely, thereby potentially reducing access to care. Id.

RESPONSE: Disputed. The Abt Study acknowledged and discussed the impact of workforce shortages and the feasibility of additional costs to facilities. *See, e.g.*, Abt Study at viii, xii, xx, xxi, 19, 35-37; *Id.* at xiv, 114-19. In any event, CMS also considered and addressed each of these factors in its

rulemaking. *See, e.g.*, 89 Fed. Reg. at 40,885, 40,878, 40,970, 40,949-50; AR_00069990, 00069994, 00069996, 00070002-03, 00070118-123, 00070039-41.

Promulgation of the Rule

42. CMS issued a proposed rule in September of 2023 that introduced new minimum staffing standards for LTC facilities. *See* 88 Fed. Reg. 61,352 (Sept. 6, 2023).

RESPONSE: Undisputed.

43. CMS received approximately 46,000 public comments—some of which warned CMS that the proposed rule exceeded CMS's statutory authority, contravened Congress's considered decision to keep flexible staffing standards, and failed to consider the barriers nursing homes would face with compliance. *See* 88 Fed. Reg. 40883.

RESPONSE: Undisputed, but incomplete, and incorrect citation. CMS also received numerous comments supportive of the proposed rule and CMS's statutory authority, and CMS's consideration of compliance and implementation issues. *See* 89 Fed. Reg. at 40,883; AR_00000209-69362.

44. CMS published the Rule in May of 2024. *See id.*

RESPONSE: Undisputed.

45. CMS claims that the minimum staffing standard is supported by "literature evidence, analysis of staffing data and health outcomes, discussions with residents, staff, and industry." *See* 89 Fed. Reg. at 40,877.

RESPONSE: Undisputed.

46. Citing the inconclusive and truncated six-month Abt Study, CMS claims that this was enough to conclude that an overly-broad staffing requirement was necessary. *See* 89 Fed. Reg. at 40,881, 40,877.

RESPONSE: Disputed as to the characterization of the Abt Study as "inconclusive and truncated," which implicates a legal conclusion instead of a fact and is therefore inappropriately included in the

Statement of Material Facts. Also disputed as to the suggestion that CMS claimed reliance on the Abt Study alone as support for the Final Rule. *See* 88 Fed. Reg. 61,359-65 (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.*, Abt Study at 8-14.

47. Yet, CMS acknowledges that "[t]here is no clear, consistent, and universal methodology for setting specific minimum staffing standards" as evidenced by the 38 states and the District of Columbia that have adopted their own nurse-to-patient ratios. *Id.* at 40881.

RESPONSE: Disputed. This quotation from the Final Rule paraphrasing the Proposed Rule's discussion of the 2022 Abt Study refers to the existing state of affairs prior to the adoption of the Final Rule, and the quotation is not an admission that the Final Rule itself fails to set forth a clear and consistent methodology for the specific minimum staffing requirements challenged in this case. 89 Fed. Reg. at 40,881.

48. CMS asserts that "various provisions" across 42 U.S.C. §§ 1395i-3 and 1396r contain "separate authority" for it to impose the Rule. *See* 89 Fed. Reg. at 40,879, 40,890-9:

- The Secretary may impose "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. § 1395i-3(d)(4)(B); id. § 1396r(d)(4)(B).
- An LTC facility "must provide services and activities to attain or maintain the highest practicable physical, mental, and psychological well-being of each resident in accordance with a written plan of care." 42 U.S.C. § 1395i-3(b)(2); id. § 1396r(b)(2).
- An LTC facility "must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident." 42 U.S.C. § 1395i-3(b)(1)(A); id. § 1396r(b)(1)(A).

RESPONSE: Undisputed.

The Rule's Provisions

49. The Rule imposes two mandatory minimum-staffing requirements on LTC facilities.

RESPONSE: Undisputed.

50. First, the Rule triples the required hours per day of RN services. It requires LTC facilities to have an RN "onsite 24 hours per day, for 7 days a week that is available to provide direct resident care" ("24/7 requirement"). 89 Fed. Reg. at 40997.

RESPONSE: The first sentence implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. The legal conclusion in the first sentence is disputed for the reasons explained in Defendants' briefing. The second sentence is undisputed.

51. Meanwhile, the Medicare and Medicaid statutes require that LTC facilities "[u]se the services of [an RN] for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1395i-3(b)(4)(C)(i); *accord id.* § 1396r(b)(4)(C)(i).

RESPONSE: Undisputed, but incomplete. Both statutes also require facilities to meet "such other requirements relating to the health, safety and well-being of residents . . . as the Secretary may find necessary." 42 U.S.C. §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B).

52. Second, the Rule abandons the flexible, qualitative statutory requirement that LTC facilities "provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1395i-3(b)(4)(C)(i); *accord id.* § 1396r(b)(4)(C)(i).

RESPONSE: Disputed as to the characterization that the Final Rule "abandons" the statutory requirements, which implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. In any event, the Final Rule does not abandon the statutory requirements, which still apply to covered facilities alongside the regulatory requirements of the Final Rule. As CMS explained, "a higher total, RN, and NA staffing level will likely be required" pursuant to the statutory requirements, if "the acuity needs of residents in a facility require a higher level of care, as the acuity needs in many facilities will[.]" 89 Fed. Reg. at 40,877.

53. Instead, the Rule requires that "[t]he facility must meet or exceed a minimum of 3.48 [HPRD] for total nurse staffing," which must include a "minimum of 0.55 [HPRD] for registered nurses," and a "minimum of 2.45 [HPRD] for nurse aides." 89 Fed. Reg. at 40996.

RESPONSE: Disputed to the extent this paragraph adopts the inaccurate characterization of the Final Rule as displacing the statutory requirements, which is addressed in response to paragraph 52, *see supra* ¶ 52. Undisputed that the Final Rule requires that "[t]he facility must meet or exceed a minimum of 3.48 [HPRD] for total nurse staffing," which must include a "minimum of 0.55 [HPRD] for registered nurses," and a "minimum of 2.45 [HPRD] for nurse aides." 89 Fed. Reg. at 40,996.

54. Previously, federal regulations mirrored Congress's qualitative statutory requirements to keep nursing staff available 24-hours per day. *See* 42 C.F.R. § 483.30.

RESPONSE: Disputed. CMS has long promulgated and maintained additional staffing requirements via regulation pursuant to 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B). *See, e.g.*, 42 C.F.R. § 483.60(a)(1); 42 C.F.R. § 483.80(b)(4).

55. Those regulations never specified a quantitative staffing requirement. *Id.*; *Cf.* 89 Fed. Reg. 40,876, 40,996-97.

RESPONSE: Disputed. CMS has long promulgated and maintained additional staffing requirements via regulation pursuant to 42 U.S.C. §§ 1396r(d)(4)(B), 1395i-3(d)(4)(B), including those requiring employment of a minimum number of specific staff types. *See, e.g.*, 42 C.F.R. § 483.60(a)(1) (requiring employment of at least one "qualified dietitian or other clinically qualified nutrition professional"); 42 C.F.R. § 483.80(b)(4) (requiring employment of at least one "infection preventio[nist]").

56. Regarding the statutory waivers, the Rule permits Medicare participants to qualify for a statutory waiver of the 24/7 RN requirement, but not the HPRD requirements. *Id.* at 40,997-98.

RESPONSE: Disputed. The Final Rule "does not purport to eliminate or modify the existing statutory waiver." 89 Fed. Reg. at 40,878.

57. The Rule also permits Medicaid participants to qualify for the statutory waiver concerning the new 24/7 RN requirement and 0.55 RN HPRD requirement, but not for the 3.48 total nurse HPRD nor 2.45 NA HPRD requirements. *Id.* at 40,997.

RESPONSE: Disputed. The Final Rule "does not purport to eliminate or modify the existing statutory waiver." *Id.* at 40,878.

58. The Rule proposes a "hardship exemption," ostensibly allowing partial relief from the 24/7 requirement and minimum HPRD requirements. *Id.* at 40,998.

RESPONSE: Undisputed that the Final Rule incorporates a hardship exemption for both the 24/7 RN and HPRD requirements. Disputed as to Plaintiffs' characterization of the exemption as merely "ostensibly allowing partial relief," which implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts.

59. Departing from the statutory waiver criteria, the Rules requires a facility to establish that it meets all four regulatory requirements to qualify: (1) proving a significant local shortage of health care staff; (2) demonstrating unsuccessful recruitment efforts despite offering competitive wages; (3) documenting financial expenditures on staffing relative to revenue; and (4) qualified facilities must publicly disclose their exemption status. *Id.* at 40,998.

RESPONSE: Disputed. Plaintiffs' assertion that the Final Rule "depart[s] from the statutory waiver criteria" implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. The Final Rule "does not purport to eliminate or modify the existing statutory waiver." *Id.* at 40,878. Plaintiffs' summary of the regulatory waiver criteria is also incomplete. Under the Final Rule, regulatory exemption eligibility is based on: (1) workforce unavailability, as measured by having a nursing workforce per labor category that is a minimum of 20% below the national average for the applicable nurse staffing type; (2) the facility's good faith efforts to hire and retain staff; (3) the facility's documentation of its financial commitment to staffing; (4) the facility's

posting of a notice of its exemption status in a prominent and public location in each resident facility; and (5) the facility's provision of individual notice of its exemption status and the degree to which it is not in compliance with the requirements to its residents and the Office of the State Long-Term Care Ombudsman. *Id.* at 40,877-78.[2] This exemption eligibility determination has no effect on the previously-existing statutory waivers. *See id.*

60. Even if granted on the case-by-case determination, *see* 89 Fed. Reg. at 40886, the exemption only provides an 8-hour reprieve from the 24/7 RN requirement, leaving facilities with the requirement to staff for a minimum of 16 hours per day, 7 days per week. *Id.* at 40,998.

RESPONSE: Undisputed, but incomplete and misleading. An independent statutory waiver for all RN hours over 40 hours per week is also available to qualifying facilities. *See* 42 U.S.C. §§ 1396r(b)(4)(C)(ii), 1395i-3(b)(4)(C)(ii). The Final Rule "does not purport to eliminate or modify the existing statutory waiver." *Id.* at 40,878.

Enhanced Facility Assessment ("EFA")

61. The Rule's EFA implemented on August 8, 2024, requires providers to conduct a comprehensive evaluation of their facility, residents, staff, and resident families to determine staffing and other needs. 89 Fed. Reg. 40,881, 40,906.

RESPONSE: Undisputed.

62. Specifically, the Rule mandates LTC facilities to ensure the "active involvement" of direct care staff and their representatives, and to "solicit and consider input" from residents, their representatives, and family members. *Id.* at 40,908. LeadingAge Kansas has requested guidance from

[2] However, a facility will not be eligible for an exemption if it: (1) has failed to submit Payroll Based Journal ("PBJ") data; (2) is a Special Focus Facility; (3) has been cited for widespread insufficient staffing with resultant resident actual harm or a pattern of insufficient staffing with resultant resident actual harm; or (4) has been cited at the "immediate jeopardy" level of severity with respect to insufficient staffing within the 12 months preceding the survey during which non-compliance is identified. 89 Fed. Reg. at 40,878.

the state survey agency contracted by CMS to carry out healthcare surveys of nursing home providers in Kansas on this provision but did not receive adequate guidance.

RESPONSE: The first sentence is undisputed. As to the second sentence, Plaintiffs' assertion that LeadingAge Kansas "did not receive adequate guidance" implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts.

63. The Rule requires facilities to "review and update" the EFA at least annually, without clear guidance on when updates are "necessary"—thus, leading to potential civil penalties. *Id.* at 40,999.

RESPONSE: Undisputed that the Final Rule requires facilities to "review and update" the EFA at least annually. Disputed as to Plaintiffs' assertion that the Final Rule does not provide "clear guidance on when updates are 'necessary[,]'" which implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts.

64. LTC facilities must also create "contingency planning," despite already having emergency plans in place. *Id.* at 41,000. Overall, the EFA imposes administrative burdens and vague requirements that could result in fiscal penalties.

RESPONSE: Undisputed that the Final Rule requires facilities create "contingency planning." Disputed as to the characterization that such planning is duplicative of existing emergency plans, and disputed that "the EFA imposes administrative burdens and vague requirements that could result in fiscal penalties," which implicate legal conclusions instead of facts and are therefore inappropriately included in the Statement of Material Facts.

65. CMS estimates the cost at $4,955 per facility. 89 Fed. Reg. at 40,939. The Rule requires EFAs conducted on all LTC facilities without considering the acuity and needs of the residents to determine staffing levels or evaluate unique circumstances.

RESPONSE: Undisputed as to the estimated cost. As to the second sentence, for which no record citation is provided, it is undisputed that the Final Rule requires covered facilities to conduct EFAs, but disputed that the facility assessment may be conducted without considering the acuity and needs of the residents. *See.id.* at 40,877 ("We are further modifying the requirements to ensure that facilities have an efficient process for consistently assessing and documenting the necessary resources and staff that the facility requires to provide ongoing care for its population *that is based on the specific needs of its residents*" (emphasis added)).

66. The Rule also requires states, through their Medicaid agencies, to provide "institutional payment transparency reporting" which means they must provide to CMS a yearly report on the percentage of Medicaid payments that are spent on direct compensation services versus administrative overhead costs. *See* 89 Fed. Reg. 40,995. The Rule also requires that this information be posted on state websites. 89 Fed. Reg. 40,990.

RESPONSE: Undisputed.

CMS's Omissions from the Rule

67. Nowhere in the Abt Study does CMS suggest that LTC facilities across the country should require an on-site RN 24 hours per day, 7 days per week.

RESPONSE: Disputed, and lacking citation. The Abt Study expressly noted that "[a]ll but one article explicitly noted that nursing home reform should include 24/7 RN coverage in every nursing home" Abt Study at 12 (citing sources).

68. CMS does not explain how it determined its 3.48, 0.55, or 2.45 HPRD requirements.

RESPONSE: Disputed, and lacking citation. Plaintiffs' assertion that CMS did not explain its determination implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. In any event, CMS fully explained its selection of the HPRD levels chosen. *See, e.g.*, 89 Fed. Reg. at 40,891-95.

69. It claims that the 3.48, 0.55, and 2.45 HPRD levels "were developed using case-mix adjusted data sources." 89 Fed. Reg. at 40,877.

RESPONSE: Undisputed, but incomplete. Plaintiffs' statement cites only to the Final Rule's summary of provisions, while CMS further explained its selection of the HPRD levels chosen on additional grounds throughout the body of the Final Rule. *See, e.g.*, *id.* at 40,891-95.

70. CMS claims that the 0.55 and 2.45 levels, but not the 3.48 level, were discussed during the notice of proposed rulemaking. *See* 88 Fed. Reg. 61,352 (Sept. 6, 2023); 89 Fed. Reg. at 40,891.

RESPONSE: Undisputed that the 0.55 RN and 2.45 NA HPRD levels were discussed in the notice of proposed rulemaking. Disputed as to the assertion that CMS did not claim to have discussed a 3.48 total nurse HPRD level in the notice of proposed rulemaking. *See* 89 Fed. Reg. at 40891 ("We also solicited comments on establishing an alternative total nurse staffing standard, such as 3.48 HPRD, in place of a requirement only for RNs and NAs, or in addition to a requirement for RNs and NAs that could also encompass other nursing staff types. We considered an alternative standard of 3.48 HPRD for total nurse staffing—inclusive of the 0.55 HPRD of RNs and 2.45 HPRD of NAs minimum standards—based on the literature evidence" (citing 88 Fed. Reg. at 61,259-61,366)).

71. In the notice of proposed rulemaking, CMS indicated that based on findings from the Abt Study, additional data sources, "two listening sessions," and literature reviews, they proposed minimum staffing levels of 0.55 HPRD for RNs and 2.45 HPRD for NAs. 88 Fed. Reg. at 61369.

RESPONSE: Undisputed, but incomplete. CMS also discussed, considered, and solicited comments on a total nurse staffing standard "such as 3.48 HPRD" in the notice of proposed rulemaking. *See* 88 Fed. Reg. at 61,259-61,366; 89 Fed. Reg. at 40,891.

72. However, the Abt Study does not substantiate these specific levels.

RESPONSE: Disputed, and lacking citation. The assertion that the Abt Study did not substantiate these levels implicates a legal conclusion instead of a fact and is therefore inappropriately included in

the Statement of Material Facts. The legal conclusion is disputed for the reasons explained in Defendants' briefing.

73. CMS provides no rationale for the 3.48 HPRD requirement in either the notice of proposed rulemaking or the Rule, aside from vaguely stating it was developed using "case-mix adjusted data sources." 89 Fed. Reg. at 40,877.

RESPONSE: Disputed. The assertion that CMS provided no rationale for the 3.48 HPRD requirement implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. In any event, CMS fully explained its rationale for selection of a 3.48 HPRD total nurse staffing standard. *See, e.g.*, *id.* at 40,891-95.

74. CMS's minimum staffing ratios require LTC facilities to ignore the variability in resident acuity and needs across different facilities.

RESPONSE: Disputed, and lacking citation. The assertion that the minimum staffing ratios require LTC facilities to ignore variability in resident acuity and needs across facilities implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. In any event, CMS explained that "many facilities will need to staff above the minimum standards to meet the acuity needs of their residents depending on case-mix and as mandated by the facility assessment required at [42 C.F.R.] § 483.71." 89 Fed. Reg. at 40,891. LTC facilities are also required by statute to provide staffing "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).

75. CMS fails to explain why requiring facilities with lower acuity residents to maintain higher staffing than needed is necessary for increasing quality of care.

RESPONSE: Disputed, and lacking citation. The assertion that CMS failed to explain its rationale for the staffing requirements implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. In any event, CMS fully explained why

the staffing requirements are necessary for resident health and safety in the Final Rule. *See, e.g.*, 89 Fed. Reg. at 40,891-95.

76. CMS fails to account for the ongoing shortage of nursing staff across the country and only offers $75 million to help "increase the [LTC] workforce" that it "expects" will be used for "tuition reimbursement." 89 Fed. Reg. 40,885-86.

RESPONSE: Disputed. The assertion that CMS failed to account for an ongoing shortage of nursing staff implicates a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. In any event, CMS adequately considered and accounted for the workforce challenges in LTC facilities. *See, e.g.*, *id.* at 40,885-87.

77. $75 million is a miniscule fraction of what is needed to comply or alleviate many of the affected LTC facilities, and it fails to address the foundational problem.

RESPONSE: Disputed, and lacking citation. The assertion that CMS failed to address an existing staffing shortage problem represents a legal conclusion instead of a fact and is therefore inappropriately included in the Statement of Material Facts. In any event, CMS adequately considered and accounted for the workforce challenges in LTC facilities. *See, e.g.*, *id.* at 40,885-87.

78. Therefore, LTC facilities will ultimately be on the hook for the remaining $43 billion compliance cost of the Rule without assistance from the federal government.

RESPONSE: Disputed, and lacking citation. All facilities covered by the requirements of the Final Rule receive assistance from the federal government under the Medicare and Medicaid programs at a minimum. The additional costs will be factored into Medicare and Medicaid reimbursement. *See* 42 U.S.C. § 1395yy(e)(5)(A); Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2025, 89 Fed. Reg. 64,048, 64,065 (Aug. 6, 2024); *United States v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039, 1044 (5th Cir. 1984) (explaining that Medicaid is a joint federal-state

program, which "provides to state governments federal funds that the state, after establishing a federally approved plan, uses to pay for medical aid for the poor and disadvantaged").

79. According to the Rule itself, the costs are projected to exceed $5 billion per year after the rule is fully implemented. 89 Fed. Red. at 40,970, tbl. 22; *see id.* at 40,949.

RESPONSE: Undisputed, but incomplete. The cost figure cited does "not include adjustments for any exemptions that [CMS] may provide, which could reduce the rule's cost," 89 Fed. Reg. at 40,955.

80. Outside studies have placed the cost of even reaching more than $7 billion per year. Id. at 40,950.

RESPONSE: Undisputed, but incomplete and misleading. CMS explained its concerns with the accuracy of the $7 billion figure referenced in this paragraph in the Final Rule. *See id.* at 40,950-52.

* * *

Dated: April 3, 2025

Respectfully submitted,

YAAKOV M. ROTH
Acting Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Andrew J. Rising
ANDREW J. RISING
ALLISON M. WALTER
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW, Rm. 12520
Washington, D.C. 20005
Phone: (202) 514-0265
E-mail: andrew.j.rising@usdoj.gov

Counsel for Defendants