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 & Human Services, *et al.*,[1] *Defendants*.	Civil Action No. 1:24-cv-110

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR JUDGMENT ON THE ADMINISTRATIVE RECORD

[1] Plaintiffs note the substitution of parties, per Federal Rule of Civil Procedure 25(d).

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INTRODUCTION

Defendants, the Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services (HHS), and their respective agency heads (collectively: CMS), have imposed crushing staffing requirements on long-term care facilities (LTCs) across the country, as well as facility assessments and reporting requirements in support, which apply to both LTCs and States. CMS's Rule (*see* 89 Fed. Reg. 40,876) is unlawful, exceeds its statutory authority, and is arbitrary and capricious.

Plaintiffs moved for summary judgment on March 3, 2025, and filed a memorandum in support. *See* Dkt. 118 and 118-1. On the same day, CMS moved for judgment on the administrative record. *See* Dkt. 122 and 122-1. These cross-motions are substantially similar. For challenges to agency rulemaking under the APA, the Court's task is to review the record and determine whether, as a matter of law, the agency's decision is arbitrary, capricious, or otherwise contrary to law. *See* 5 U.S.C. § 706. Plaintiffs therefore submitted, in support of their motion for summary judgment, an Appendix and a Statement of Undisputed Material Facts, as well as a detailed background section, with all relevant references to the administrative record. *See* Dkt. 118-1, 118-2, and 118-3. Accordingly, Plaintiffs do not believe a specific response to the administrative record is necessary at this time. Where Plaintiffs object to CMS's characterization or other description of the record, these objections are noted in the argument.

CMS's arguments cannot save the Rule. Congress already set statutory minimum staffing standards for LTCs that participate in Medicaid and Medicaid. They require LTCs to employ a registered nurse (RN) for 8 hours a day, 7 days a week, and they authorize a waiver for those that cannot meet the minimum requirement. With respect to other licensed nurses, LTCs must maintain coverage 24 hours a day, 7 days a week, sufficient to meet the needs of residents. Those flexible standards, focused on the needs of LTC residents, are wiped out by the Rule, which

triples the statutory RN minimum and replaces the statutory waiver with a new, more stringent one. And it replaces the flexible nurse staffing requirements with arbitrary and unsupported staff-to-resident ratios, effectively turning the law's resident-focused standard into a worker-focused standard that fails to respond to local conditions and resident needs.

CMS has no authority to rewrite the law. Its allegedly "broad authority" to promulgate health and safety rules is not a license to legislate. And the Rule's impact—billions in compliance costs, catastrophic closures of LTCs that cannot meet the mandates, and the erasure of state authority over LTCs—makes CMS's extravagant claims of regulatory authority even less plausible. And none of the Rule's mandates are supported by the record. CMS failed to explain its policy, failed to consider how LTCs and States benefitted from the prior policy, and failed to consider whether its mandates were realistic at all.

CMS ultimately fails to demonstrate its statutory authority or justify its unsupported Rule. In an attempt to limit the damage to the Rule, CMS argues that only some parts of the Rule should be vacated. But no part of the Rule would have been promulgated by itself, since all the pieces support the general policy to force LTCs to hire dramatically more nursing staff. And CMS makes no attempt to explain how or why any of the parts of the Rule could survive, so severance is inappropriate. In any case, the entire Rule is unlawful and the APA authorizes vacatur of unlawful rules. Plaintiffs respectfully request the Court to enter judgment for Plaintiffs and to vacate CMS's unlawful Rule.

ARGUMENT

I. CMS LACKS AUTHORITY TO ISSUE THE RULE.

"An agency's promulgation of rules without valid statutory authority implicates core notions of the separation of powers, and [courts] are required by Congress to set these regulations aside." *United States ex rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1257 (8th

Cir. 1998). "If congressional intent is clearly discernable, the agency must act in accordance with that intent." *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 870 (8th Cir. 2021). Here, that intent is readily discernable and demonstrates that Congress did not delegate authority to CMS to promulgate the Rule. Its one-size-fits-all staffing requirements are contrary to statute and to decades of considered congressional judgment on the issue.

CMS acknowledges that it is authorized to act only to the extent permitted by Congress. *Nat'l Fed'n of Indep. Bus. v. Dep't of Labor*, 595 U.S. 109, 117 (2022) (administrative agencies "possess only the authority that Congress has provided"); *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006) (agencies can promulgate rules only "pursuant to authority Congress has delegated to [them]"). *see* Dkt. 122-1 at 11. Accordingly, it lacks any power to act "unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). And Congress has expressly prohibited the Secretary of HHS from publishing rules and regulations that are "inconsistent with" the law. 42 U.S.C. § 1302(a). None of CMS's arguments change this status quo. Just as none of the cases cited by CMS is applicable, since none involves the conflicting statutory provisions and decades of legislative and regulatory history present here. *E.g.*, *Northport Health Servs. of Ark. LLC v. HHS*, 14 F.4th 856, 870 (8th Cir. 2021); *Biden v. Missouri*, 595 U.S. 87 (2022).

Despite CMS's claim of "capacious" and "broad authority" in the statutory language, it relies on provisions that fail to provide any authority to mandate staffing requirements for LTCs. Even CMS itself does not contend that the statutory provisions concerning staffing give it authority for the Rule. Instead, it relies upon "various provisions" elsewhere in 42 U.S.C. §§ 1395i-3 and 1396r that contain "separate authority" for this novel requirement, 89 Fed. Reg. at 40879, 40890-91, and on provisions that do not provide rulemaking authority at all. These provisions state that: (1) An LTC must meet "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); (2) an LTC facility "must provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care," 42 U.S.C. § § 1396r(b)(2); *accord id.* § 1395i-3(b)(2); and (3) 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. § 1396r(b)(1)(A); *accord id.* § 1395i-3(b)(1)(A).

The Rule is exactly the sort of power grab that the Supreme Court cautioned against when it recognized the principle that Congress "does not alter fundamental details of a regulatory scheme in vague terms or ancillary provision—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Thus, courts should be especially skeptical of agency action, like the Rule, where the agency uses "a wafer-thin reed on which to rest such sweeping power." *Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 594 U.S. 758, 765 (2021). CMS lacked statutory authority to promulgate the Rule, and it should be vacated.

A. The 24/7 RN Requirement Exceeds and Conflicts with CMS's Statutory Authority

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). The Rule triples that, requiring 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. CMS cites two statutory provisions in support of its authority to adopt the 24/7 RN requirement: 42 U.S.C. §§ 1396r(d)(4)(B) and 1395i-3(d)(4)(B). Dkt. 122-1 at 14. These are generic provisions that permit the Secretary of HHS to 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." Neither mentions any grant of authority to promulgate new staffing or hours requirements. Further, these provisions are tucked away under an "Other" subheading, which is housed under an equally insignificant "Miscellaneous" subheading, which is itself under the "mousehole" heading "Requirements relating to administration and other matters." No matter how hard CMS tries, the elephant of the Rule cannot hide there. *Cf. Am. Trucking Ass'ns*, 531 U.S. at 468. Particularly because Congress addressed staffing requirements for LTCs in a separate statutory provision, it is implausible that CMS obtained authority to alter that standard through rulemaking in a "miscellaneous," "other" statutory provision.

CMS adamantly asserts its delegated authority to "fill up the details of a statutory scheme." Dkt. 122-1 at 14. But here, there are no "details" to fill up nor any room for "flexibility." Congress spoke to the specific issue. 42 U.S.C. § 1396r(b)(4)(C)(i). Accordingly, whatever authority the Secretary might otherwise have to "fill up" details relating to health or safety, no such authority exists in the face of Congress's direct judgment on staffing.

Far from granting CMS this authority, Congress made the considered judgment that 8 hours was the minimum RN time and that a flexible standard that allowed variation depending on geographical and other considerations was appropriate. From the beginning, Congress has adopted a flexible, qualitative approach to staffing in nursing homes that is in stark contrast to the Rule. It has rejected changes to the law that would mandate inflexible staffing requirements and declined to require 24-hour/7-day-a-week RN coverage. *See* Pub. L. No. 92-603 § 278, 86 Stat. 1329, 1425-27 (declaring that all LTC facilities provide "24-hour nurse service[d] which is sufficient" to meet patient needs, including employing at least one RN full-time); *id.* § 267, 86 Stat. at 1450 (introducing nurse-staffing waiver provisions for rural facilities).

Until now, the agencies involved in regulating LTCs—CMS and its predecessors—have

always adhered to Congress's approach. For example, during the notice-and-comment period for the 1973 regulations, the SSA received comments urging it to deviate from Congress's flexible, qualitative approach to instead require a rigid nurse-to-patient ratio. See 39 Fed. Reg. 2,238, 2,239 (Jan. 17, 1974). But the SSA refused, since "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.* Again in 1980, when HHS proposed a "general revision" of the regulations involving the administration of Medicare and Medicaid programs, it declined to implement specific staffing ratios. See 45 Fed. Reg. 47,368, 47,371, 47,287 (July 14, 1980). Then, in 1987, Congress redefined nursing home categories and imposed the current staffing floor by requiring an RN to be on duty for at least 8 hours per day, 7 days a week. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4201(a), 101 Stat. 1330-161 (Dec. 22, 1987); *id.* § 4211(a), 101 Stat. 1330-186. Congress studied "the appropriateness of establishing minimum caregiver to resident ratios at this time." Pub. L. No. 101-508 §§ 4008(h), 4801(a), 104 Stat. 1338 (Nov. 5, 1990). Though it included waiver provisions, *id.*, it decided not to implement mandatory ratios. *See* 42 C.F.R. § 483.35(a)-(b) (2016).

In 2016, CMS dismissed another push for mandatory staffing ratios and a 24/7 RN requirement. *See* 81 Fed. Reg. 68,688, 68,754-56 (Oct. 4, 2016). It again concluded that a "one-size-fits-all approach" to staffing was "inappropriate," while "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"). Instead, CMS determined that regulations should focus "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. That was because "establishing a specific number of staff hours of nursing care could result in staffing to that number rather than to the needs of

the resident population," "could negatively impact the development of innovative care options," and could be "particularly challenging in some rural and underserved areas." *Id.*; 81 Fed. Reg. at 68,755. CMS acknowledged approvingly the "widespread variability in existing minimum standards" adopted by 38 states and the District of Columbia. 89 Fed. Reg. at 40,880. And it further explained its rejection of a one-size-fits-all staffing requirement by noting that "[t]he 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 68,755.

In 2021, Congress again considered and rejected amendments to the Social Security Act that would have imposed a 24/7 RN requirement for LTCs. And it even declined to commission a report to study the establishment of minimum staff to resident ratios. *See* Section 132000, Registered Professional Nurses, and section 30720, Nurse Staffing Requirements, respectively. Build Back Better Act, HR 5376, 117th Cong., 1st sess., Congressional Record 167, no. 201, daily ed. (November 18, 2021).

The Rule is indefensible when viewed against that history and the statutory text. Congress has rejected mandatory 24/7 RN coverage. *See* 42 U.S.C. § 1396r(b)(4)(C)(i); *accord id.* §1395i-3(b)(4)(C)(i) (LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week."). Throughout the previous regulatory history, CMS and HHS have adhered to this judgment and rightly affirmed the congressional decision on this issue.

CMS's argument that the phrase "at least" grants them authority to add to the statutory minimum misunderstands the statutory scheme and violates the separation of powers. Congress is empowered to set minimum statutory requirements from which private actors—here, LTCs—and state regulatory authorities can then depart upwards, depending on the particular needs of a given community or set of circumstances. The statute sets a minimum (and flexible) RN

requirement through use of the phrase "at least"; nowhere did Congress give the Defendants authority to set a different or maximum standard. Agencies cannot be permitted to engage in this sort of power grab whenever Congress sets a statutory minimum.

The Rule also nullifies the statutory RN waiver, which is available to certain facilities that cannot meet the statute's 8/7 RN requirement. *See* 42 U.S.C. § 1396r(b)(4)(C)(ii); *accord id.* § 1395i-3(b)(4)(C)(ii). The Rule's waiver provisions, however, provide only an 8-hour per day exemption to the 24-hour required staffing. 89 Fed. Reg. at 40,953. This means that an LTC facility will never be allowed to have less than 16 hours of nursing staff per day. CMS does not have a good explanation for this conflict. It describes the statutory waiver as "independent" from the Rule, and insists that the Rule "does not purport to eliminate or modify" that waiver. *See* Dkt. 122-1 at 10, fn. 3. But elsewhere, it describes the Rule's staffing mandates as a separate requirement from the statutory staffing requirements. *See* Dkt. 122-1 at 22 ("Nor do the challenged HPRD requirements purport to alter or relieve facilities' *separate* statutory obligation to staff at a level sufficient to meet the nursing needs of residents."). CMS simply does not, and cannot, explain how an LTC could obtain a statutory waiver once the Rule's staffing mandate becomes effective. Congress did not delegate CMS authority to void the statutory waiver.

Moreover, any suggestion that the statutory language is ambiguous does not alter the Court's analysis. In the first instance, "statutory ambiguity … is not a reliable indicator of actual delegation of discretionary authority to agencies." *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2272 (2024). Appropriately, a court "may not defer to an agency interpretation of the law simply because the statute is ambiguous." *Id.* at 2273. The court instead must "independently interpret the statute and effectuate the will of Congress subject to constitutional limitations," *even if* "the *best reading* of a statute is that it delegates authority to an agency." *Id.* at 2263. Here, both the statutory text and history show the best reading is that no rulemaking power sufficient

to uphold the Rule was delegated to CMS.

The authority that CMS cites to support its supposed authority is inapposite. While it claims that Congress frequently uses the phrase "at least" simply to set a floor from which the Secretary may depart upwards, its example from FNHRA involves a statutory provision expressly granting the Secretary authority to set certain, specified requirements "for providers of such services that are at least as strict as" preexisting requirements. Dkt. 122-1 at 17; Pub. L. No. 101-508, 104 Stat. at 1388-50. In contrast, the statutory provisions establishing that LTC facilities must use RN services for at least 8 hours a day do not grant the Secretary authority to deviate from that standard. This difference is critical. When Congress wants to authorize an agency to further regulate in an area to which it establishes standards, it says so expressly. Here, Congress provided no such authority.

CMS grasps at straws with its other examples as well. When Congress required LTCs to "provide (or arrange for the provision of) … dietary services that assure that meals meet the daily nutritional and special dietary needs of each resident," 42 U.S.C. § 1396r(b)(4)(A), it did so only "[t]o the extent needed to fulfill all plans of care" that a resident's medical team prepared, *id.* § 1396r(b)(2). That regulation, which provides flexible guidance the LTC may use to meet the requirement "to the extent" it even applies—*i.e.*, by hiring a "qualified dietitian *or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis*," 42 C.F.R. § 483.60(a)(1)—is a far cry from the Rule's inflexible mandates, which contradict other parts of the statute.

Similarly, the statutory requirement that LTCs "establish and maintain an infection control program," 42 U.S.C. § 1396r(d)(3)(A), is not contradicted by CMS's regulation requiring that, in such a program, the LTC must "designate" an individual as the "infection preventionist" and that that individual must work at least part-time at the facility and have "completed

specialized training in infection prevention and control," as many facility staff often already are. 42 C.F.R. § 483.80(b)(4). Nor are there decades of legislative and regulatory history rejecting the need to designate an "infection preventionist." Moreover, nothing in *Biden v. Missouri*, undercuts Plaintiffs' position. Despite CMS's frequent invocation, that case is not comparable because it involved a rule requiring LTC staff to be vaccinated against COVID-19, without any competing statutory authority or legislative or regulatory history addressing COVID-19 or the vaccination of LTC staff. It certainly had nothing to do with the level of staffing.

CMS not only fails to identify any provision in which Congress delegated authority to issue new staffing standards, but also the only provisions on which CMS relies for authority for the Rule do not address staffing at all. Instead, those provisions are generic "miscellaneous" and "other" authority that appear elsewhere in the statute. *See* 89 Fed. Reg. at 40,898. "General language" in a different part of a statute "will not be held to apply to a matter specifically dealt with in another part of the same enactment." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645-46 (2012) (internal quotation omitted). CMS's argument that these "miscellaneous" and "other" provisions bestow authority for them to promulgate the Rule is the exact sort of power grab that the Supreme Court repeatedly has rejected and which this Court should also reject. *See Ala. Ass'n of Realtors*, 594 U.S. at 765.

B. The HPRD Requirements Exceed and Conflict with CMS's Statutory Authority

CMS similarly lacks authority to mandate the HPRD requirements in the Rule. These requirements set forth an arbitrary number of the hours per resident day for specific nurse positions. Just as with the RN requirement discussed above, the federal regulations existing prior to the Rule mirrored Congress's qualitative requirements to keep nursing staff available 24-hours per day without specifying a quantitative staffing requirement. *See* 42 C.F.R. § 483.30.

And just as with the 24/7 RN Requirement, for the HPRD requirements CMS once again

relied solely upon "miscellaneous" and "other" statutory provisions for its sweeping regulatory action. And, once again, the Rule's HPRD requirements conflict with Congress's considered judgment that a flexible standard was best.

The cases cited by CMS show exactly why its argument that it had authority to impose the HPRD requirements in the Rule fails. In *Loper Bright*, the Supreme Court recognized that when Congress "delegates discretionary authority to an agency," its role is to "effectuate the will of Congress," with courts ensuring the agency stays within the boundaries of the delegated authority. 144 S. Ct. at 2263. Notably, the examples discussed by the Court involved direct delegations to the agency as to specific matters—a sharp contrast to the statute provisions here. For example, in *Michigan v. EPA*, in the Clean Air Act, "Congress instructed EPA to add power plants to the program if (but only if) the Agency finds regulation 'appropriate and necessary.'" 576 U.S. 743, 752 (2015) (quoting 42 U.S.C. § 7412(n)(1)(A)). And 33 U.S.C. § 1312(a) required the EPA Administrator to establish effluent limitations when pollutants from a specific source interfered with the attainment of water quality "which shall assure" various outcomes, including the "protection of public health and "public water supplies." *Id.* 576 U.S. at 752 n.6. The other regulatory examples cited by CMS as examples where Congress delegated authority to "fill up the details" are similarly not comparable and merely repeat the same arguments that CMS made with respect to the 24/7 RN requirement and that Plaintiffs refute above. *See* Dkt. 122-1 at 23.

CMS also confusingly cites to *Bostock*'s statement that there is no "such thing as a 'canon of donut holes,'" but that has zero application here. In *Bostock v. Clayton County*, the court referred to the argument that Title VII's application to sex discrimination could exclude subtypes of sex discrimination, such as "motherhood discrimination" or sexual orientation discrimination, even though Congress failed to carve out those specific types of sex discrimination from the statute. 590 U.S. 644, 669-70 (2020). No such situation exists here, where Congress did not delegate to

CMS authority to alter its statutory staffing provisions. *Bostock*'s condemnation of a "canon of donut holes" might be applicable, for example, if Congress had delegated to CMS the authority to set HPRD nursing staff requirements, and plaintiffs were arguing that such authority did not extend to nursing assistants. The idea is that if Congress establishes a general rule and does not exclude some specific cases, then the general rule applies. But that is simply not applicable here.

Congress recognized that LTCs and state officials are closest to their communities and better understand the needs of their particular communities. Yet, CMS promulgated a Rule with no evidentiary or legal basis that is in contravention of the statutory provisions relating to LTC staffing. Had Congress intended to give CMS rulemaking authority on this issue, it would have included that delegation in the staffing provisions. It did not. Thus, CMS is forced to claim authority under "miscellaneous" and "other" provisions that were never intended for such sweeping power. CMS even acknowledges that the HPRD requirements do not "alter or relieve" LTC's statutory obligation to staff at levels "sufficient to meet the nursing needs of [] residents," Dkt. 122-1 at 22, because the HPRD staffing levels set a separate "baseline" that CMS purportedly found "necessary" for the "health and safety of residents."

Rather than avoiding a statutory conflict, as CMS claims, CMS's defense illustrates the statutory conflict. CMS is essentially claiming that the level of staffing that is sufficient to meet resident needs—and which therefore satisfies the statutory requirement—is somehow simultaneously below the level of staffing that is necessary—under the Rule—to protect resident health and safety. In other words, the Rule applies itself to a staffing level that is sufficient to meet resident needs, but insufficient to protect resident health and safety. This absurd result is the product of CMS exceeding its authority and promulgating an unlawful Rule.

C. The Rule violates the major questions doctrine

The Rule violates the major questions doctrine because it regulates an area of vast economic and political significance, and intrudes on state authority, without clear congressional authorization to do so. Clear authorization is impossible if the Rule violates the statute, which the Rule does. But even a merely plausible statutory justification would not be sufficient under the major questions doctrine.

The major questions doctrine instructs courts to be highly skeptical of agency action with a profound economic or political impact. Agency regulation on major questions should make any court "hesitate and look for clear congressional authorization before proceeding." *N.C. Coastal Fisheries Reform Grp. v. Capt. Gaston LLC*, 76 F.4th 291, 297 (4th Cir. 2023). The doctrine therefore asks courts to use "common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

CMS gets the doctrine completely wrong. To start, it cites *Iverson v. United States*, 973 F.3d 843 (8th Cir. 2020)—a case which did not address the major questions doctrine at all—for the proposition that courts should rely on canons of interpretation only when a statute employs "words [of] obscure or doubtful meaning." *Id.* at 853. In other words, CMS denies that major questions should receive any extra skepticism. This amounts to a rejection of the major questions doctrine, which is the only way CMS can defend the Rule.

The correct application of the major questions doctrine requires the Court to first determine if the Rule regulates on a major question (i.e. if the agency is "asserting highly consequential power"). *West Virginia v. EPA*, 597 U.S. 697, 724 (2022). If it does, the Court should be skeptical of the agency's authority and subject the Rule to a higher level of scrutiny to ensure that agency authority does not go "beyond what Congress could reasonably be understood to

have granted." *Id*. That higher level of scrutiny means the Court looks for "clear congressional authorization." *Id*. at 723.

CMS misstates the major questions doctrine by narrowing it to the point of irrelevance. It insists the doctrine applies only when two conditions are met: (1) an agency must claim an "extraordinary grant of regulatory authority by asserting extravagant statutory power over the national economy" and (2) that claim "must reflect a fundamental revision of the statute, changing it from one sort of scheme of regulation into an entirely different kind." Dkt. 122-1 (cleaned up). That is not the major questions doctrine. CMS limits what might be considered a "major question," (and thereby triggers a higher level of scrutiny) by narrowing it to only its economic element ("power over the national economy"), and then further narrows the doctrine's application by limiting it to only one of the various indicia of clear authorization that courts have used when applying the major questions doctrine. No court can adopt this approach.

1. The Rule triggers the major questions doctrine

When properly considered, the major questions doctrine applies to the Rule. First, the Rule has vast economic significance. The Rule's own estimate puts its cost at a minimum of $43 billion. In *Alabama Association. of Realtors v. HHS*, , the Supreme Court found that agency action with a $50 billion price tag was of vast economic significance, which triggered the major questions doctrine.[2] 594 U.S. at 764. The Rule's price tag is similar, so the Rule therefore has a similarly vast economic impact which should cause this Court to be skeptical of CMS's

[2] CMS asserts that Plaintiffs' reliance on *Alabama* is "misplaced." Dkt. 122-1 at 28. And it seems to argue that Plaintiffs cite that case as evidence of certain impermissible "downstream" effects of the Rule. But Plaintiffs have not made anything resembling that argument anywhere. *Alabama* is cited as evidence that $43 billion dollars justifies the higher level of scrutiny that the major questions doctrine requires.

authority and to look for clear congressional authorization of that authority (*i.e.* to employ the major questions doctrine).

CMS's formulation gets the major questions doctrine backward: the point of the doctrine is to highlight what type of agency claims to statutory authority deserves higher scrutiny, and only then to determine if the agency's claimed authority fits neatly within the statute.[3] And even though CMS's own misstatement of the major questions doctrine refers only to a regulation's economic significance ("extravagant statutory power over the national economy," Dkt. 122-1 at 29), CMS later claims that "the economic significance of an agency action cannot alone trigger the major questions doctrine" as long as the agency action "fits neatly within the language of the statute." *Id.* at 30 (cleaned up). This is simply wrong. *See Biden v. Nebraska*, 143 S.Ct. 2355, 2375 (2023) (concluding doctrine applies to a "mass [student] debt cancellation program" with purely economic consequences); *see also West Virginia*, 597 U.S. at 744 (Gorsuch, J., concurring) ("[A]n agency must point to clear congressional authorization when it seeks to…require billions of dollars in spending by private persons or entities") (cleaned up). Here, the Rule's costs are significant, so the statutory authority which CMS claims authorizes those costs deserves a higher level of scrutiny by this Court.

The same is true of the Rule's vast political significance. The Rule affects the vast majority of LTCs throughout the country and threatens to close many of them which will not be able to comply with the staffing mandates. The social consequences are potentially dire. Any purported health benefit from the Rule therefore comes at a steep potential cost—precisely the

[3] *See, e.g., Biden v. Nebraska*, 143 S.Ct. at 2381 (J. Barrett, concurring) ("In some cases, the court's *initial* skepticism [about an agency's claim to 'extravagant statutory power'] might be overcome by text directly authorizing the agency action or context demonstrating that the agency's interpretation is convincing… If so, the court must adopt the agency's reading despite the 'majorness' of the question.") (emphasis added).

kind of "basic and consequential tradeoff… that Congress would likely have intended for itself." *West Virginia*, 597 U.S. at 730.

Finally, adding a third and compounding basis for skepticism, the Rule has troubling federalism implications. The Rule acknowledges that 38 states have adopted their own staffing standards which vary between them. *See* 89 Fed. Reg. at 40,881. And the Rule's universal staffing mandate therefore overrides minimum staffing laws in "nearly all states." 89 Fed. Reg. 40,877. The Court should be skeptical of any claim to statutory authority that allegedly justifies this intrusion into an area of state authority. *West Virginia*, 596 U.S. at 744 (Gorsuch, J., concurring) ("When an agency seeks to intrude into an area that is the particular domain of state law… courts must be certain of Congress's intent.").

CMS misconstrues the major questions doctrine's concern with federalism, essentially arguing that any rule that is ultimately permissible under the Constitution cannot implicate the doctrine. See Dkt. 122-1 at 31. The concern with overriding state authority, however, is not based on an unconstitutional intrusion into state authority (which would implicate the Spending Clause, for example), but on the proper interpretation of statutory authority. When Congress overrides state laws, it does so explicitly, not by implication. *West Virginia*, 596 U.S. at 744 (Gorsuch, J., concurring). So when, as here, a court sees an agency vitiating nearly every state's laws establishing minimum staffing requirements, it should expect to see clear authorization from Congress.

In sum, a Rule that costs at least $43 billion, that risks driving a large number of LTCs out of business, and which overrides laws in most states qualifies as a "major question." It is a rule that triggers the higher scrutiny required by the major questions doctrine.

2. The Rule lacks clear congressional authorization

Accordingly, the Court should look, not for "broad authority" or authority to "fill up the details" (see Dkt. 122-1 at 31), but for "clear authorization." And clear authorization for imposing minimum staffing requirements and the related assessment and reporting requirements does not exist.

Indicia of clear authorization, or its absence, include (1) whether the agency relies on "[o]blique or elliptical language" or "seek[s] to hide elephants in mouseholes;" (2) "the age and focus of the statute the agency invokes in relation to the problem the agency seeks to address;" and (3) "the agency's past interpretations of the relevant statute." *West Virginia*, 597 U.S. at 746–48 (Gorsuch, J., concurring) (citations and internal quotation marks omitted). Each of these "telling clues" of an absence of clear authorization appears in this case.

First, CMS claims its statutory authority to set new minimum staffing requirements is found in "other" authority in the statute, rather than the provisions which specifically concern minimum staffing. Whereas agencies are warned against regulating on major questions through reliance on "broad or general language" and "gap filler" provisions—(*Id.* at 746) (citing *Whitman v. American Trucking Assns., Inc*, 531 U.S. 457, 468 (2001)) (cleaned up)—CMS cites its "broad authority" to "fill up the details." Dkt. 122-1 at 31. That justification is a textbook example of the absence of clear authorization.

Second, the "focus of the statute the agency invokes in relation to the problem the agency seeks to address" also indicates an absence of clear authorization. Minimum staffing requirements are addressed in a separate statutory provision. This is unlike in *Biden v. Missouri*, where the Supreme Court found that CMS's staff vaccination requirements were justified by the same broad provisions CMS cites for the Rule. In *Missouri*, there was no connection between staff vaccination and 24/7 RN presence or 24-hour nurse staffing sufficient to meet resident

needs. But staff vaccination was nonetheless deemed necessary for resident health and safety. So it was plausible that staff vaccination during a pandemic may have been the kind of problem on which the "health and safety" authority from sections 1395i–3(d)(4)(B) and 1396r(d)(4)(B) was focused. That dynamic does not exist with the Rule. Minimum staffing is set by statute, so CMS's use of those same "health and safety" provisions to address staffing levels "deploy[s] an old statute focused on one problem to solve a new and different problem [which] may also be a warning sign that it is acting without clear congressional authority." *West Virginia*, 597 U.S. at 747.

Finally, CMS has never imposed minimum staffing mandates, or asserted its ability to do so on the basis of its "health and safety authorities." This, too, is a sign that clear congressional authority is lacking. *See West Virginia*, 597 U.S. at 724 ("the want of assertion of power by those who presumably would be alert to exercise it, is equally significant in determining whether such power was actually conferred.").

Individually and together, these "telling clues" show that clear authorization for the Rule does not exist. And CMS cannot refute them by positively articulating any clear statutory authorization. CMS points merely to Congress's delegation to CMS to "fill up the details of the statutory scheme" through its authority to regulate the "requirements relating to the health and safety of residents." Dkt. 122-1 at 31 (citing *Loper Bright* 603 U.S. at 395 and 42 U.S.C. §§ 1396r(d)(4)(B) & 1395i-3(d)(4)(B)). It calls this authority "express[] delegation" for the Rule. CMS is wrong.

CMS's reliance on *Loper Bright* is misplaced, since the regulation challenged in *Loper Bright* does not concern a major question and the case therefore does not address the standard for "clear authorization." *See Loper Bright*, 603 U.S. at 384. So what might count as express delegation in another case would be inadequate for establishing clear authorization. In any case, as

discussed above, CMS lacks any statutory authority to promulgate minimum staffing requirements, so there is no express delegation. And there can be no "details" to add to the statutory scheme when those details are already expressly included in the statute. CMS's account of its statutory authority for the Rule would be insufficient authorization for any rule, and it does not come close to establishing the clear authorization that is required for major questions. The Court should therefore find that the Rule violates the major questions doctrine.

D. The Rule casts constitutional doubt on CMS's authorizing statute

If CMS's statutory authority permits it to promulgate the Rule, that delegation of authority is unconstitutional. The Rule imposes billions of dollars in costs, overrides state laws, and effectively rewrites other provisions of the Medicaid and Medicare statutes. CMS claims that its regulatory power for the Rule comes from "broad authority" delegated by Congress to enact rules which require LTCs to "meet such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." 42 U.S.C. § 1396r(d)(4)(B), *accord id.* § 1395i-3(d)(4)(B); *see* Dkt. 122-1 at 32. If that authority justifies the Rule, there is no limit on what CMS can do.

CMS correctly describes the standard for permissible delegations of statutory authority: a Congressional delegation of authority to an agency requires an "intelligible principle." *See* Dkt. 122-1 at 32 (citing *Bhztti v. Fed. Hous. Fin. Agency*, 15 F.4th 848, 854 (8th Cir. 2021)). And 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).

Though CMS describes this standard as "not demanding," it nonetheless fails to even try to meet it. It gives one conclusory assertion that "Congress plainly supplied an intelligible principle to govern the Secretary's exercise of his health and safety rulemaking authority." Dkt.

122-1 at 33. But it never gets around to describing what that intelligible principle is for the Medicaid and Medicare statutory delegations it relies on. And more importantly, it never mentions the boundaries of its statutory authority—not even a conclusory statement that there are some boundaries. That does not satisfy the constitutional requirement: a delegation of statutory authority may be "broad, but not boundless." *Saxton v. Fed. Hous. Fin. Auth.*, 901 F.3d 954, 960 (8th Cir. 2018) (Stras., J., concurring).

CMS's inability to explain an intelligible principle or to describe *any* boundaries to its authority is not surprising in light of the authority it claims in the Rule. In the Rule, CMS claims the authority to rewrite statutory limits on minimum staffing and erase statutory waivers for LTCs and replace them with more stringent waivers. This is equivalent to boundless authority to do whatever CMS wants to do—in effect, authority to legislate in place of Congress. If CMS's interpretation is accepted, what would stop it from expanding Medicare and Medicaid eligibility (*see, e.g.*, 42 U.S.C. § 1382) or altering the statutory rights of residents (*see, e.g.*, 42 U.S.C. § 1396r(c)(1)) so long as it could claim these statutory revisions were "relat[ed] to the health and safety of residents?" Since CMS asserts the power to legislate and cannot describe any constitutional limits to that statutory authority, the authority required to uphold the Rule is an unconstitutional delegation.

In order to avoid giving the statute an unconstitutional interpretation, the Court should employ the canon of constitutional doubt and opt for a narrower construction of CMS's statutory authority. And any narrower construction—which rejects CMS's boundless authority to do absolutely anything "relating to the health and safety of residents"—must hold that CMS exceeded its lawful authority in promulgating the Rule.

* * *

The Rule is unlawful and exceeds CMS's statutory authority. Both the major questions

doctrine and the canon of constitutional doubt support a finding that the Rule is unlawful. The Court should therefore enter judgment in favor of Plaintiffs.

II. CMS'S DECISION TO PROMULGATE THE RULE WAS ARBITRARY AND CAPRICIOUS AND UNSUPPORTED BY THE RECORD

The APA's arbitrary-and-capricious standard requires agency action to be "reasonable and reasonably explained." *E.g.*, *Texas v. United States*, 40 F.4th 205, 226 (5th Cir. 2022) (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). The court "must set aside any action premised on reasoning that fails to account for relevant factors or evinces a clear error of judgment." *Id.* An agency acts arbitrarily and capriciously when it departs sharply from prior practice without reasonable explanation or fails ignores alternatives to its action or the affected communities' reliance on the prior rule. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020). A regulation can be deemed arbitrary and capricious if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *In re Operation of Mo. River Sys. Litig.*, 421 F.3d 618, 628 (8th Cir. 2005). Failing to account for costs is failure to consider an important part of the problem. *Michigan v. EPA*, 576 U.S. at 752-53. "Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Id.* And when an agency changes a longstanding policy, it must "show that there are good reasons for the new policy" and "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016) (quoting *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S.

502, 515 (2009)).

By promulgating the Rule, CMS acted arbitrarily and capriciously in multiple ways. It (1) engaged in a sharp departure from past practice without reasonable explanation, (2) failed to consider reliance interests, and (3) failed to consider important aspects of the problem. Its claim to have "collected information" and identified health and safety issues tied to "understaffing in nursing homes" is not reasonably supported by the actual evidence as it relates to the Rule and does not meet the legal standard for reasoned decisionmaking.

A. CMS Failed to Reasonably Explain Its Decision to Sharply Depart from Past Practice to Promulgate the Rule

CMS claims, contradictorily, both that the Rule is "no departure at all" from CMS's past position, and that it somehow also reasonably explained the decision to depart from its past position. These paired admissions doom its motion. "To be sure, the requirement that an agency provide reasoned explanation for its actions would ordinarily demand that it display awareness that it *is* changing position. An agency may not, for example, depart from a prior policy sub silentio or simply disregard rules that are still on the books." *Fox Television Stations*, 566 U.S. at 515 (emphasis in original). Put simply, an explanation for a departure cannot be reasoned, as a matter of law, if the agency does not acknowledge that it is changing its position to begin with.

CMS's assertion that the Rule is "no departure at all" ends the inquiry because the regulatory history indisputably shows that the Rule is, in fact, a departure. It is an undeniable fact that for 50 years CMS has consistently declined to mandate nursing staffing quotes. While much of this history is detailed above, the abbreviated version is that in 1974, the Social Security Administration declined to adopt a nationwide staffing ratio requirement for nursing homes.

Since then, CMS and its predecessors have consistently rejected staffing mandates.[4] Most recently, in 2016, CMS again rejected requests to adopt minimum staffing rules, reiterating that "[t]his is a complex issue and we do not agree that a 'one size fits all' approach is best.... Our approach would require that facilities take into account the number of residents in a facility, those residents' acuity and diagnosis." 81 Fed. Reg. 68,688, 68755 (Oct. 4, 2016).

CMS's description of the Rule as "consisten[t] [with] the agency's position" in the past is pure fiction. CMS misleadingly claims that its decision in 1974 not to adopt "a specific ratio of nursing staff to patients" is consistent with the Rule because "CMS has still not adopted such a fixed standard" but merely set "*minimum* HPRD staffing requirements." Dkt. 122-1 at 40. Not only is this a distinction without a difference, it also ignores the reality of the regulatory history. Congress and CMS declined to adopt either specific ratios or mandatory minimum HPRD staffing requirements (or a 24/7 RN requirement) for decades. The regulatory history demonstrates this fact. In 1974, CMS did not adopt such requirements, *i.e.*, it considered and rejected such requirements. *See* Dkt. 122-1 (acknowledging this fact). Then, in 1980 CMS (then known as Health Care Financing Administration) again expressly declined to adopt "nursing staff ratios or minimum number of nursing hours per patient per day."

CMS then switches gears (because the undeniable evidence shows that Rule is *not*

[4] *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. 38,582, 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.").

consistent with the regulatory and legislative history) and claims that the past decisions rejecting specific staffing ratios and mandatory minimum HPRD staffing requirements were merely due to "lack of sufficient data." Dkt. 122-1 at 41. While this might explain a *rationale* for prior practice, it does not change the ultimate fact fatal to CMS's case: it never implemented staffing quotas prior to the rule. And by implementing staffing quotas, the Rule did depart from past practice. Neither CMS's brief nor the Rule itself shows the necessary awareness of departure from past practice. By not displaying such awareness and trying to depart from past policy *sub silentio*, it is impossible for CMS to have reasonably explained this departure.

In any event, the regulatory history shows that CMS recognized significant drawbacks to any sort of minimum staffing mandate or mandatory 24/7 RN requirement—undercutting their entire argument that the Rule is consistent with the regulatory history. *See* Dkt. 122-1 at 42. CMS has long viewed a 24-hour RN requirement as impractical and rightly believed that mandatory nursing staff requirements should be sensitive to "patient mix." *See, e.g.*, 52 Fed. Reg. 38,583, 38,586 (Oct. 16, 1987). CMS consistently took the position that the staffing 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." 80 Fed. Reg. 42,168, 42,201 (July 16, 2015); *see also* 81 Fed. Reg. 68,688, 68755 (Oct. 4, 2016) ("[t]his is a complex issue and we do not agree that a 'one size fits all' approach is best.").

But even if CMS had acknowledged the policy departure, the Rule is not reasonably explained. Its brief and rulemaking are long on words but short on actual reasons that support the Rule. While CMS presents a full litany of horrors that a few bad actors in the nursing home industry have unfortunately brought to life, the vast majority of LTC facilities provide important

quality care for the elderly when those closest to them are unable to do so for medical, financial, geographic, or other reasons. Thus, CMS does not allege that the Rule will solve shortcomings in care. *See* Dkt. 122-1 at 34 (noting correlation but no causal relationship between staffing and health outcomes and omitting any claim that Rule will improve health and safety for all subject LTCs).

CMS tries to cover its lack of reasoned explanation by claiming it "relied on copious research" to propose the Rule. Dkt. 122-1 at 34. And yet CMS still cannot identify any direct evidence supporting the Rule's onerous and inflexible staffing mandates, EFA, and Medicaid reporting requirements. CMS relied primarily on the Abt study but even the study itself acknowledged that it was done on a compressed timeframe because of the Biden-Harris administration's request to push through the Rule. *See* Abt Study at xix ("This study was conducted on a compressed timeframe, with data collection and analysis included in this report primarily completed between June and December 2022. The short duration reflects the time-sensitive nature of the study and CMS's timeline for proposing a minimum staffing requirement in support of the Presidential initiative"). A study that was done on a compressed timeframe at the request of the agency making the Rule can hardly support reasoned decisionmaking.

In the end, the Abt Study does not support the Rule. In fact, the Abt Study did "not identif[y] a minimum staffing level to ensure safe and quality care." Abt Study at 115.[5] Nor did it recommend 24-hour nursing care. It only referred to some of the literature that had previously recommended it. Instead, the Study found that imposition of a minimum staffing level would

[5] The Abt Study does not support the *specific* staffing levels at all. CMS provides no rationale, for example, for the 3.48 HPRD requirement in either the notice of proposed rulemaking or the Final Rule beyond vague references to what it refers to as a mishmash of "case-mix adjusted data sources." 89 Fed. Reg. at 40,877.

create problems for nursing homes, specifically "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. The study further cautioned that "respondents reported concerns that nursing homes may not be able to achieve required staffing levels, may reduce admissions to meet requirements, or may close entirely, thus potentially reducing access to care." *Id.* at 122. Defendants effectively cherry-picked what was beneficial from the study—which they commissioned, on a compressed timeframe—to justify the Rule while ignoring facts that cut against policy preferences of the Biden-Harris administration. That is certainly arbitrary and capricious.

In addition, there are several relevant findings that the Abt Study did not make: it did not conclude that a minimum staffing requirement would result in definitive benefits. The 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). The 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. The 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.

And it's sad revisionist history for CMS to claim (*see* Dkt. 122-1 at 46) that the impact of COVID-19 on people who were elderly, already in poor health, or living in group settings where

airborne viruses are naturally spread more easily, was due to insufficient staffing.[6] But regardless, the COVID-19 emergency formally ended April 10, 2023,[7] almost five months before publication of the proposed Rule, so any COVID-related justification is inapplicable.

On the substance, CMS identifies no reasonable justification for the duplicative and thus needlessly onerous Medicaid reporting requirement or EFA, and it is in fact their motion as to these requirements that fails to give notice of their arguments. Nor does CMS show that it gave consideration to the incredible costs that each requirement imposes on LTCs and the States. *See Michigan v. EPA*, 576 U.S. at 752-53 ("Consideration of costs reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions."). Plaintiffs' complaint and declarations detailed these costs. CMS's failure to consider this issue was another way in which it acted arbitrarily and capriciously.

B. CMS Failed to Account for Reliance Interests

CMS misunderstands what the reliance interests are and, as a result, could not have seriously considered them. Plaintiffs fully understand that the Rule "sets the floor" for staffing requirements. The problem, however, is that the Rule sets a high floor that is unnecessary for many LTCs to provide safe and quality care. States and LTC facilities have long relied on having the flexibility to determine staffing levels at LTC facilities. And plenty of LTCs have achieved appropriate care without the artificial floor the Rule sets. The Rule takes away decades of flexibility that both states and LTC facilities have had in crafting the appropriate nursing home

[6] *See, e.g.*, Underlying Conditions and the Higher Risk for Severe COVID-19, Center for Disease Control and Prevention, https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html (noting that "Age is the strongest risk factor for severe COVID-19 outcomes… Residents of long-term care facilities are also at increased risk, making up less than 1% of the U.S. population but accounting for more than 35% of all COVID-19 deaths.")
[7] *See* Pub. L. 118-3, 137 Stat. 6 (April 10, 2023).

staffing and does not seriously consider their reliance on this practice.

In the decades that the flexible staffing mandate has been in place, states have responded by implementing staffing requirements tailored to their citizens' needs. In turn, LTCs have devoted considerable resources to meeting the state requirements and working with local lawmakers to achieve a workable standard and ensure that they are complying. CMS concedes that its 24/7 RN requirement imposes a one-size-fits-all requirement, 89 Fed. Reg. at 40,908. Such an approach is not only unworkable in a nation comprised of such diverse states, but it also upends decades of an intentional balance by Congress to set a minimum standard that states then may supplement.

A few examples exemplify the unique approaches that states have worked hard to adopt—given their individual circumstances and the realities of their workforce and budgetary landscape—to ensure that their senior citizens are appropriately protected:

- Kentucky does not set a numerical staffing requirement for nursing homes. Rather, Kentucky adopts a flexible approach requiring "twenty-four (24) hour nursing services with a sufficient number of nursing personnel on duty at all times to meet the total needs of residents." 902 Ky. Admin. Reg. 20:048, § 3(2)(a). Although Kentucky requires a charge nurse to be always on duty, a licensed practical nurse may serve in that role if a registered nurse is on call. *Id.* at § 2(10)(l).

- Missouri law requires skilled nursing facilities to have an RN on duty in the facility for the day shift, and either an LPN or RN for both evening and night shifts. An RN also must be on call any time only an LPN is on duty. And all residential care facilities must have at least one employee for every forty residents. In addition, Missouri residential care facilities must employ a licensed nurse for eight hours per week per thirty residents to monitor each resident's condition and medication. 19 C.S.R. § 20-85.042; *id.* § 30-86.042 & .043.

- North Dakota has, for decades, set a minimum staffing requirement obligating facilities to have an RN on duty for eight hours per day. *See* N.D. Admin. Code § 33-07-03.2-14 (effective July 1, 1996). As of the first quarter of 2023, only *one* of North Dakota's 76 nursing facilities would comply with the Rule's new HPRD standards.

- West Virginia requires each nursing home in the State to have an RN on duty in the facility for at least eight consecutive hours, seven days a week. W. Va. Code R. § 64-13-8.14.4. If there is not an RN on duty, West Virginia law requires an RN to be on

call. *Id.* § 64-13-8.14.5. West Virginia also requires nursing homes to provide at least "2.25 hours of nursing personnel time per resident per day." *Id.* § 64-13-8.14.1.

These varying standards sit alongside wide variations in circumstances within the different states. State Medicaid rates for nursing home services vary from $170 per day to over $400 per day. AHCA Cmt.6. Some states have a relatively steady supply of RNs and NAs, while many others are facing a massive shortage. *See, e.g.*, 89 Fed. Reg. at 40,957, 40,976; 81 Fed. Reg. at 6,755 (noting "geographic disparity in supply" of nursing staff). Rather than "highlight[ing] the need for national minimum-staffing standards," the "widespread variability in existing minimum staffing standards" adopted by 38 States and the District of Columbia underscores that "different local circumstances . . . make different staffing levels appropriate (and higher levels impracticable) in different areas of the country." *Compare* 89 Fed. Reg. at 40,880, *with* AHCA Cmt.6. By imposing rigid nationwide requirements that "exceed the existing minimum staffing requirements in nearly all States," 89 Fed. Reg. at 40877, CMS not only ignored Congress but also state governments whose state-law minimum staffing requirements reflect local conditions.

CMS's claim that the HPRD requirement is actually "tailored to each LTC facility" misunderstands the nature of LTC staffing and the nursing labor market. It is not the *total number* of hours worked by each type of nursing staff that is flexible; of course that will vary depending on the size of a nursing home. It is the mandated *mix* and *proportionality* of the types of staffing that is inflexibly mandated.

The type of nursing staff required for an LTC must depend on the resident acuity. In some LTCs, such as the Dooley Center, where the acuity is relatively low with no major diagnosis or skill needs requiring RN care 24/7 or the HRPD requirement, the mandated staffing mix makes little sense. *See* Dkt. 30-25 ¶ 9 , Appendix. 264-65 (Dkt. 118-3). For example, evaluating a period in 2024, the Dooley Center has "found no significant correlation between RN staffing levels and

reduction in falls or infection rate." *Id.* ¶ 6, App. 263-64. It made a similar finding with respect to NA hours. Thus, there were periods during which Dooley Center would not have been noncompliant with the Final Rule because it did not meet the HPRD requirements for RNs and NAs, even though LPN hours exceeded the HPRD requirements and it found no correlation between patient care and the mix of nursing staff hours. State authority over staffing has largely addressed these concerns, and States and LTCs rely on the continuation of local arrangements.

Instead of explaining how the Rule considered these particular reliance interests, CMS simply cites to pages in the Proposed and Rule that do not even address this issue. *See* Dkt. 122-1 at 49 (citing 89 Fed. Reg. 40877, 40886, 40904, 40955, 40994; 88 Fed. Reg. 61353, 61363, 61374, 61426). "When an agency changes course…it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Regents of the Univ. of Cal.*, 591 U.S. at 30 (internal quotations omitted). "It would be arbitrary or capricious to ignore such matters." *F.C.C.*, 556 U.S. at 515. That is precisely what CMS has done. In both the Rule and this litigation, CMS has ignored the serious reliance interests that states and LTC facilities have had in longstanding policies and instead tried to ram through a $43 billion mandate. That is not only wrong but it is arbitrary and capricious.

C. CMS Failed to Consider Important Aspects of the Problem

The Rule is arbitrary and capricious because it fails to consider both the extreme difficulty of complying with the mandates and the staggering costs it puts on LTCs. "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider [or] entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Inc.*, 463 U.S. 29, 43 (1983). Contrary to CMS's assertion that it offered a reasoned explanation for adopting the Rule and considered the underlying problem, its own arguments in its brief and the record evidence

shows that there was no such explanation.

First, as to ***workforce shortages***, the Rule fails to consider the possibility that it may not be reasonably possible for many LTCs to comply with the Rule. The organizational and provider plaintiffs previously detailed the hardship they already face in hiring staff and the impossibility of implementing the Rule's minimum staffing requirements because of the inadequate supply of RNs and NAs in their states and local communities. They further explain how the waivers and exemptions in the Rule provide no realistic assistance to their LTC facilities. And they explain how the EFAs are arbitrary and unduly burdensome. *See, e.g.*, Dkt. 30-18, ¶¶ 15-30, App. 200-08; Dkt. 30-20, ¶¶ 4-8, App. 224-30; Dkt. 30-11, ¶¶ 10-16, App. 128-32; Decl. 30-25, ¶ 9, App. 264-66; *see also* AHCA Cmt.1-2 5, 11-13, 18; Leading Age Cmt.1-2, 4. CMS barely acknowledged this issue, noting merely that the new requirements "exceed the existing minimum staffing requirements in nearly all States" and will require increased staffing "in more than 79 percent of nursing facilities nationwide." 89 Fed. Reg. at 40877.

In its brief, CMS cites a report by ASPE (Assistant Secretary for Planning and Evaluation, HHS) that allegedly shows that, as of May 2024, a majority of LTCs already provide at least 24 hours of total RN staffing per day. Dkt. 122-1 at 50. But that report was published on June 28, 2024, seven weeks after the Rule was published. *See* 89 Fed. Reg. at 40,876. Therefore, CMS cannot rely on that report to defend the Rule in litigation. "The basic rule here is clear: An agency must defend its actions based on the reasons it gave when it acted." *Regents of the Univ. of Cal.*, 591 U.S. at 24.

CMS also dismissively suggests that the staggering fact that "more than 79 percent of nursing facilities nationwide" cannot meet the new requirements with their current staff, 89 Fed. Reg. at 40887, merely means that these LTCs might already meet three of the four onerous staffing mandates or need hire only one more staff member. But even if this were true (and CMS

has no evidence that it is), that is a significant burden. The LeadingAge plaintiffs, representing thousands of nursing homes in 21 states, documented at length their many members' existential concerns due to the extreme difficulty of meeting the staffing requirements.

In fact, CMS estimates that LTC facilities will need to hire an additional 15,906 additional RNs to meet the 24/7 RN requirement and 0.55 RN HPRD requirement (an increase of about 11.8%), plus an additional 77,611 NAs to meet the 2.45 NA HPRD requirement and 3.48 total nurse HPRD requirement (an increase of about 17.2%). *See* 89 Fed. Reg. at 40958, 40,977-80. Those increases are unattainable at a time when many LTC facilities are already experiencing extreme difficulty finding qualified RNs and NAs to fill vacant positions, and when staffing shortages are expected only to worsen. *See generally* Dkt. 30-15; Dkt. 30-11; Dkt. 30-18; Dkt. 30-20; *see also, e.g.*, AHCA Cmt.5; LeadingAge Cmt.1. Put simply, "staffing mandates do not create more caregivers, nor do they drive caregivers to work in long term care." AHCA Cmt.1.

The Rule also irrationally discounts the vital role of LPNs/LVNs, who hold nearly 230,000 jobs in LTC facilities across the country and undisputedly "provide important services to [their] residents." 89 Fed. Reg. at 40881; *see* Dkt. 30-11 ¶¶ 11, 14, App. 129-32; Dkt. 30-8, ¶ 9, App. 104-05; Dkt. 30-14 ¶ 14, 160-61; AHCA Cmt.6; LeadingAge Cmt.2. As commenters pointed out, the Rule creates an incentive for LTC facilities "to terminate LPN/LVNs and replace them with . . . [less qualified] nurse aides" in order to meet the 2.45 NA HPRD requirement.

CMS's response to the overwhelming evidence that many LTCs will not be able to comply with the Rule was an irrational assertion that "[a] total nurse staffing standard will guard[] against it." 89 Fed. Reg. at 40,892. But that's obviously wrong. For example, a facility that already provides high-quality care through average staffing of 0.55 RN HPRD, 1.25 LVN/LPN HPRD, and 1.7 NA HPRD would satisfy the 3.48 total nurse HPRD requirement but would need an additional 0.75 NA HPRD to satisfy the 2.45 NA HPRD requirement. *See, e.g.*, Dkt.

30-25, ¶ 6, App. 263-64 (Dooley Center staffing includes 4.64 total nurse HPRD but it would have failed the Rule's required 0.55 RN HPRD 39% of the time). The Rule pressures LTC facilities to replace experienced LPNs/LVNs with less-qualified new nurses to meet CMS's arbitrary quota of 2.45 NA HPRD. And CMS's claim that the 100,000 workers who left nursing home employment during the COVID-19 workforce represent a ready workforce ready to return to nursing home employment under the right salary and working conditions is wishful thinking.

CMS's claim that LeadingAge, the national affiliate of several Plaintiffs, "called for a 24/7 RN coverage requirement" is a gross mischaracterization that exemplifies their lack of rational consideration. *See* Dkt. 122-1 at 50, fn. 17. The publication (in support of a *legislative* proposal) cited by CMS shows that LeadingAge National made clear that "several steps are needed to achieve RNs being available 24 hours a day in nursing homes" and those steps must take place prior to any such (Congressionally authorized) requirement.[8] Those steps included significant financial incentives to RNs, RN students, schools and universities, and nursing homes themselves; a national campaign to recruit RNs into nursing homes; and far greater flexibility in meeting any 24/7requirement with greater availability of waivers for small, rural nursing homes, those in areas with severe workforce shortages, and patient populations that do not require or benefit from 24-hour RN care. *Id*. The Rule lacks these supportive measures.

CMS relies on the "pendency of a $75 million campaign to expand the nursing workforce" through financial incentives to work in nursing homes. *See* Dkt. 122-1 at 52. But this one-time financial incentive is speculative, uncertain, and self-evidently insufficient when compared to the total costs of the Rule. It was arbitrary and capricious to insist that this small amount of contingent funding would "ensure compliance is feasible."

[8] *See* AHCA, *Care For Our Seniors Act*, *available at* https://perma.cc/86GE-P32V.

Nor is the delayed implementation a salve for the workforce shortages. The Rule does not deny that there are not nearly enough RNs and NAs available to enable future compliance by the 79% of LTC facilities that are not presently in compliance with the Rule's new mandates. The delayed implementation provides no relief when there is no way for LTCs to "train" and certify the nursing staff required by the Rule, especially those nursing homes located in rural counties where eligible staff simply do not reside or are leaving for other locations. The mandate doesn't somehow create a larger nursing home workforce; rather, forecasts expect hundreds of thousands of healthcare professionals to leave the workforce in the coming years. *See* AHCA Cmt.5; *see id.* at 2 ("The phase-in provisions are frankly meaningless considering the growing caregiver shortage."); LeadingAge Cmt.7 (similar); *see also* Dkt. 30-18, ¶¶ 18-21, App. 202-04 (describing dire trends in healthcare workforce); Dkt. 30-11, ¶ 10, App. 128-29 (similar); Dkt. 30-15, ¶ 7, App. 169-72 (similar).

The uncertain possibility of obtaining a temporary hardship exemption offers no relief to the many nursing homes facing these structural population trends. Instead of being able to proactively explain why it should be entitled to an exemption, facilities that cannot meet CMS's arbitrary requirements will face a perpetual risk of being sanctioned for non-compliance. *See* AHCA Cmt.6, 33-34; LeadingAge Cmt.6 (criticizing CMS's approach as "unnecessarily punitive"). CMS repeatedly emphasizes that the hardship exemption is meant for "limited circumstances," 89 Fed. Reg. at 40,894, and that many facilities in areas of the country with severe shortages of available RNs and NAs would not qualify for an exemption because there are so many "other requirements" that must be met "to obtain an exemption." *Id.* at 40,953. LeadingAge plaintiffs affirmed the difficulty of obtaining a hardship exemption. *See also, e.g.*, Dkt. 30-20, ¶ 7, App. 228-29 (describing unachievable nature of waiver and exemptions for LTC facilities); Dkt. 30-23, ¶ 9, App. 253-54 (similar); Dkt. 30-11, ¶ 16, App. 132 (similar).

Second, as to ***implementation costs***, the Rule fails to reasonably consider the staggering costs, estimated by CMS to be $5 billion per year and by others as high as $7 billion. *See* 89 Fed. Reg. at 40,949, 40,970; *id.* at 40,950. The Rule does not provide any additional funding for Medicare or Medicaid, so CMS "assume[s] that LTC facilities . . . will bear the[se] costs." *Id.* at 40,949. As a red herring, CMS claims that the fact that an agency rule increases costs does not make the rule arbitrary. Be that as it may, the Rule is arbitrary because Defendants *failed to consider* these costs and the resulting burden on regulated entities.

LTC facilities are in no position to take on this huge financial burden. AHCA Cmt.5; LeadingAge Cmt.1-2; THCA Cmt.3. Almost 60% of LTC facilities already have negative operating margins; more than 500 LTC facilities closed over the course of the COVID-19 pandemic; and the costs associated with these new staffing mandates would likely force many more facilities to close. AHCA Cmt.5; *see* LeadingAge Cmt.1-2; *see also, e.g.*, Dkt. 30-11, ¶ 12, App. 130-31 (estimated costs for Kansas LTCs to comply with Rule on minimum staffing standards range between $64 million and $92.7 million in the first year, at an average annual cost of $211,905 per facility); Dkt. 30-8, ¶ 8, App. 102-103 (estimating total cost of $20 million for South Dakota facilities to comply with Rule).

It is irrational for CMS to point to the higher proportion of costs shouldered by Medicare and Medicaid—backed by the U.S. Government—as evidence that small, often rural and nonprofit nursing homes can therefore afford their share. This did not constitute reasonable consideration of the issue. Medicaid and Medicare reimbursements are historically underfunded, leaving States and LTCs responsible for covering the shortfall. And despite their exposition on how reimbursement rates are established, CMS doesn't even pretend that any increase in these reimbursements will ever cover the shortfall.

CMS gives no indication that it considered the impact of the increased costs for States

and LTCs. Instead, the Rule notes that CMS "assume[s] that LTC facilities … will bear the rule's costs." 89 Fed. Reg. at 40,949. The cost of delivering quality care already exceeds Medicaid/Medicare reimbursement rates, meaning that the increased costs from the Rule will further jeopardize nursing homes' ability to serve our older population. *See* Dkt. 30-9 ¶ 6, App. 109-10; Dkt. 30-11 ¶ 12, App. 130-31. As just one example, a nursing home in Maryland obtains 82% of its revenues from Medicaid. The Rule would more than double its payroll, putting the nursing home out of business. Dkt. 30-12 ¶ 5, App. 135-36.

Finally, as to the ***availability of a hardship exemption***, CMS's discussion of the hardship exemption demonstrates that it cannot offer a reasonable justification for the rule. To obtain the hardship exemption, LTC facilities must (1) prove a significant local shortage of health care staff; (2) demonstrate unsuccessful recruitment efforts despite offering competitive wages; (3) document financial expenditures on staffing relative to revenue; and (4) publicly disclose their exemption status. 89 Fed. Reg. 40,998. 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. And, as discussed above, CMS has stated that the exemption applies only in "limited circumstances," 89 Fed. Reg. at 40,894, so it will be extremely difficult for most LTCs to qualify for the exemption.

CMS confirms that it is impossible to know in advance whether one will qualify for an exemption and that the process is a multi-factor determination inscrutable to outsiders. Considering that 79% of LTCs are currently estimated as not in compliance with the Rule's staffing mandates, it is cold comfort that CMS's "preliminary analysis" found that "more than 29 percent" could be eligible for at an exemption from the 24/7 RN requirements, and smaller percentages for the HPRD requirement. CMS also splits hairs over the difference between a

citation and an enforcement action, without denying that an LTC viewed as having "widespread" or a "pattern of insufficient staffing that" resulted in jeopardy of harm to residents would be subject to enforcement action. All this shows that CMS failed to consider that this Rule will be extremely difficult to comply with, even with the hardship exemption, and that a multitude of nursing homes would go out of business. This failure is arbitrary and capricious.

D. Plaintiffs APA challenge includes the EFA and Medicaid reporting

Finally, CMS is wrong that Plaintiffs fail to meet their Rule 8 burden with regard to the EFA and Medicaid reporting requirements. A complaint must satisfy Fed. R. Civ. Proc. 8(a)(2), and provide "a short and plain statement of the claim showing that the pleader is entitled to relief." The "statement need only give the defendant fair notice of what the … claim is and the grounds upon which it rests." *Erickson v. Pardus*, 551 U.S. 89, 93 (2007). Plaintiffs readily meet this standard with respect to the EFA and Medicaid Reporting requirements. As an initial matter, those two requirements are an inseparable part of the Rule, such that if the Rule is vacated, they are also vacated. Further, Plaintiffs' complaint has multiple paragraphs describing the infirmities of the two requirements. *E.g.*, Dkt. 1 at 38-39, 60-61 (describing how the EFA "detracts from the essential administration and direct resident care necessary for quality and safety"; constitutes "a significant burden on staff because it diverts time away from direct resident care"; imposes duplicative contingency planning requirements; and subjects LTCs to "vague requirements that could result in steep civil penalties"); *id.* at 5, 41 (describing how the Rule's reporting requirements impose duplicative and unnecessary costs).

And the prayer for relief specifically seeks a declaration that the EFA exceeds CMS's statutory authority and is arbitrary, capricious, or otherwise not in accordance with the law and an order vacating and setting aside the EFA and permanently enjoining Defendants from taking any action to enforce that requirement. *Id.* at 61-62. From all of this, and as evidenced by their

briefing both at the preliminary injunction and summary judgment stages of the case, Defendants are certainly on notice of Plaintiffs' claims and intent to have the entire Rule, including the EFA and Medicaid Reporting requirements invalidated.

Moreover, to the extent the EFA and transparency reporting requirements support and enhance the minimum staffing mandates, they are arbitrary and capricious as well. CMS announced that it "expect[s] that many facilities will need to staff above the minimum standards… as mandated by the facility assessment required at § 483.71". 89 Fed. Reg. at 40,891.[9] So if CMS failed to explain its sharp departure from past practice, in which it did not previously mandate onerous minimum staffing requirements, it also failed to consider an equally sharp departure when it mandated an EFA that is designed to implement even more onerous staffing requirements. If CMS failed to consider the reliance interests of LTCs and States, which established and complied with staffing requirements appropriate for varied local conditions, then it also failed to consider the same reliance interests with respect to the EFA and transparency reporting requirements that similarly overturn all the arrangements on which they relied.[10] And if CMS failed to adequately consider the extreme and sometimes insurmountable difficulty many LTCs will face hiring sufficient staff to comply with the Rule, then an EFA requirement designed to force LTCs to hire even more staff is an even more important aspect of the problem which CMS failed to consider. In short, each of the arbitrary and capricious grounds for vacatur also applies to the EFA and the transparency reporting requirements.

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[9] *See also id.* at 40,892 ("We emphasized in the proposed rule and reiterate here that facilities 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* at § 483.71) (emphasis added).

[10] *See, e.g., id.* at 40,916 ("We believe the diversity among facilities and State reporting practices and employment laws is why a broad, national reporting requirement is necessary…").

The Court should therefore find that the Rule is arbitrary and capricious and vacate the Rule.

III. THE ENTIRE RULE SHOULD BE VACATED

Under the APA, unlawful rules should be "set aside" and vacated. *See* 5 U.S.C. § 706. The Eighth Circuit has accordingly described vacatur as the "default remedy" (*Missouri v. Trump*, 128 F.4th 979, 997 (8th Cir. 2025)) and "ordinary practice" (*Iowa v. Council on Environmental Quality*, No. 1:24-cv-89, 2025 WL 598928 at *21 (N.D. Iowa Feb. 23, 2025)) when an agency issues an unlawful rule. *See also Iowa League of Cities v. E.P.A.*, 711 F.3d 844, 854 (8th Cir. 2013) (vacating unlawful agency action under section 706 of APA); *United Food Commercial Workers Union, Local No. 663 v. United States Department of Agriculture*, 532 F.Supp. 3d 741, 778 (D. Minn. 2021) (noting unlawful action "normally warrants vacatur" and that "vacatur is the only remedy expressly contemplated by the APA"); *Regents of the Univ. of Cal.*, 591 U.S. at 9 (unlawful agency action must "be vacated"); *Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 144 S. Ct. 2440, 2460 (2024) (Kavanaugh, J., concurring) ("[T]he APA authorizes vacatur of agency rules.").

This Rule is unlawful; it should be vacated. In its brief, CMS nods at various other partial remedies, including declaratory relief which announces the unlawfulness of the Rule, or an injunction limited to the parties which would prevent enforcement of the Rule against Plaintiffs. *See* Dkt. 122-1 at 74-75. But its reference to general equitable principles ignores the statutory remedy under the APA as well as Eighth Circuit precedent. That was why every case CMS cites in support of its plea for a limited injunction concerned either jurisdictional issues (*see Gill v. Whitford*, 585 U.S. 48, 73 (2018) (remanding to district court to address plaintiffs' standing)), or the issuance of a *preliminary* injunction, not with a final determination that an agency action was unlawful. *See Rodgers v. Bryant*, 942 F.3d 452, 466 (8th Cir. 2019) (Stras, J. concurring in part) (explaining the need for careful consideration before granting broad *preliminary* injunctions

because "[t]here has been no final determination yet, so the court's decision necessarily rested on an educated guess about the outcome of the case, based on a limited record and arguments that may not be fully developed."); *California v. Azar*, 911 F.3d 558, 584 (9th Cir. 2018) (addressing only the scope of the district court's *preliminary* injunction); *Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, (2020) (staying a district court's *preliminary* injunction).

CMS cites only a single case to suggest otherwise. *See* Dkt. 122-1 at 62 (citing *U.S. Steel Corp. v. EPA*, 649 F.2d 572, 577 (8th Cir. 1981). That case is inapposite. *U.S. Steel* concerned the EPA's failure to engage in notice and comment rulemaking, as required by 5 U.S.C. § 553(b), when it designated non-attainment zones under the Clean Air Act. *See id.* at 574. EPA's rule was clearly lawful and mandated by statute, so the court ordered the agency to keep the rule but to revise the specific non-attainment designations following notice and comment. By contrast, CMS has not committed a procedural violation—it has substantively violated the law. And that clearly requires vacatur under the APA.

Vacatur is appropriate for the entire Rule because the Rule is a coherent whole, which cannot be severed. Thus the entire Rule is unlawful and the entire Rule is arbitrary and capricious. CMS has a burden to show that any provisions it wishes to save would have been enacted even in the absence of any vacated provisions, and to show that the provisions, which they want saved, function independently from the vacated provisions. *See, e.g.*, *Missouri v. Trump*, 128 F.4th at 998. They do not make this showing.

Contrary to CMS, Plaintiffs have challenged the lawfulness of the both the EFA requirement and the Medicaid Institutional Payment Transparency Reporting requirement by alleging, and proving, that the Rule is arbitrary and capricious. *See* Dkt. 118-1 at 33-35.

Both the EFA and the transparency reporting requirements support the minimum staffing requirements and are designed to support additional staff mandates and to facilitate

enforcement of the Rule. The EFA is an "important complement" to the staffing mandates, which supports the staffing mandates by requiring facilities to "use their facility assessment to develop and maintain a staffing plan to maximize recruitment and retention of nursing staff." 89 Fed. Reg. at 40,906. For this reason, the EFA is described "Phase 1" of a three-phase plan to implement the "final policy," where Phases 2 and 3 directly impose the staffing mandates. *See* 89 Fed. Reg. at 40,912.

The state transparency reporting is similarly integral to the Rule's combined policy. CMS believes it "could help identify facilities that are outliers in terms of allocating Medicaid payments for compensation for direct care workers and support staff, which could be relevant when examining understaffing or staff turnover at certain facilities." 89 Fed. Reg. at 40,916-17. This provision is intended to highlight where "understaffing" (i.e. noncompliance with the Rule) may be the result of excessive "non-compensation facility expenditures." *See* 89 Fed. Reg. at 40,916.[11] The transparency reporting thus forces the States—at State expense—to provide continuing data to CMS in order to justify the Rule's staffing mandates. Neither the EFA nor the state transparency reporting would have been adopted without the staffing mandates.

Finally, and as explained more fully in Plaintiffs' Motion for Summary Judgment (Dkt. 118-1 at 33-35), CMS has a burden to show they would have adopted any provision they wish preserved on its own, without the unlawful parts. *See North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008). And they must show that severing the unlawful parts of the Rule does not

[11] *See also id.* at 40,948 ("In response to concerns about the chronic understaffing... we proposed new Federal reporting requirements that are intended to promote public transparency."); *id.* at 40,991 ("We believe that gathering and sharing data about the amount of Medicaid payments going to the compensation of workers is a critical step in the larger effort to understand the ways we can enact future policies that support the institutional care workforce.").

"impair the function" of what remains. *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988). CMS fails to meet this burden.

Contrary to CMS's assertion, a boilerplate severability clause is not dispositive of the severability question. *See, e.g.*, *Mayor of Baltimore v. Azar*, 973 F.3d 258, 292 (4th Cir. 2020). CMS cites *Advantage Media, L.L.C. v. City of Eden Prairie*, 456 F.3d 793, 800 (8th Cir. 2006) as evidence that the Eighth Circuit defers to broad severability clauses, but the case merely applies severability considerations at the standing stage; it does not change the Court's analysis.

That analysis will show that the close connection between the EFA and transparency reporting requirements, on the one hand, and the minimum staffing requirements, on the other, undermines any argument for severability. The mutually supporting provisions—staffing mandates strengthened by the EFA and transparency reporting—are strong evidence that none of the Rule would have been enacted on its own.

And the Rule's severability clause does not help, except to provide conclusory statements about the ability of two parts of the Rule to operate independently. Though it declares that every provision is intended to be severable, it offers only two details: it asserts that any of the individual minimum staffing requirements can operate independently of the other staffing requirements, and the Medicaid transparency reporting requirement can operate independently of the staffing requirements. 89 Fed. Reg. at 40,913. There is no mention of the EFA's survival if the staffing mandates, by themselves, are declared unlawful. The severability clause's bare statement of CMS's intentions—more accurately described as "hopes"—concerning severability do not meet CMS's burden to show which parts of the Rule, if any, can be severed from the rest.

CONCLUSION

For the foregoing reasons, the Court should enter a final judgment in favor of Plaintiffs.

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