

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

STATE OF KANSAS, STATE OF SOUTH CAROLINA, STATE OF IOWA, STATE OF ALABAMA, STATE OF ALASKA, STATE OF ARKANSAS, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF IDAHO, STATE OF INDIANA, COMMONWEALTH OF KENTUCKY, STATE OF MISSOURI, STATE OF MONTANA, STATE OF NEBRASKA, STATE OF OKLAHOMA, STATE OF NORTH DAKOTA, STATE OF SOUTH DAKOTA, STATE OF UTAH, COMMONWEALTH OF VIRGINIA, STATE OF WEST VIRGINIA, LEADINGAGE KANSAS, LEADINGAGE SOUTH CAROLINA, LEADINGAGE IOWA, LEADINGAGE COLORADO, LEADINGAGE MARYLAND, LEADINGAGE MICHIGAN, LEADINGAGE MINNESOTA, LEADINGAGE MISSOURI, LEADINGAGE NEBRASKA, LEADINGAGE NEW JERSEY/DELAWARE, LEADINGAGE OHIO, LEADINGAGE OKLAHOMA, LEADINGAGE PA, SOUTH DAKOTA ASSOCIATION OF HEALTHCARE ORGANIZATIONS, LEADINGAGE SOUTHEAST, LEADINGAGE TENNESSEE, LEADINGAGE VIRGINIA, DOOLEY CENTER, WESLEY TOWERS,
Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES; and CHIQUITA BROOKS-LASURE, in her official capacity of Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

Civil Action No. 1:24-cv-00110

REPLY MEMORANDUM IN SUPPORT OF
MOTION FOR PRELIMINARY
INJUNCTION

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INTRODUCTION

Defendants' Response magnifies why Plaintiffs are entitled to a preliminary injunction. Instead of engaging with the Rule and the law as is, Defendants present their arguments based on what they believe both should be. And rather than engaging in a coherent defense of the Rule, Defendants throw out a hodgepodge of legal arguments in a desperate attempt to save it. But none of their arguments change the fact that the Rule and the law inherently conflict. In fact, their Response does not even address some of the arguments raised in Plaintiffs' motion. For example, Defendants fail to respond Plaintiffs' argument that the Rule conflicts with the statute because it mandates 24-hour nursing care for all nursing homes absent a waiver when the statute anticipates at least some circumstances where that would not be the case. In other instances, Defendants fail to cite binding precedent that contradicts their arguments on issues such as the major questions doctrine. Finally, Defendants take positions directly contradictory to cases they cite when arguing whether the rule is arbitrary and capricious. In the end, Defendants' Response demonstrates the impossibility of defending the Rule, because there is simply no universe in which it is lawful. And despite Defendants' best efforts to minimize it, there is no doubt that Plaintiffs have experienced and will continue to experience irreparable harm as a result of the Rule. Defendants on the other hand face no harm from the Court hitting the pause button on an unlawful Rule while allowing the case to reach final judgment. The Court should grant an injunction that is nationwide in scope.

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

Defendants throw the kitchen sink in their Response in the hopes that the Rule can be salvaged. But their Response magnifies the problems with a Rule that is (1) contrary to statute, (2) flunks the major questions doctrine, (3) exceeds Defendants' statutory authority, and (4) is

arbitrary and capricious. If the Court agrees with Plaintiffs on any one of these, Plaintiffs have met their burden of likelihood of success on the merits.

A. The 24-Hour Mandate is Contrary to Statute

A glaring omission from Defendants' Response is that it never responds to a key argument in Plaintiffs' Motion which is that for the Rule to be remotely lawful, any staffing mandates for nursing care must be less than 24 hours. LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. §1396r(b)(4)(C)(i); *accord id.* § 1395i-3(b)(4)(C)(i). Congress only requires 24-hour nursing staff "which are sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i)(I); *accord id.* § 1395i-3(b)(4)(C)(I). But the Rule mandates that *all* LTC facilities "must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week." 89 Fed. Reg. at 40,997. It effectively writes the phrase "which are sufficient to meet the nursing needs of its residents" out of the statute by requiring every facility regardless of the nursing needs of its residents to have 24-hour nursing care unless they get a waiver.

What was Defendants' answer to this obvious problem in the Rule? Complete silence. The Court should treat that as a concession that the agency does not have the authority to mandate 24-hour nursing care. And that would be the correct interpretation. The plain language of the statute demonstrates that there would be at least *some* instances where 24-hour nurse staffing would not be required without seeking a waiver. If not, the "which are sufficient to meet the nursing needs of its residents" language would have no purpose. The Rule turns all of this on its head by demanding via executive fiat that *all* nursing homes have 24-hour nurse staffing unless they receive a waiver. "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001). Defendants got caught playing sorcerer and have no defense. On that basis alone, the court can find the Rule is unlawful.

B. Defendants Misapprehend the Major Questions Doctrine

Even if the Rule did not directly conflict with the statute, it still exceeded Defendants' authority. The primary reason is that it flunks the major questions doctrine. Defendants misapprehend when the major questions doctrine is triggered and in doing so, omit binding precedent that contradicts their arguments. Defendants put forth a muddled test for when the major questions doctrine applies that has no basis in law. But in reality, the test is simple. If there is an agency action of vast political or economic significance, clear Congressional authorization is required. *See West Virginia v. EPA*, 597 U.S., 697, 743-44 (2022) (Gorsuch, J., concurring) ("this Court has said that an agency must point to clear congressional authorization when it seeks to...*require 'billions of dollars in spending' by private persons or entities*") (emphasis added) (internal citation omitted)).

Defendants curiously state that "the economic significance of an agency action cannot alone trigger the major questions doctrine." Def. Resp. at 25. In addition, Defendants argue that the \$43 billion price tag of the Rule has a gap with other cases where the doctrine was triggered that is "too large to warrant applying the major questions doctrine here based on economic significance." *Id.* Both are wrong and ignore binding 8th Circuit precedent. In *Missouri v. Biden*, 112 F.4th 531, 537 (8th Cir. 2024), the court addressed whether the major questions doctrine was triggered in the \$475 billion SAVE plan for student loan forgiveness and concluded that "[t]he economic impact of SAVE is roughly nine times larger than the \$50 billion that triggered heightened scrutiny in *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*" (emphasis added). In other words, the price tag of at least \$43 billion for the Rule is approximately equivalent to the \$50 billion that binding 8th Circuit precedent has held triggered heightened scrutiny under the major questions doctrine. Defendants make no effort to distinguish the present case from *Missouri*. In fact, that case is found nowhere in their brief. Regardless, any attempt to distinguish it would be futile as

the Rule is of vast economic significance and triggers “heightened scrutiny” under the major questions doctrine.

Beyond the economic impact of the Rule, it is also of vast political significance because it would fundamentally alter the landscape of the nursing home industry in a manner that impacts 97% of all nursing homes and exceeds the minimum staffing requirements for nursing homes in “nearly all states.” 89 Fed. Reg. at 40,877. Finally, the major questions doctrine is triggered because the Rule is “intruding on powers reserved to the States.” *West Virginia*, 597 U.S. at 744 (Gorsuch, J. concurring). At that point, “heightened scrutiny” is triggered and Defendants must demonstrate they have clear Congressional authorization to implement the Rule.

C. Defendants Cannot Demonstrate “Clear Congressional Authorization”

The Defendants only argue that the major questions doctrine is not triggered by the Rule. They make no effort to explain whether or not they meet the “heightened scrutiny” requirement of the major questions doctrine. The court should treat that as a concession. Regardless, they cannot demonstrate plausible authorization, much less clear congressional authorization, as both the 24-hour nurse staffing provisions and staffing ratios are not authorized by statute.

I. 24-Hour Rule

Defendants operate in an alternate universe where a miscellaneous authority within the statute allows it broad authority to implement a 24-hour nurse staffing requirement. Perhaps if they were working from a blank slate a plausible case could be made for that argument. But they are not. That is because the statute already addresses staffing requirements and only requires 8-hours of continuous nurse staffing at LTC facilities. *See* 42 U.S.C. § 1396r(b)(4)(C)(i)(II); *accord* § 1395i-3(b)(4)(C)(i)(II). Instead of acknowledging this reality, Defendants claim that the statute “left the door open to a regulatory 24/7 RN coverage requirement by using the words ‘at least’ in its statutory 8/7 RN coverage mandate.” Def. Resp. at 17-18. In Defendants’ view as long as they

are not blatantly violating the statute (which for the reasons noted above they are), that provides authorization for them to take such actions. This argument flips the general versus specific cannon of statutory interpretation on its head.

Courts have been clear that this “cannon has full application...to statutes...in which a general authorization and a more limited, specific authorization exist side-by-side.” *RadLax Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012). This “general enactment must be taken to affect only such cases within its general language as are not within the provisions of the particular enactment” and are applicable “wherever an act contains general provisions and also special ones upon a subject, which, standing alone, the general provisions would include.” *United States v. Chase*, 135 U.S. 255, 260 (1890). In a case where “clause (ii) is a detailed provision that spells out the requirements for selling collateral free of liens, while clause (iii) is a broadly worded provision that says nothing about such a sale,” the “canon explains that the ‘general language’ of clause (iii), ‘although broad enough to include it, will not be held to apply to a matter specifically dealt with’ in clause (ii).” *Radlax Gateway Hotel*, 566 U.S. at 646 (internal citation omitted).

In this case, Defendants effectively concede that they are relying on a generalized statutory authority that they claim allows “broad policy discretion.” Def. Resp. at 14. But instead of wrestling with why the Rule is an exception to the general/specific cannon, Defendants pretend it does not exist. They argue that there is no such cannon where “Congress’s failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception.” Def. Resp. at 17. This misses the mark. This is not a case where Congress was silent on 24-hour staffing. It’s a case where Congress spoke directly and set a minimum of 8-hours and the conditions upon which 24-hour staffing is required. At that point, Defendants’ general authority under a miscellaneous provision cannot be held to apply to the specific portion of the

statute that discusses the continuous care requirements for nurses in LTC facilities. Rather than demonstrating clear authorization for the 24-hour nursing care provision, Defendants cannot point to any authority at all.

2. Staffing Ratios

The staffing ratios fare no better. This was another instance where a specific section of the statute allows staffing to “meet the nursing needs of its residents.” *See* 42 U.S.C. § 1396r(b)(4)(C)(i)(I); *accord* § 1395i-3(b)(4)(C)(i)(I). Congress understood flexibility is required and declined to mandate ratios. Once again, Defendants ignore this flexibility and claim that its general authority in a separate provision of the statute allows it to mandate minimum staffing beyond what the specific statutory provisions require. For the reasons noted above, that is impermissible.

3. Defendants Rely on Cases for Authority That Have No Relevance to the Rule

Contrary to Defendants’ assertions, *Biden v. Missouri*, 595 U.S. 87 (2022) (*per curiam*) and *Northport Health Servs. Of Ark, LLC v. HHS*, 14 F.4th 856 (8th Cir. 2021) have no bearing on this case. *Biden* addressed whether the agency can mandate the COVID-19 vaccine to healthcare workers when the underlying statute provided a similar general authority as they are claiming here. *Biden*, 595 U.S. at 93. This case is easily distinguished in that the Medicare and Medicaid statutes are silent on vaccine mandates and the Court concluded the general authority under such statutes to care for the health and safety of hospital patients was enough to authorize it. *Id.* Here, the relevant statutes have specific provisions that address nursing home staffing and the Rule goes beyond what Congress explicitly authorized. Even if Congress provided “broad delegation” in the generalized provision of the statute, it does not extend to areas where Congress spoke explicitly. *Northport* has even less application to the Rule. As with *Biden*, it addressed a matter

(arbitration) that the Medicaid and Medicare statute did not directly address. *Northport Health*, 14 F.4th at 870. In addition, the dicta from that case that Defendants rely on dealt with a separate statutory provision than the one at issue and concluded that the statute was ambiguous. *Id.* The agency action was only upheld on *Chevron* deference, which is no longer the law. See generally *Loper Bright Enterprises v. Raimondo*, 144 S.Ct. 2244 (2024). In short, none of these cases have any bearing on the Rule at issue in this case.

4. Constitutional Doubt

Instead of forming a coherent defense for why the Rule is lawful, Defendants put forth a hodgepodge of arguments in hopes of saving it. This approach demonstrates how unintelligible Defendants' interpretation of the Rule is. And if the court were to accept Defendants' interpretation, it would cast constitutional doubt on the statute. If an agency can utilize a general statutory provision to rewrite (and even contradict) a more specific provision of the same statute, Congress would have delegated authority to the agency without an intelligible principled, which they cannot do.

But the Court need not go there as the Rule is unlawful in a multitude of ways. The Rule exceeds and contradicts the statute it relies on for authority. This is especially true in light of the fact that its subject to "heightened scrutiny" under the major questions doctrine. Ultimately, Defendants cannot demonstrate any authorization for the Rule, much less clear authorization. As a result, Plaintiffs are likely to succeed on the merits.

D. The Final Rule is the Very Definition of Arbitrary and Capricious Rulemaking

Defendants' Response demonstrates how cavalierly they handled the rulemaking process. For example, they take the internally contradictory position that the Rule was "no departure at all" (Def. Resp. at 33) while at the same time claiming even if there was a sharp departure they adequately explained it. At other times, Defendants claim the Rule adequately

considered reliance interests but do not even argue the specific interests that were raised in Plaintiffs' motion. They even cite a study released after the Rule was published in justifying their rationale. Overall, it demonstrates that the Rule was not the result of a reasoned decision-making but the product of rushed efforts to push through the policy preferences of the Biden-Harris administration.

I. Defendants Fail to Display Awareness of Change of Position

Defendants make a stunning admission that the Rule is “no departure at all” from past practice. They then take the position that even if it was a departure they adequately explained it. That is not how it works. “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.” *F.C.C. v. Fox Television Stations, Inc.*, 566 U.S. 502, 515 (2009) (emphases in original).¹ In other words, an explanation for a departure cannot be reasoned if there is no acknowledgment that it is changing position to begin with, which is precisely what Defendants try to do. But Defendants cannot have their cake and eat it too. Either there is no departure at all or there is one and they acknowledge it. By saying the Rule is “no departure at all,” Defendants foreclose any argument that the sharp departure was reasonably explained.

The only serious question left for the court at that point is whether the Rule represents a departure from prior practice. If the court answers in the affirmative that is game, set, and match, as Defendants' position that the Rule is “no departure at all” is fatal to any claim that it was reasonably explained. And there is no doubt that it represents a change of position.

¹ Defendants cite *F.C.C.* in their Response (Def. Resp. at 37) but leave out this important holding of the case.

Plaintiffs explained in thorough detail the 50 years of Defendants consistently declining to issue staffing quotas and will not repeat the history here. But suffice to say, this Rule represents a departure from 50 years of that consistent position. Even Defendants acknowledge the following: (1) in a 1974 rule, “CMS declined to adopt a comment suggesting ‘a specific ratio of nursing staff to patients’” (Def. Resp. at 33 (internal citation omitted)), (2) that “[i]n 1980, CMS declined to implement a minimum nursing staff ratio (*Id.*),” (3) that in 2016, CMS “was not implementing minimum standards” (*Id.* at 34). Defendants contend, without authority, that the Rule is not a departure from past practice because they had limited data to make the determination that these staffing ratios were required or remained open to the possibility that they might one day have some in the future. While that might explain the rationale of prior practice, it does not change the ultimate inconvenient fact to Defendants’ case, which is they never implemented staffing quotas prior to the Rule. And by implementing staffing quotas, the Rule *did* depart from past practice. Beyond the Defendants’ Response, nothing in the Rule itself indicates Defendants displayed the necessary awareness of departure from past practice. By not displaying awareness they are changing positions and trying to depart from past policy *sub silentio*, it is impossible for Defendants to claim the departure is reasonably explained.

But even if Defendants had acknowledged the departure, it was still not reasonably explained. Defendants rely 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 Defendants who are making the Rule is hardly reasoned decision-making. Regardless, the Abt study never recommended 24-hour nursing care. It only referred to some of the literature that had previously recommended it. Abt. Study at 12. In fact, the study also cautioned, “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.” Abt Study at 122. Defendants effectively cherry-picked what was beneficial from the study 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.²

2. Defendants Did Not Even Pretend to Understand Reliance Interests

Defendants’ Response also presents another error fatal to the Rule. They misapprehend what the reliance interests are and as a result, could not have seriously considered them. Defendants contend that Plaintiffs are engaging in a “mischaracterization” of the Rule and hold that it “does not dictate the correct staffing level for any particular facility, but rather, it sets the floor.” Def. Resp. at 38. Plaintiffs are well aware that the Rule sets a (high) floor and that is precisely the problem. As noted in Plaintiffs’ motion, states and LTC facilities have long relied on having the flexibility to determine staffing levels at LTC facilities. This is because plenty of LTC facilities have achieved appropriate care without the artificial “floor” the Rule sets. The

² Defendants also rely heavily on justifications related to the COVID-19 pandemic. Def. Resp. at 36-38. Since the COVID-19 emergency no longer exists (and did not at the time the Rule was published), it cannot justify the Rule. And Defendants did not even attempt to argue that COVID-19 conditions apply to any other infectious disease conditions. In its discussion of COVID-19, CMS did acknowledge, however, that LTC facilities “experienced high worker turnover” and that they have been “slower to recover than the nursing workforce in other healthcare settings.” 89 Fed. Reg. at 40,880. This only shows that it will be challenging to comply with the Rule’s staffing mandates, since so many LTC nurses left the field during and following the pandemic.

issue is that the Rule takes away decades of flexibility that both states and LTC facilities have had in crafting the appropriate nursing home staffing and does not seriously consider their reliance on this practice. Defendants' Response magnifies that problem. Instead of explaining how the Rule considered this particular reliance interest, it simply cites to pages in the Proposed and Final Rule that do not even address this issue. Def. Resp. at 40.

"When an agency changes course...it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Department of Homeland Security v. Regents of the University of California*, 591 U.S. 1, 30 (2020) (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 Defendants have done in this case. In both the Rule and this litigation, Defendants have 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 they are on the hook for. That is not only wrong but it is arbitrary and capricious.

3. Failure to Consider Important Aspects of the Problem

Defendants' claim that they offered a reasoned explanation for adopting the Rule and considered the underlying problem is belied by the record evidence and the arguments in their brief. First, as to workforce shortages, Defendants did not rely upon the ASPE report they cite as showing that, as of May 2024, most facilities meet at least one of the staffing requirements of the Final Rule. That report was published on June 28, 2024. With the proposed rule published on September 6, 2023, and the Final Rule published on May 10, 2024, this report had not even been published yet. 89 Fed. Reg. at 40,876. Therefore, Defendants 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." *Department of Homeland Security*, 591 U.S. at 24.

Defendants go on to make up additional data out of thin air, suggesting that many

facilities already meet three out of four minimum requirements and need only hire a single NA— with zero evidence that this is true for any nursing home in the country. Meanwhile, the LeadingAge plaintiffs, representing thousands of nursing homes in 21 states, documented at length their many members’ existential concerns due to the near, if not actual impossibility of meeting the staffing requirements.

Defendants’ 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 consideration. The publication cited by Defendants shows that LeadingAge National was 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 requirement. 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 24/7 requirement 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. The Final Rule lacks these supportive measures.

Ultimately, Defendants rely on the same Abt Study that Plaintiffs critiqued at length in their opening brief. This study did not identify any minimum staffing level as ensuring safe and quality care and instead found that nursing homes would face barriers to hiring for any minimum staffing requirement. It determined that 43% to 90% of nursing homes would have to add staff to meet the staffing requirement. See Pls. Br. 8. In other words, the study that Defendants actually relied upon for the Rule made findings contrary to the report Defendants now cite as post-hoc justification for an indefensible rule.

Defendants also claim that about 100,000 workers who left nursing home employment during the COVID-19 pandemic could return to nursing home employment if certain salary and

working conditions were met. But Defendants make no effort to evaluate whether these former employees qualify for the positions required by the staffing mandate, or if they have any interest in returning to such employment no matter the benefits, or if they are located in states where the staffing shortages are most acute. In short, Defendants made no reasonable assessment of whether these individuals could help LTCs comply. They made no reasonable assessment of the population trends, healthcare workforce shortages, and rural workforce realities that make compliance extremely difficult if not impossible. Defendants' "plan" to provide "significant funding" to eventually grow the nursing workforce offers no panacea. It is speculative and uncertain. The funding is not finalized and certainly does not provide a reasonable explanation for a staffing mandate that has caused alarm among thousands of nursing homes working to keep their residents in the communities they know and trust.

The delayed implementation provides no relief when there is no way for LTCs to "train" and certify the nursing staff required by the Final 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. Pls. Br. 30. The uncertain possibility of obtaining a temporary hardship exemption offers no relief to the many nursing homes facing these structural population trends. Defendants' wishful thinking cannot substitute their failure to provide a reasonable explanation for a Final Rule that many LTCs will be unable to comply with or must start incurring costs now to even hope to comply by the time the Final Rule is fully implemented.

Second, regarding implementation costs, it is irrational for Defendants to point to the higher costs shouldered by Medicare and Medicaid—backed by the U.S. Government—as evidence that the relatively lower cost thrust onto small, often rural and nonprofit nursing

homes constitutes reasonable consideration of the issue. The pages of the Final Rule cited by Defendants as containing their consideration of the costs—89 Fed. Reg. at 40,878, 40,970, 40,949-50—primarily note the costs without considering what those costs mean for LTCs and their residents. Moreover, Medicaid and Medicare reimbursements are historically underfunded, leaving States and LTCs responsible for covering the shortfall. Defendants give no indication that they considered the impact of the increased costs for States and LTCs. Instead, the Final 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 Final Rule will further jeopardize nursing homes’ ability to serve our older population. *See* Lively Decl. ¶ 6 (Dkt. 30-9); Monger Decl. ¶ 12 (Dkt. 30-11). As just one example, a nursing home in Maryland obtains 82% of its revenues from Medicaid. The Final Rule would more than double its payroll, putting the nursing home out of business. Ciborowski Decl. ¶ 5 (Dkt. 30-12).

Defendants’ discussion of the hardship exemption demonstrates that they cannot offer a reasonable justification for the rule. Defendants confirm that it is impossible to know in advance whether one will qualify for an exemption and the process is a multi-factor determination inscrutable to outsiders and decided by CMS. All this shows that Defendants failed to consider that this Rule is impossible to comply with and that a multitude of nursing homes would go out of business. This failure is arbitrary and capricious.

II. PLAINTIFFS EASILY SATISY THE REMAINING PI FACTORS

A. The Final Rule Irreparably Harms Plaintiffs

Defendants don’t dispute that the private plaintiffs and states who operate their own nursing homes are already experiencing significant financial harms or that the healthcare workforce dynamics necessitate that they must undertake efforts now in order to comply when

the Rule is fully implemented. Nor do Defendants dispute that hardship waivers will be difficult if not impossible for most private plaintiffs to obtain. Instead, Defendants attempt to slice and dice Plaintiffs' challenge to the Final Rule into a gerrymandered version that includes only the 24/7 RN and HPRD requirements and then rely upon inapplicable caselaw to suggest that Plaintiffs' costs are either self-inflicted or due to market forces that have nothing to do with the Rule, when neither is true.

Defendants implicitly admit, as they must, that costs spent now to ensure compliance with a rule going into effect in the future constitutes irreparable harm as a matter of law. The only cases they cite do not hold otherwise. In *Wyoming v. U.S. Dep't of the Interior*, No. 2:16-CV-028-SWS, 2017 WL 161428, at *11 (D. Wyo. Jan. 16, 2017), the court found that just in that particular instance the plaintiffs' "alleged expenses" due to their immediate actions to engage in "Rule implementation and compliance planning" were "too uncertain and speculative to constitute irreparable harm." The lack of certainty as to the irreparable harm arose from the court's findings that (1) the plaintiffs' regulations would operate in tandem with an existing rule without conflict; and (2) the defendant was required to coordinate with States when an enforcement proceeding would adversely affect production of state or private mineral interest. *Id.* at *10-*11. Meanwhile, *Univ. of Tex. v. Camenisch*, 451 U.S. 390 (1981), recites the uncontested principle that a preliminary injunction is meant to preserve the status quo until the issue can be resolved in a trial on the merits. That's exactly what Plaintiffs seek. The expenses here are not uncertain or speculative; rather multiple plaintiffs provided this Court with evidence of the costs they are currently incurring and will continue to incur through the Final Rule fully going into effect. Defendants do not challenge this specific and detailed evidence.

Defendants' half-hearted assertion that Plaintiffs' harms are "purely economic" and "not caused by the Final Rule" fail on both the law and the facts. First, Defendants barely argue that

the “purely economic” nature of the harm is a barrier to issuance of a preliminary injunction and cite no law in support. This is because the economic nature of the harm is not a barrier when the defendant is the federal government against which damages cannot be recovered, thus making such harm irreparable. This principle is so well established that courts recognize that “complying with an agency order later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs ... because federal agencies generally enjoy sovereign immunity for any monetary damages.” See *Wages & White Lion Invs., LLC v. U.S. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021) (cleaned up).

Defendants are also incorrect that these harms occurred in the past and are not going to occur in the future. The harms imposed by the EFA requirement is continuous and ongoing. The Rule requires each LTC to “review and update [the EFA], as necessary, and *at least* annually” and “whenever there is, or the facility plans for, any change that would require a substantial modification *to any part of*” the EFA. 89 Fed. Reg. 40,999 (emphases added). The LTCs lack guidance both as to when updates are “necessary” and how they are to craft the EFA. As a result, nursing homes are forced to be ever vigilant in updating their EFAs and soliciting the required input. The associated costs quickly add up and Plaintiffs presented multiple declarations about the harm this is causing and will continue to cause. See, e.g., Ciborowski Decl. ¶ 11 (Dkt. 30-12); Andrew’s Decl. ¶ 7 (Dkt. 30-22); Bates Decl. ¶ 9 (Dkt. 30-15). Defendants have no response to these declarations and offer nothing except a conclusory statement that the harms occurred only in the past.

Second, Plaintiffs’ evidence details at length that the increased costs and burdens that they are having to undertake now are anything but “self-inflicted.” Rather, Plaintiffs’ increased costs and administrative burdens arise directly from provisions of the Rule already in effect (the EFAs) or incredibly onerous staffing requirements that will be impossible for them to achieve

unless they begin ramping up now—if at all. Defendants planned for LTCs to need time to implement the new requirements, recognizing that the Rule’s phase-in period would “allow all facilities the time needed to prepare and comply with the new requirements specifically to recruit, retain, and hire nurse staff as needed.” 89 Fed. Reg. at 40,894. Defendants cannot now claim that the LTCs are engaged in “self-harm” when they are using the period before the staffing requirements go into effect for the very purpose that the Rule intended. As to the factual record, Defendants don’t challenge the evidence that the Plaintiffs put forward detailing the costs and burdens they are incurring. *See, e.g.*, Andrews Decl. ¶ 11; Van Ree Decl. ¶ 9; Ciborowski Decl. ¶ 6; South Decl. ¶ 4. On the legal side, the cases that Defendants rely upon simply don’t apply here. *H&R Block Tax Servs. LLC v. Santiago*, 2019 WL 1415466 (W.D. Mo. Mar. 28, 2019), involved harm to *defendants* from defendants’ breach of non-compete covenants that was self-inflicted and the “restraints being placed on Defendants [were] no greater than those to which they already agreed.” In *Sierra Club v. U.S. Army Corps. Of Eng’rs*, 645 F.3d 978 (8th Cir. 2011), the party seeking an injunction had spent millions on the construction that it sought to continue before the permit had issued and ignored the defendant’s warning that the movant was proceeding at its own risk. Defendants attempt to scapegoat the workforce shortage rather than the Rule for the Plaintiffs’ harm. But the Rule exists in the world as it is, not as Defendants might wish it to be. The workforce shortage is the context for the incredible difficulty and expense that the Rule imposes on the Plaintiffs. And Plaintiffs cannot possibly be expected to wait to hire staff that may not be available later (and risk getting sanctioned by Defendants for being out of compliance with the Rule) in hopes that they might prevail in court at a later date. This harm they have incurred through hiring staff is hardly “self-inflicted.”

Moreover, Defendants are flat wrong that Plaintiffs challenge only the 24/7 RN requirement and the HPRD requirements. Plaintiffs challenge the Final Rule in toto, and

specifically argue that the Final Rule fails under the major questions doctrine, that Defendants do not have authorization to issue the Final Rule; that the Final Rule conflicts with statute; and the Rule is arbitrary and capricious. None of these arguments carves out the EFA provision; rather the EFA provision is a central piece of the unlawful Final Rule and directly relates to the staffing quotas. Plaintiffs argue specifically throughout their brief that the EFA requirement is “vague” (Pls. Br. 2, 15, 16) and “unreasonable” (*id.* at 4). That Plaintiffs used the 24/7 RN and HPRD requirements as examples of how Defendants exceeded their statutory authority and acted arbitrarily and capriciously does not mean that they somehow had statutory authority for *any* of the Final Rule.

It is not surprising that Defendants seek to carve out the EFA portion of the Final Rule from Plaintiffs’ challenge. The EFA requirement is already in effect and imposing thousands of dollars in compliance costs annually on each LTC—completely undermining Defendants’ argument that the Final Rule’s provisions go into effect two years after it was published (about a year and a half from now) and thus any current costs are “self-inflicted.” In fact, Defendants *admit* that the EFA will cost each LTC facility subject to the Final Rule thousands of dollars, 89 Fed. Reg. 40,939, and, of course, Plaintiffs’ experience is that the costs are far higher. *See* Thurlow Decl. ¶ 7 (Dkt. 30-14); Porter Decl. ¶ 9 (Dkt. 30-25); Mains Decl. ¶ 5 (Dkt. 30-24). And Defendants implicitly acknowledge that hardship waivers will be rare and difficult, as they do not rebut Plaintiffs’ evidence of this fact. *See, e.g.,* South Decl. ¶ 7 (Dkt. 30-20); Wallace Decl. ¶ 9 (Dkt. 30-23); Monger Decl. ¶ 16 (Dkt. 30-11) (describing unachievable nature of waiver and exemption process).

Besides these imminent and irreparable harms that will be suffered by LTCs and the States which operate LTCs, Defendants completely fail to address, let alone refute, the other harms alleged by the Plaintiff States. These harms include costs related to “institutional payment

transparency reporting,” increased Medicaid and Medicare expenses, and increased administrative burdens due to complaints and waiver requests which will occur due to the Final Rule. Beyond the costs to the States that are admitted in the Final Rule itself (*see* 89 Fed. Reg. at 40,991), Plaintiff States submitted declarations from nine states verifying the imminent harms (*See* Dkt. 30, Exs. 2-8, 27-28). Defendants have no response to any of these. They should therefore be accepted as true, and as admitted by Defendants.

Finally, Defendants’ timeliness argument fails. “The issue is whether the length of delay was unreasonable, an issue that turns on the facts of each case.” *Safety-Kleen Sys. v. Hennkens*, 301 F.3d 931, 936 (8th Cir. 2002) (internal quotation marks omitted) (seven-month delay not unreasonable); *see also Facility Guidelines Inst., Inc. v. Upcodes, Inc.*, 677 F. Supp. 3d 955, 976 (E.D. Mo. June 15, 2023) (delay of four to five months not unreasonable); *Minn. Chamber of Commerce v. Choi*, 707 F.3d 846, 869 (D. Minn. 2023) (five-month delay “not dispositive). Here, Plaintiffs are forced to walk a tightrope between delaying their request for a preliminary injunction and obtaining confirmation and evidence that the Final Rule is in fact harming them. Had Plaintiffs moved earlier, Defendants almost certainly would argue that their harms were speculative and uncertain, whereas now, Plaintiffs are actually experiencing the increased costs and burdens of the EFAs and taking steps to ensure they can meet the staffing requirements when they go into full effect. Defendants cite no authority for their proposition that Plaintiffs must rush into court before having evidence of irreparable harm or be foreclosed from any injunctive relief in the future. And none exists. Plaintiffs have met their burden of showing irreparable harm.

B. The Balance of the Equities and Public Interest Favor Plaintiffs

Defendants mischaracterize Plaintiffs’ arguments and the facts in arguing that the balance of the equities and public interest favor Defendants. These two factors heavily favor Plaintiffs. “[W]hen balancing the equities, the key question is whether the movant’s likely harm

without a preliminary injunction exceeds the nonmovant's likely harm with a preliminary injunction in place.” *Missouri*, 112 F.4th at 538 (internal quotations omitted). Here, the harm to the Plaintiffs greatly exceeds that to Defendants. Defendants provide zero explanation as to how enjoining the Final Rule would cause them any form of irreparable injury, especially when Defendants argue at length about the delayed implementation of the staffing requirements. And although the Rule is imminently imposing costs on Plaintiffs, its delayed implementation means Defendants suffer no harm from pausing it.

The public interest also favors Plaintiffs, as the public has no interest in an unlawful regulation. Defendants cite *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (Def. Resp. at 52) for the proposition that an injunction would prevent CMS from “effectuating statutes enacted by representatives of [the] people” and thereby harm the U.S., but this gets the situation backwards. The Rule is not a statute. And Congress (not an executive branch agency) dictates what the public interest is through statute. Congress has only required an 8-hour nurse staffing mandate and flexibility on ratios. Defendants are in turn going *against* the Congressionally determined public interest by implementing a Rule that is contrary to what Congress has decided. The bottom line is there is no legally cognizable harm to Defendants in hitting the pause button on an unlawful Rule while the case is being litigated. Plaintiffs on the other hand have experienced and will continue to experience irreparable harm every day that the Rule is in effect. The balance of equities sharply favors Plaintiffs.

III. AN INJUNCTION SHOULD APPLY NATIONWIDE

Despite Defendants’ arguments to the contrary, familiar principles of administrative law dictate that this Court should enjoin the entire Rule on a nationwide basis. With respect to Defendants’ severability argument, Defendants rely heavily on the presence of the Final Rule’s severability clause to support its argument that any injunction should only apply to the 24/7 RN

and HPRD requirements. But the presence of a severability clause in a final rule in and of itself is not outcome dispositive of a severability analysis. *See Mayor of Baltimore v. Azar*, 973 F.3d 258, 292 (4th Cir. 2020) (holding that a final rule was not severable despite the presence of a severability statement contained in the rule).

Instead, this Court should consider whether the Defendants would have “adopted the [remaining] portion on its own.” *North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008). And even if this Court thinks Defendants might have done so, it must still consider whether severance would ultimately “impair the function” of the rule. *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988). Beyond pointing to the severability clause itself, Defendants offer no arguments to show that they would have adopted the remaining portions of the Final Rule. They make no attempt to show that the remaining portions of the Rule could function on their own. This is unsurprising because the central, overarching purpose of the rule is to establish the challenged staffing standards. *See* 89 Fed. Reg. at 40,876 (“This final rule establishes minimum staffing standards to address ongoing safety and quality concerns for the 1.2 million residents receiving services in Medicare and Medicaid certified Long Term Care (LTC) facilities each day.”). Given Defendants’ failure to make this showing, this Court should reject Defendants’ severability argument.³

Turning to their next argument, Defendants contend that the scope of an injunction should be limited to facilities operated by Plaintiffs and their members. However, this argument ignores or misapprehends principles of equitable jurisprudence that must guide this Court’s inquiry. As recently explained by the Eighth Circuit, “[c]rafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as

³ In any event, and as discussed above, this argument also fails because Plaintiffs challenge the Final Rule in toto.

the substance of the legal issues its presents.” *Nebraska v. Biden*, 52 4th 1044, 1048 (8th Cir. 2022) (quoting *Trump v. Int’l Refugee Assistance Project*, 582 U.S. 571, 579 (2017)).

One such equitable principle is that “the scope of injunctive relief is dictated by the extent of the violation established, not by the geographical extent of the plaintiff class.” *Id.* (quoting *Rodgers v. Bryant*, 942 F.3d 451, 458 (8th Cir. 2019)). And perhaps for this reason, and as explained in Plaintiffs’ Motion, the “ordinary result” that occurs when “a reviewing court determines that agency regulations are unlawful” is that “the rules are vacated—not that their application to the individual petitioners is proscribed.” *Nat’l Min. Ass’n v. U.S. Army Corps of Engineers*, 145 F.3d 1399, 1409 (D.C. Cir. 1998). For the reasons outlined above, Plaintiffs have established that the Final Rule is unlawful in multiple respects—and not merely invalid as applied to any one Plaintiff. For this reason, the Rule should be enjoined nationwide.

Another equitable principle is that any injunctive relief must be “workable” and no more burdensome than necessary to the defendant. *Nebraska*, 52 4th at 1048. Given the diverse coalition of Plaintiffs in this case, including sovereign States and associational groups from across the country, a piecemeal injunction would be both unworkable and unduly burdensome.

CONCLUSION

Defendants’ Response only magnified how unlawful the Rule is. Unfortunately, the Rule has caused and will continue to cause irreparable harm to Plaintiffs unless this Court intervenes. The prudent course of action would be to hit the pause button on the Rule so that Plaintiffs will not bear further costs as a result of a Rule that should have never been implemented in the first place. The court should do that through granting a preliminary injunction.

Respectfully submitted,

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