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

STATE OF KANSAS, et al., Plaintiffs, vs. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, et al., Defendants.	No. C24-110-LTS-KEM **ORDER ON MOTION FOR PRELIMINARY INJUNCTION**

I. INTRODUCTION

This case is before me on the plaintiffs'[1] motion (Doc. 30) for preliminary injunction. The defendants[2] filed a resistance (Doc. 72) and the plaintiffs filed a reply (Doc. 78). On December 5, 2024, I heard oral arguments by teleconference.

II. PROCEDURAL AND FACTUAL HISTORY

On October 8, 2024, the plaintiffs filed a complaint (Doc. 1) alleging that the Biden-Harris administration's Final Rule – "Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional

[1] The plaintiffs include 20 states, 17 affiliates of LeadingAge (a trade association of non-profit nursing facilities) and two Kansas nursing home facilities. I will refer to all of the plaintiffs collectively as "the plaintiffs," the state plaintiffs as "the States" and the non-state plaintiffs as "the Organizations."

[2] The named defendants are Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services, the United States Department of Health and Human Services, the Centers for Medicare and Medicaid Services and Chiquita Brooks-Lasure, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services. I will refer to all of the defendants collectively as "the Government."

Payment Transparency Reporting" (Final Rule) – violates various provisions of the Administrative Procedure Act (APA). 89 Fed. Reg. 40876 (May 10, 2024). Specifically, the plaintiffs argue that the Final Rule (1) lacks statutory authority, (2) is contrary to law and (3) is arbitrary and capricious. Doc. 1 at 42-61. The plaintiffs filed their motion for a preliminary injunction on October 22, 2024.

A. Medicaid and Medicare Statutes

In 1965, Congress established the Medicaid and Medicare programs by amending the Social Security Act. Pub. L. No. 89-97, 79 Stat. 286 (July 30, 1965). Medicare provides health insurance to "nearly 60 million aged or disabled Americans." *Northport Health Servs. of Ark., LLC v. U.S. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 863 (8th Cir. 2021) (quoting *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019)); *see also* 42 U.S.C. § 1395 *et seq*. Medicaid is a joint federal-state program in which the federal government provides approximately $600 billion in financial assistance to states to offer healthcare coverage to low-income individuals. *See* 42 U.S.C. § 1396 *et seq*.; *see also Northport*, 14 F.4th at 863. The Secretary of the Department of Health and Human Services (HHS) administers both programs through the Centers for Medicare and Medicaid Services (CMS), a sub-agency of HHS. *See* CENTERS FOR MEDICARE & MEDICAID SERVICES, CMS.gov (last visited Jan. 5, 2025).

Nursing homes that participate in Medicare and Medicaid must comply with certain statutory requirements. *See* 42 U.S.C. § 1395i-3 (Medicare); *see* 42 U.S.C. § 1396r (Medicaid). As these statutory requirements under Medicare and Medicaid are largely the same, these nursing homes are often collectively known as "long-term care" (LTC) facilities. In addition, LTC facilities must comply with CMS's regulations, as they are applicable to all LTC facilities that participate in Medicare and/or Medicaid. *See* 42 C.F.R. §§ 483.1-.95; *see also Northport*, 14 F.4th at 863.

B. CMS Rulemaking Process and the Final Rule

On February 22, 2022, the Biden-Harris administration announced its intent to implement several reforms to "improve the safety and quality of nursing home care, hold nursing homes accountable for the care they provide, and make the quality of care and facility ownership more transparent so that potential residents and their loved ones can make informed decisions about care." *FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's NursingHomes*, THE WHITE HOUSE (Feb. 28, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/. To this end, the administration directed CMS to "conduct a new research study to determine the level and type of staffing needed to ensure safe and quality care and [] issue proposed rules within one year." *Id.* CMS commissioned Abt Associates to complete this research study. *See* ABT ASSOCIATES, Nursing Home Staffing Study Comprehensive Report (June 2023), https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf.

Abt Associates' study (the study) found that increased staffing improves patient welfare in LTC facilities but also recognized the pervasive staffing challenges in the industry. Specifically, the study found that nursing homes with higher staff-to-resident ratios provide better care and addressed the COVID-19 pandemic more successfully. *Id.* at 1; Doc. 72 at 17. However, the study noted that existing literature "does not provide a clear evidence basis for setting a minimum staffing level." ABT ASSOCIATES, Nursing Home Staffing Study Comprehensive Report at xi. The study also found that increases in the nurse hours per resident per day result in a "corresponding increase in potential quality and safety improvements, and a decrease in expected delayed and omitted care." *Id.* at xiii; Doc. 72 at 17. Although Abt Associates found that increased staffing will lead to better care, the study recounted that nursing homes are struggling to hire and retain workers. Additionally, stakeholders expressed a variety of concerns, including

lack of adequate staffing as well as workforce and cost constraints. ABT ASSOCIATES, Nursing Home Staffing Study Comprehensive Report at xii. Moreover, some stakeholders suggested that resident acuity should be considered when setting a minimum staffing requirement. *Id.*

Upon completion of the study, CMS issued a notice of a proposed rule in September 2023. The proposed rule contained four main proposals: (1) a requirement that a registered nurse (RN) must be on site 24 hours per day, 7 days a week, (2) minimum nurse staffing standards of 0.55 hours per resident day (HPRD) for RNs and 2.45 HPRD for Nurse Aids (NAs), (3) enhanced facility assessment (EFA) requirements and (4) Medicaid reporting requirements. Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 88 Fed. Reg. 61352 (proposed Sept. 6, 2023). CMS received 46,520 comments in response to the proposed rule. *See* Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40883 (May 10, 2024).

CMS's Final Rule, promulgated on May 10, 2024, largely mirrors the proposed rule. 89 Fed. Reg. 40876. The Final Rule includes: (1) a requirement that a RN be on site 24 hours per day, 7 days per week, (2) a minimum nursing staffing standard of 3.48 HPRD of nursing care, with at least 0.55 RN HPRD and at least 2.45 NA HRPD, (3) revision of the existing facility assessment requirements and (4) Medicaid institutional payment transparency reporting requirements. 89 Fed. Reg. 40877. To ease some of the Final Rule's financial burden, CMS has dedicated over $75 million "to launch an initiative to help increase the long-term care workforce." 89 Fed. Reg. 40885. Moreover, the Final Rule provides additional time and flexibility for LTC facilities to implement the changes, including staggered implementation dates over a five-year period and providing for some exemptions from the minimum staffing standards. 89 Fed. Reg. 40886.

In its Final Rule, CMS asserts that various provisions in Sections 1819 and 1919 of the Social Security Act [42 U.S.C. §§ 1395i-3 and 1396r] grant it authority for the issuance of the HPRD and 24/7 RN requirements.[3] *See* 89 Fed. Reg. 40890-91. First, CMS states that §§ 1819(d)(4)(B) and 1919(d)(4)(B) of the Social Security Act support its authority to establish these requirements, as these sections "instruct the Secretary to issue such regulations relating to the health, safety, and well-being of residents as the Secretary may find necessary." 89 Fed. Reg. 40890. Moreover, CMS contends that §§ 1819(b)(2) and 1919(b)(2) provide additional support for CMS's authority to establish these requirements, as those sections "require facilities to provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." *Id.*

Finally, CMS states that §§ 1819(b)(1)(A) and 1919(b)(1)(A) "require that a SNF [skilled nursing facility] or NF [nursing facility] must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the safety and quality of life of each resident," which it asserts provides further support for the Final Rule's staffing requirements. 89 Fed. Reg. 40891. However, as the plaintiffs assert and the Government concedes in its brief, the only provisions of the Social Security Act that expressly permit the promulgation of additional requirements by the Secretary are §§ 1395i-3(d)(4)(b) and 1396r(d)(4)(B), which state that LTC facilities must "meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary." *See* Doc. 30-1 at 23; *see also* Doc. 72 at 21-22.

[3] The Medicare and Medicaid statutes speak directly to staffing requirements as well. They require LTC facilities to "provide 24-hour licensed nursing service which is sufficient to meet the nursing needs of its residents" and "use the services of a registered professional nurse at least 8 consecutive hours a day, 7 days a week." *See* 42 U.S.C. § 1395i-3(b)(4)(C)(i) (Medicare); *see also* 42 U.S.C. § 1396r(b)(4)(C)(i) (Medicaid) (same). Both statutes permit waivers for these requirements. *See* 42 U.S.C. § 1395i-3(b)(4)(C)(ii) (Medicare) *and* 42 U.S.C. § 1396r(b)(3)(C)(ii) (Medicaid).

Although the statutory basis for CMS's promulgation of new Medicaid reporting requirements do not appear to be contested by the plaintiffs (*see* Doc. 30-1 at 6), CMS asserts that it relied on two main provisions of the Social Security Act to issue these requirements – §§ 1902(a)(30)(A) and 1902(a)(6). 89 Fed. Reg. 40914 (noting that § 1902(a)(30)(A) "requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care. . ." and § 1902(a)(6) "requires State Medicaid agencies to make such reports. . . as the Secretary may from time to time require, and to comply with such provisions as the Secretary may find necessary to assure the correctness and verification of such reports.").

The statutory basis for the EFA requirement appears similarly uncontested by the plaintiffs. *See* Doc. 30-1 at 6. Prior to the promulgation of the Final Rule, LTC facilities were already required to complete facility assessments. The Final Rule relocated the facility assessment requirement from a subpart to a stand-alone provision and added new substantive requirements. CMS did not articulate the statutory basis for the new substantive requirements in the Final Rule. *See* 89 Fed. Reg. 40905.

Each requirement of the Final Rule has a different implementation timeline. The 24/7 RN requirement must be implemented by May 11, 2026, for non-rural facilities and by May 10, 2027, for rural facilities as defined by the Office of Management and Budget. The HRPD requirements must be implemented by May 10, 2027, for non-rural facilities and by May 10, 2029, for rural facilities. The EFA requirement took effect on August 8, 2024, for all facilities. The Medicaid transparency reporting requirements must be implemented by all States and territories with Medicaid-certified facilities by May 10, 2028. 89 Fed. Reg. 40876.

Despite these different implementation timelines, the Final Rule acknowledges that costs will be incurred before the respective effective implementation dates. CMS estimated that the staffing requirements will result in an estimated cost of approximately $53 million in year one, $1.43 billion in year two and $4.38 billion in year three. 89

Fed. Reg. 40949. Additionally, CMS estimates that the Medicaid reporting provision will cost states $183,851 for the first four years. 89 Fed. Reg. 40991.

III. ANALYSIS

The plaintiffs seek entry of a preliminary injunction as to the entire Final Rule. They assert that the Final Rule exceeds CMS's statutory authority, violates the major questions doctrine and is arbitrary and capricious. *See* Doc. 30-1 at 20-35. Additionally, the plaintiffs assert that they are suffering irreparable harm from the financial burdens of the Final Rule and contend that the balance of equities and the public interest favor injunctive relief. *Id.* at 35-38. Finally, they request that the injunction apply nationwide to "preserve[] the national status quo and protect[] Plaintiffs from the Final Rule's destabilizing effects on nursing homes across the country." Doc. 30-1 at 39.

A. Preliminary Injunction Standard

The purpose of a preliminary injunction is to "preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). The Eighth Circuit Court of Appeals has stated:

> When evaluating whether to issue a preliminary injunction, a district court should consider four factors: (1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties; (3) the probability that the movant will succeed on the merits; and (4) the public interest.

Roudachevski v. All–American Care Centers, Inc., 648 F.3d 701, 705 (8th Cir. 2011) (citing *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (en banc)). In this circuit, these are often referred to as the *"Dataphase"* factors. While no single factor is dispositive, the Eighth Circuit has stated that "likelihood of success on the merits is most significant." *Laclede Gas Co. v. St. Charles Cnty., Mo.*, 713 F.3d 413, 419 (8th Cir. 2013) (quoting *Minn. Ass'n of Nurse Anesthetists v. Unity Hosp.*, 59 F.3d 80, 83 (8th Cir. 1995)).

In applying these factors, the court must keep in mind that a preliminary injunction is "an extraordinary remedy never awarded as of right." *Morehouse Enters., LLC v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 78 F.4th 1011, 1016 (8th Cir. 2023) (citation omitted). As such, the party seeking injunctive relief bears the burden of proving that it is appropriate. *Roudachevski*, 648 F.3d at 705. "When there is an adequate remedy at law, a preliminary injunction is not appropriate." *Watkins Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003) (citing *Modern Computer Sys., Inc. v. Modern Banking Sys., Inc.*, 871 F.2d 734, 738 (8th Cir. 1989)).

B. Irreparable Harm

Although likelihood of success on the merits is often described as the most significant factor in a preliminary injunction analysis, a failure to show irreparable harm may be dispositive. *Adventist Health Sys./SunBelt, Inc. v. United States Dep't of Health & Hum. Servs.*, 17 F.4th 793, 806 (8th Cir. 2021) ("The failure to show irreparable harm is an 'independently sufficient basis upon which to deny a preliminary injunction.'") (citation omitted); *see also Glenwood Bridge, Inc. v. City of Minneapolis*, 940 F.2d 367, 371 (8th Cir. 1991) (irreparable harm is a "threshold inquiry" in granting or denying preliminary injunction). I will begin my analysis with this factor because, for the reasons discussed in detail below, it largely dictates the outcome of the plaintiffs' motion for a preliminary injunction.

To demonstrate irreparable harm, "a party must show that the harm is certain and great and of such imminence that there is a clear and present need for equitable relief." *Morehouse Enters., LLC v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 78 F.4th 1011, 1017 (8th Cir. 2023) (quoting *Dakotans for Health v. Noem*, 52 F.4th 381, 392 (8th Cir. 2022); *see also Tumey v. Mycroft AI, Inc.*, 27 F.4th 657, 665 (8th Cir. 2022) ("The movant must show that 'irreparable injury is *likely* in the absence of an injunction,' not merely a 'possibility' of irreparable harm before a decision on the merits can be rendered.") (emphasis in original) (quoting *Winter v. Natural Resources Defense*

Council, Inc., 555 U.S. 7, 22 (2008)). The irreparable harm requirement is demanding. *See Am. Meat Inst. v. U.S. Dep't of Agric.*, 968 F. Supp. 2d 38, 75 (D.D.C. 2013) ("There is no doubt that '[t]he irreparable injury requirement erects a very high bar for a movant.'") (quoting *Coalition for Common Sense in Gov't Procurement v. United States*, 576 F. Supp. 2d 162, 168 (D.D.C. 2008)).

1. The Parties' Arguments

The Organizations argue that they will suffer irreparable harm from the Final Rule because of the financial strain that it imposes, workforce shortages, current compliance costs and the burdensome EFA requirements. Doc. 30-1 at 35-36. First, they argue that the Final Rule will cost each LTC facility hundreds of thousands of dollars to implement.[4] *Id.* at 35. Further, they contend that the additional hiring required by the Final Rule is nearly impossible considering the healthcare workforce shortages, which are more exacerbated in the long-term care setting. *Id.* at 35-36. Because of these workforce challenges, the Organizations assert that many LTC facilities must start complying with the staffing mandates now to ensure that they will meet the requirements by the designated implementation dates. *Id.* at 36. Finally, they argue that the Final Rule's EFA requirement, which is already in effect, imposes significant costs and administrative burdens. *Id.*

The States contend that they will experience many of the same harms as the Organizations. First, they argue that state-run LTC facilities will experience the similar financial hardships as the organizational LTC facilities with the increased staffing requirements, workforce shortages and the EFA requirements. *Id.* at 36-37. The States assert that they will incur additional Medicaid and Medicare expenses and costs due to

[4] For example, the plaintiffs assert that in South Carolina the estimated implementation cost is over $550,000 per nursing home. This cost is even higher in Pennsylvania, with an estimated cost of $689,000 per provider. Doc. 30-1 at 35.

the Medicaid reporting requirement and the increased staffing costs at LTC facilities. *Id.* at 37. Finally, the States argue that they will incur additional administrative costs with complaints and waiver requests as they predict that LTC facilities will be unable to comply with the Final Rule. *Id.*

The Government asserts that because the 24/7 RN requirement and HPRD requirements will not be implemented for several years, the plaintiffs will not experience irreparable harm without an injunction. Doc. 72 at 60. The Government does not address irreparable harm regarding the EFA and Medicaid reporting requirements, as it contends that the plaintiffs do not substantively challenge those provisions.[5] *Id.* The Government asserts that the Final Rule has a staggered implementation for both the 24/7 RN requirement and the HPRD requirements. *Id.*; *see* 89 Fed. Reg. 40894 (discussing "phased implementation up to 5 years for rural facilities and up to 3 years for non-rural facilities"). The Government further notes that the earliest any facility could be harmed by the Final Rule is in two years—when the 24/7 RN rule will take effect in urban areas. Doc. 72 at 60; *see* 89 Fed. Reg. 40910. It asserts that this multi-year delay in implementation does not create irreparable harm, as the merits of the plaintiffs' challenge can be resolved in less than two years. Doc. 72 at 60. Moreover, the Government contends that the harms alleged by the plaintiffs are "purely economic," "self-inflicted" and, as to the plaintiffs' argument regarding workforce shortages—not caused by the Final Rule. *Id.* at 61. Finally, the Government argues that the plaintiffs' delay in filing

[5] In their reply brief and during oral argument, the plaintiffs maintained that they are challenging the entirety of the rule – not just the 24/7 RN requirement and the HPRD requirements. *See* Doc. 78 at 20-21; *see also* Doc. 94 at 26. However, the plaintiffs did not address either the EFA requirement or the Medicaid reporting requirement in their discussion of likelihood of success in their briefs. *See* Doc. 30-1 at 20-35; *see also* Doc. 78 at 4-17. Nonetheless, the plaintiffs assert that they made sufficient arguments as to likelihood of success as they contended that the EFA provision was "vague" and "unreasonable." Doc. 78 at 21. The Government maintains that the plaintiffs did not address likelihood of success on the merits with respect to the EFA requirement, but it asserts that in any case, the deadline for compliance with this requirement has already passed so irreparable harm cannot be alleged. Doc. 72 at 62.

the present motion for a preliminary injunction also undercuts their assertion that they are suffering irreparable harm. *Id.* at 62.

In response, the plaintiffs first contend that the economic nature of the harm is not a barrier to the court's entry of a preliminary injunction, as monetary damages cannot be recovered from the federal government due to sovereign immunity. Doc. 78 at 19. Additionally, they assert that the harms from the EFA requirement are continuous and ongoing. *Id.* Moreover, they dispute that they are engaged in "self-harm" by beginning to hire staff to meet the Final Rule's requirements, as they contend that the delayed implementation period was specifically designed for this purpose. *Id.* at 20. Finally, they assert that their delay in seeking injunctive relief was not unreasonable. *Id.* at 22.

2. Substantive Provisions of the Final Rule

Because the plaintiffs' allegations of irreparable harm primarily concern compliance costs associated with the Final Rule, I will first address that matter. There appears to be a circuit split as to whether compliance costs constitute irreparable harm. Some circuits have held that "compliance costs do not qualify as irreparable harm because they commonly result from new government regulation." *See Commonwealth v. Biden*, 57 F.4th 545, 556 (6th Cir. 2023) (recognizing that many of their "sister circuits" have held that compliance costs are not irreparable harm but holding that "the peculiarity and size of a harm affects its weight in the equitable balance") (citing *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005), *Am. Hosp. Ass'n v. Harris*, 625 F.2d 1328, 1331 (7th Cir. 1980), *and A.O. Smith Corp. v. FTC*, 530 F.2d 515, 527 (3d Cir. 1976)). Other circuits have found that complying with a regulation later held invalid almost always produces irreparable harm from nonrecoverable costs. *See Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016); *see also Crowe & Dunlevy, P.C. v. Stidham*, 640 F.3d 1140, 1157 (10th Cir. 2011).

Although this issue has never been squarely addressed by the Eighth Circuit, the court has stated that "[t]he importance of preliminary injunctive relief is heightened"

when monetary damages are unavailable because of sovereign immunity. *Entergy, Arkansas, Inc. v. Nebraska*, 210 F.3d 887, 899 (8th Cir. 2000). I hold that the compliance costs incurred to comply with a potentially invalid regulation, such as the Final Rule, may constitute irreparable harm. I will address each aspect of the Final Rule in turn.

a. 24/7 RN Requirement and HPRD Requirements

At this stage of the case, I will assume that the Final Rule's 24/7 RN requirement and HPRD requirements will impose tremendous costs on LTC facilities that could result in closures if compliance is not economically feasible. Additionally, the economic nature of the plaintiffs' alleged harms does not preclude relief. Although economic loss is not irreparable harm if damages are available, losses will not be recoverable from the Government due to sovereign immunity. *See Gen. Motors Corp. v. Harry Brown's LLC*, 563 F.3d 312, 319 (8th Cir. 2009) ("economic loss is not irreparable harm so long as losses are recoverable"); *see also Entergy, Arkansas, Inc.*, 210 F.3d at 899 ("[t]he importance of preliminary injunctive relief is heightened" when monetary damages are unavailable because of sovereign immunity).

However, because the 24/7 RN requirement and the HPRD requirements do not take effect until May 2026, at the earliest, I find that the plaintiffs' challenges to the financial and compliance burdens presented by those requirements are too speculative to constitute irreparable harm for purpose of a preliminary injunction.[6] In seeking injunctive relief, a party must show that the injury alleged is "of such *imminence* that there is a

[6] Additionally, the plaintiffs' argument that workforce shortages in the healthcare industry constitute irreparable harm is misplaced. The Final Rule did not create the workforce shortage in the healthcare industry. Such an argument is proper in challenging CMS's action as arbitrary and capricious—not in alleging that the Final Rule causes irreparable harm. *See McClung v. Paul*, 788 F.3d 822, 828 (8th Cir. 2015) (finding an agency decision arbitrary and capricious if an agency "entirely failed to consider an important aspect of the problem").

clear and present need for equitable relief." *Morehouse Enters., LLC v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 78 F.4th 1011, 1018 (8th Cir. 2023) (emphasis in original) (quotations omitted) (citations omitted). The plaintiffs allege that LTC facilities are bearing the costs of the 24/7 RN requirement and the HPRD requirements now because of the workforce shortages in the healthcare industry. Doc. 30-1 at 36. However, the extent to which LTC facilities are incurring hiring costs now to ensure compliance with the Final Rule is unclear. Indeed, while 26 plaintiffs submitted declarations, only a few state that they are currently engaged in hiring and incurring costs to ensure compliance with the minimum staffing requirements.[7] *See* Doc 30-22 at 9, ¶ 11 ("At least several of our nursing homes are already making staffing changes, attempting to hire additional RNs rather than LPNs, and increasing hiring efforts in preparation for the Final Rule's staffing mandates going into effect."); Doc. 30-10 at 8, ¶ 9 (LTC facilities in Iowa "are attempting to hire RNs over LPNs whenever possible. . . and engaging in aggressive recruitment strategies such as sign-on and recruitment bonuses. . ."); Doc. 30-12 at 3-4, ¶ 6 ("our members have already begun to plan for the elimination of LPN positions"). While these declarations suggest that planning and attempts for hiring are currently taking place, the financial burden of these undertakings is unclear. None of the plaintiffs submitted data or cost breakdowns as to their *current* hiring efforts.

Instead, most of the declarations detail costs that the various plaintiffs will incur in the future. Indeed, many plaintiffs provided a wide range of potential costs. *See, e.g.*, Doc. 30-2 at 3, ¶ 9 (estimating that the total average costs for Idaho-operated LTC facilities to comply with the Final Rule's minimum staffing requirements to be $800,000

[7] The plaintiffs assert that a declaration from LeadingAge South Carolina provides additional support for their assertion that many providers are already expending resources towards hiring. Doc. 30-1 at 36 (citing Doc. 30-20 at 3, ¶ 4). However, LeadingAge South Carolina's declaration merely asserts that it is currently experiencing staffing shortages and that one facility has had an open RN position for over a year. Doc. 30-20 at 3, ¶ 4.

per facility); *see also* Doc. 30-8 at 5, ¶ 7 (asserting that the South Dakota Association of Health Care Organizations estimated that costs associated with temporary/travel nurses to be between $300,000 and $1,600,000 per year and estimates that this cost will increase "exponentially if the Final Rule's staffing mandate goes into effect"); *see* Doc. 30-22 at 2, ¶ 5 (stating that the "significant and irreparable harm that the Final Rule imposes on Virginia nursing home providers will be especially severe in rural and underserved areas"). These wide ranges demonstrate that while the staffing requirements of the Final Rule will certainly impose financial burdens, the extent of the harm is simply too uncertain at this point, as the earliest any facility could be subject to the Final Rule is May 11, 2026. This weighs against a finding of irreparable harm. *See S.J.W. ex rel. Wilson v. Lee's Summit R-7 Sch. Dist.*, 696 F.3d 771, 779 (8th Cir. 2012) ("Speculative harm does not support a preliminary injunction."); *see also Mock v. Garland*, 697 F. Supp. 3d 564, 577 (N.D. Tex. 2023) ("Irreparable harm must also be concrete, non-speculative, and more than merely de minimis.") (emphasis omitted).

Further, many of the plaintiffs' declarations note that the compliance costs associated with the Final Rule's staffing mandate could greatly vary depending on their use of contracting agencies to recruit staff. *See* Doc. 30-2 at 3, ¶ 10 (noting that hiring costs could be "higher or lower" depending on the state's reliance on contractor agencies); *see also* Doc. 30-8 at 6, ¶ 8 ("The cost for facilities will be even greater if contract staff are needed to meet the standards of the mandate."); Doc. 30-11 at 9, ¶ 12 ("Nursing homes will incur substantial costs, potentially requiring them to rely on contracted nursing agencies, which are significantly more expensive."). This also weighs against a finding of irreparable harm. *See, e.g.*, *Cayuga Nation v. Zinke*, 302 F. Supp. 3d 362, 373 (D.D.C. 2018) (finding that where "injuries depend on actions that may or may not be taken by. . . non-parties over which this Court does not have control, they are not certain[]" which "counsel[s] against granting preliminary injunctive relief.").

Nonetheless, some of the plaintiff declarations provided more precise estimates of future costs. *See, e.g.*, Doc. 30-9 at 3, ¶ 6 (Final Rule's requirements "will cost each

Colorado provider. . . an average of $399,123 per year"); *see also* Doc. 30-11 at 3, ¶ 6 (staffing mandate will cost each Kansas provider an average of $211,905 per year); *see also* Doc. 30-12 at 2, ¶ 5 (staffing mandate will cost each nursing home in Maryland an additional $642,000 per year); *see* Doc. 30-3 at 3, ¶ 10 (noting that over 70 percent of facilities in Iowa will be affected by the increased staffing requirements, which will cause an estimated state financial impact of over $25 million); *see* Doc. 30-10 at 3-4, ¶ 4a (noting that staffing requirements would result in $2.16 million annual costs on their members). While I appreciate the detailed assessments provided by many of the plaintiffs, I again find that because of the delayed implementation of the Final Rule, the plaintiffs have not adequately shown irreparable harm as to the staffing requirements. *See Wyoming v. United States Dep't of the Interior*, No. C16- 0280–SWS, 2017 WL 161428, at *11 (D. Wyo. Jan. 16, 2017) (holding that even though the Regulatory Impact Analysis stated that the Rule's requirements "would necessitate *immediate* expenditures," because many of the Rule's requirements "do not take effect for a year[,] . . . any alleged expenses associated with 'immediate action to begin Rule implementation and compliance planning' are simply too uncertain and speculative to constitute irreparable harm") (emphasis in original) (citation omitted); *cf. Chlorine Inst., Inc. v. Soo Line R.R.*, 792 F.3d 903, 915 (8th Cir. 2015) (noting that "[a]ppellants' assertion" that a harm would "inevitably result" was "too speculative" and thus insufficient to show irreparable harm).

The merits of the plaintiffs' challenges to the 24/7 RN requirement and the HPRD requirements can be addressed before May 2026, when the first staffing requirements of the Final Rule are to take effect. *See Am. Meat Inst. v. U.S. Dep't of Agric.*, 968 F. Supp. 2d 38, 75 (D.D.C. 2013) ("Perhaps the single most important prerequisite for the issuance of a preliminary injunction is a demonstration that if it is not granted the applicant is likely to suffer irreparable harm before a decision on the merits can be rendered."). The plaintiffs have not demonstrated that injunctive relief is necessary to prevent irreparable harm as to those aspects of the Final Rule.

b. EFA Requirement

The EFA requirement took effect on August 8, 2024. 89 Fed. Reg. 40876. As the initial compliance date for the EFA requirement has already passed, the Government asserts that the plaintiffs cannot demonstrate irreparable harm with respect to this aspect of the Final Rule. Doc. 72 at 62.

The Eighth Circuit has found that prior harm weighs against entering injunctive relief when a plaintiff can recover damages. *See CDI Energy Servs. v. West River Pumps, Inc.*, 567 F.3d 398, 403 (8th Cir. 2009) ("[I]t was appropriate for the district court to view the irreparable-harm factor as weighing against the issuance of a preliminary injunction. The harm that had already occurred could be remedied through damages."); *see also Adam–Mellang v. Apartment Search, Inc.,* 96 F.3d 297, 300 (8th Cir. 1996) (declining to enter a preliminary injunction when a plaintiff had "an adequate remedy at law, namely, the damages and other relief to which she will be entitled if she prevails"). Here, of course, the plaintiffs cannot recover damages from the Government due to sovereign immunity. Moreover, the Final Rule requires facilities to "review and update that assessment, as necessary, and at least annually." 89 Fed. Reg. 40999. Thus, the costs of compliance with the EFA requirement will recur on an ongoing basis. These factors tend to add some support for a finding that the EFA requirement will cause irreparable harm absent injunctive relief.

Because the plaintiffs have made a more feasible showing of irreparable harm with regard to the EFA requirement, I will consider their likelihood of success on their challenge to this provision. Ultimately, I agree with the Government that because the plaintiffs addressed the likelihood of success element only with respect to the 24/7 RN requirement and the HPRD requirements, they have not demonstrated that a preliminary injunction is appropriate with respect to the EFA requirement.

The plaintiffs raise only a few conclusory arguments regarding likelihood of success as to that requirement. First, they claim that they asserted that the EFA requirement is "vague" and "unreasonable." Doc. 78 at 21. During oral argument, the

plaintiffs asserted that the Final Rule is not severable and their arguments regarding the "arbitrary and capricious" nature of the Final Rule apply to the EFA requirement. Doc. 94 at 26-27. Moreover, the plaintiffs assert that *Missouri v. Biden*, 112 F.4th 531 (8th Cir. 2024), stands for the proposition that "irreparable harm does not need to be tied to any particular aspect of the rule that's being challenged." Doc. 94 at 26-27, 59.

These arguments are not compelling. The plaintiffs' conclusory argument that the EFA requirement is "vague" and "unreasonable" is insufficient to support a finding of likelihood of success on the merits.[8] Additionally, I do not find *Missouri v. Biden* to be particularly helpful. In that case, the Eighth Circuit stated the "district court only enjoined the ultimate forgiveness of loans, finding that States had not shown irreparable harm" with respect to two other provisions of the rule. *Biden*, 112 F.4th at 535. Notwithstanding the district court's injunction, the Government continued to forgive loans through a new "hybrid rule," which combined parts of the non-enjoined rule as well as provisions in another regulation. The Eighth Circuit noted that this hybrid rule "effectively rendered that injunction a nullity." *Id.* at 535.

Although the Eighth Circuit ultimately enjoined the entire rule, it did so only because the Government created a hybrid rule that made the district court's injunction useless. *Missouri v. Biden* does not stand for the proposition that a plaintiff may cherry-pick portions of a final rule, arguing likelihood of success as to some and irreparable harm as to others. Given plaintiffs' failure to make any serious argument that they are likely to succeed on their challenge to the EFA requirement, I find that they have failed to demonstrate that a preliminary injunction as to that requirement is appropriate.

---

[8] Indeed, "[w]hen a party seeks to enjoin a government regulation that is 'based on presumptively reasoned democratic processes,'. . . we apply a 'more rigorous threshold showing' than just a 'fair chance' of success on the merits. *Firearms Regul. Accountability Coal., Inc. v. Garland*, 112 F.4th 507, 517 (8th Cir. 2024) (quoting *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 730, 732 (8th Cir. 2008) (en banc). Therefore, such conclusory arguments do not come close to meeting the required showing.

c. Medicaid Transparency Reporting Requirements

The Medicaid institutional transparency reporting requirement does not take effect until May 10, 2028. 89 Fed. Reg. 40876. As with the 24/7 RN and the HPRD requirements, I find that this long-delayed effective date renders the alleged expenses associated with immediate action too uncertain and speculative to qualify as irreparable harm. Indeed, many of the plaintiffs' declarations make conclusory statements about the future economic harm they will incur. *See, e.g.*, Doc. 30-4 at 3, ¶ 8 ("Although this requirement does not take effect until four years after the Final Rule is published, it will impose costs on Nebraska well before that."); Doc. 30-3 at 3, ¶ 8 (same); Doc. 30-27 at 3, ¶ 8 (same); Doc. 30-7 at 3, ¶ 7 (same). Moreover, the merits of the plaintiffs' challenge to this provision can be resolved before this requirement takes effect. *See infra* Section III.B.2.a.[9]

d. Plaintiffs' Delay

Finally, the Government argues that the plaintiffs' delay in bringing a motion for a preliminary injunction of the Final Rule weighs against a finding of irreparable harm. For the reasons set forth above, it is largely unnecessary to address the "delay" argument. In short, the Government argues that the five-month delay between publication of the Final Rule and the request for a preliminary injunction was excessive and weighs against a finding of irreparable harm. The Government notes the Texas Health Care Association and several Texas-based LTC facilities filed suit challenging the Final Rule on the same grounds as the plaintiffs "less than two weeks after the promulgation of the Final Rule." Doc. 72 at 62*; see Am. Health 52 Care Ass'n v. Becerra*, 24C-114-Z-BR (N.D. Tex.) (filed May 23, 2024). Further, it asserts that the Eighth Circuit has held that a delay of

[9] Additionally, as with the EFA requirement, the plaintiffs did not make any arguments regarding the likelihood of success on the merits with respect to the Medicaid reporting requirement. *See generally* Doc. 30-1 *and* Doc. 78. Therefore, even if I found that the plaintiffs made a showing of irreparable harm, injunctive relief would not be appropriate. *See infra* Section III.B.2.b.

five months in seeking a preliminary injunction was sufficient to affirm the denial of a preliminary injunction. Doc. 72 at 63*; see Phyllis Schlafly Revocable Trust v. Cori*, 924 F.3d 1004, 1010, n.4 (8th Cir. 2019).

The plaintiffs contend that their delay was less than two months, as the EFA requirement did not take effect until August and they sought injunctive relief in October. Doc. 94 at 58. Additionally, they assert that the length of the delay is not outcome-determinative but, instead, turns on the facts of the case. Doc. 78 at 22. They argue that they were "forced to walk a tightrope," as if they challenged the rule earlier, the Government would have argued that their harms were speculative and uncertain. *Id.* By waiting, they contend that their harms are concrete because the EFA requirement took effect and many LTC facilities are beginning to take measures to ensure they can meet the staffing requirements. *Id.*

The "mere length of the delay is not determinative of whether the delay was reasonable." *Ng v. Board of Regents of University of Minnesota*, 64 F.4th 992, 998 (8th Cir. 2023) (noting that the Eighth Circuit has found delays of seven and eight months to be reasonable but has found delays of five and seventeen months to be unreasonable). And there can be little doubt that a comprehensive challenge to an agency final rule requires time and significant resources to litigate. *See McKinney ex rel. N.L.R.B. v. S. Bakeries, LLC*, 786 F.3d 1119, 1125 (8th Cir. 2015) (noting that "[c]omplicated labor disputes like this one require time to investigate and litigate"). Nonetheless, many of the plaintiffs participated in the rulemaking process and submitted analyses of the expected costs and hardships of the rule. This participation suggests that waiting five

months to challenge the rule was unnecessary, as many had already conducted research to assess the costs and harms that they would face.[10]

On the other hand, the delay in this case was not as egregious as delays seen in other cases. *See, e.g.*, *Adventist Health Sys.*, 17 F.4th at 805 (holding that the district court did not abuse its discretion in finding no irreparable harm where the plaintiffs did not challenge the Final Rule for a year after its adoption and fewer than five days before its scheduled implementation); *see also Novus Franchising, Inc. v. Dawson*, 725 F.3d 885, 894 (8th Cir. 2013) (finding that a delay of 17 months "rebuts any inference of irreparable harm"). Indeed, it appears that five months is the shortest time period that the Eighth Circuit has found to be unreasonable.

Ultimately, I find the plaintiffs' delay seeking a preliminary injunction is largely a non-factor that, at most, adds some additional, marginal support for the conclusion that the plaintiffs failed to demonstrate irreparable harm.

C. Summary

As noted above, a preliminary injunction is "an extraordinary remedy never awarded as of right." *Morehouse Enterprises, LLC*, 78 F.4th at 1016. With regard to nearly every aspect of the Final Rule, the plaintiffs have failed to demonstrate that a preliminary injunction is necessary in order to preserve the status quo and prevent irreparable harm during the pendency of these proceedings. The only potential exception involves the Final Rule's EFA requirement. However, the plaintiffs advanced no viable

---

[10] *See generally* "Medicare and Medicaid Programs: Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting," Regulations.gov, https://www.regulations.gov/document/CMS-2023-0144-0001/comment (Sept. 6, 2023); *see, e.g.*, Leading Age Nebraska, CMS-2023-0144-25564 (Nov. 3, 2023), https://www.regulations.gov/comment/CMS-2023-0144-25564 *and* Leading Age PA, CMS-2023-0144-25410 (Nov. 3, 2023), https://www.regulations.gov/comment/CMS-2023-0144-25410.

argument that they are likely to succeed on the merits of their challenge to that requirement.

Under these circumstances, I conclude that the issuance of a preliminary injunction is not appropriate.[11] I do find, however, that the interests of justice will be best served by proceeding quickly to the dispositive motions stage of this case, thus allowing the parties to address the merits directly, rather than through the lens of a motion for a preliminary injunction. In particular, the plaintiffs have raised substantial issues and concerns about Final Rule's 24/7 RN requirement and HPRD requirements. A schedule for dispositive motion briefing will be set forth below.

IV. CONCLUSION

For the reasons set forth herein, the plaintiffs' motion (Doc. 30) for a preliminary injunction as to the Final Rule is **denied**. The following schedule is hereby established with regard to dispositive motions:

1. Any dispositive motions must be filed on or before **March 3, 2025**.
2. Resistances must be filed on or before **April 3, 2025**.
3. Reply materials must be filed on or before **April 24, 2025**.

IT IS SO ORDERED this 16th day of January, 2025.

Leonard T. Strand
United States District Judge

[11] I will therefore not address the remaining *Dataphase* factors. I find it equally unnecessary to address the parties' arguments regarding severability at this time, as I have found that the plaintiffs are not entitled to injunctive relief as to any aspect of the Final Rule. Similarly, it is not necessary for me to address the plaintiffs' contention that any preliminary injunction should apply on a nationwide basis. *See* Doc. 30-1 at 38-40.