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 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. _____ **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

Senior citizens and other vulnerable members of society rely on nursing homes and similar facilities to meet their needs when family members cannot. Although the nursing home industry certainly has had its share of challenges, it fills a vital need in our communities that cannot be replaced. Instead of addressing the legitimate challenges nursing homes face, the Defendants put forward a heavy-handed mandate through its Final Rule entitled, "*Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting*" ("the Final Rule"). *See* 89 Fed. Reg. 40876 (May 10, 2024). This Final Rule poses an existential threat to the nursing home industry as many nursing homes that are already struggling will have no choice but to go out of business. And the main victims will be the patients who will have nowhere else to go. Plaintiffs represent a diverse group of States and industry organizations who aim to prevent this from happening.

This Final Rule represents not only another attempt from the Biden-Harris administration to impose its policy preferences on the rest of the country but is also monumentally costly and nearly impossible to comply with. During the public comment period, an outside study found that: (1) nursing homes will need to hire more than 100,000 additional full-time employees; (2) the Final Rule will cost nursing homes approximately $6.8 billion per year (higher than CMS's own estimate of $4 billion per year); (3) 94 percent of current skilled nursing facilities will be out of compliance with at least one of the three staffing requirements; and (4) more than 285,000 nursing home beneficiaries (or one-fourth of total nursing home residents) will be at risk of losing necessary care if nursing homes are unable to increase their workforce to meet these new standards. *See* CliftonLarson Allen LLP,

CMS Proposed Staffing Mandate, 6 ("CLA Study"), *available at* https://tinyurl.com/yc2v4t3h (July 8, 2024).

Beyond the costs, the latest Rule from the Biden-Harris Centers for Medicare & Medicaid Services (CMS) is not even close to lawful. Over forty years ago, Congress established two basic staffing requirements for nursing homes participating in both Medicare and Medicaid. *First*, nursing homes participating in these programs "must use the services of a registered professional nurse [("RN")] 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). *Second*, Congress established the flexible staffing standard that requires a nursing home "[to] provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." *Id.* § 1396r(b)(4)(C)(i); *accord id.* § 1395i-3(b)(4)(C)(i). For decades, Congress, CMS, and its predecessors have considered—and rejected—proposals to replace the flexible staffing standards with a one-size-fits-all requirement. *See e.g.*, 39 Fed. Reg. 2238, 2239 (Jan. 17, 1974); 45 Fed. Reg. 47368, 47371 (July 14, 1980); 52 Fed. Reg. 38583, 38586 (Oct. 16, 1987); 80 Fed. Reg. 42168, 42201 (July 16, 2015); 81 Fed. Reg. 68688, 68755 (Oct. 4, 2016).

Nevertheless, CMS proposed and promulgated the Final Rule that is unlawful and threatens the health, safety, and well-being of millions of nursing home patients across the country. The Final Rule departs from the longstanding staffing requirement in two ways. *First*, the Final Rule conspicuously *triples* the statutory nursing home staff requirement. It replaces Congress's directive for an RN to be present for 8 hours per day, 7 days a week, with a new mandate to have an RN "onsite [for] 24 hours per day, for 7 days a week" ("24/7 requirement"). 89 Fed. Reg. 40876, 40898. *Second*, the Final Rule abandons the flexible statutory staffing standard that is "Sufficient to meet the nursing needs" of each facility's

residents, 42 U.S.C. 1396r(b)(4)(C)(i); *accord id*. § 1395i-3(b)(4)(C)(i), in favor of a three part national requirement—irrespective of facility needs, current staffing capacity, or State law minimum staffing standards. The Final Rule requires (1) total nurse staffing of at least 3.48 hours per resident day ("HPRD"); (2) a mandate for RN staffing of at least 0.55 HPRD; and (3) nurse aid ("NA") staffing of at least 2.45 HPRD. 89 Fed. Reg. at 40877. HPRD is defined as the "total number of hours worked by each type of staff divided by the total number of residents as calculated by CMS." *Id*. Essentially, the Final Rule abandons Congress's *qualitative* and flexible staffing standard for CMS's *quantitative r*equirement that does not account for resident acuity nor individual nursing home staff capacity.

Instead of pointing out where in the applicable Congressional statute they have the authority to promulgate this Final Rule, CMS takes the audacious approach of ignoring the statute altogether. CMS points to broadly worded provisions and a "miscellaneous" rulemaking provision that allows the Secretary of Health and Human Services to impose "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." 42 U.S.C. § 1395i-3(d)(4)(B); *accord id*. 42 U.S.C. § 1396r(d)(4)(B) as justification for the Final Rule.

The wafer-thin reliance on a vague statutory provision does not allow CMS to promulgate a Final Rule that conflicts with a separate Congressional statute. But CMS's illegality is more apparent because this is a Major Questions Doctrine case. Implementing such a broad mandate that would result in *at least* $43 billion of compliance costs for nursing homes nationwide over the next ten years, without Congress "speak[ing] clearly" to the issue, is a flagrant violation of the Major Questions Doctrine. *See Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 595 U.S. 109, 117 (2022). And surely

Congress did not intend CMS to pull such an "elephant" of a mandate out of the "mouseholes" of either the Medicare or Medicaid Acts. *See Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468 (2001). This is especially true given both Congress's and CMS's longstanding policy positions for maintaining a flexible staffing standard for nursing homes.

Beyond the statutory problems with the Final Rule, it is also the very definition of arbitrary and capricious rulemaking because (1) it represents a sharp departure from past CMS policy without reasoned explanation, (2) CMS did not consider reliance interests when promulgating the Final Rule and (3) CMS did not consider important aspects of the problem such as the cost of, and impossibility of complying with, the Final Rule. In short, there is no universe in which this Final Rule is lawful.

The Final Rule also causes harm to both organizational and State plaintiffs in this case, and much of that harm is irreparable. As noted above, the costs are impossible for many nursing homes to comply with. And although the Final Rule claims to have an extended implementation period, many nursing homes bear those costs *now*. This is because CMS requires nursing homes to conduct unreasonable enhanced facility assessments (EFA) within 60 days of publication of the Final Rule. These assessments are costing each nursing significant amounts of money and labor in order to comply. And even though the staffing requirements have a 2-3-year implementation period depending on the region, the reality of a tight labor market requires nursing homes to hire *immediately* because the available supply of nurses will dwindle as the implementation date approaches. Some nursing homes have had to immediately increasing their staffing and incurred significant costs. Similarly, states have their own enhanced reporting requirements for their Medicaid programs. Although CMS

claims to have a delayed implementation period for this portion of the Final Rule, states have also had to start immediately implementing these requirements. The Final Rule acknowledges as much by pointing to costs states will incur in year one.

Plaintiffs have no option but to seek relief through this Court and request this Court to vacate, set aside, and permanently enjoin the Final Rule. In the interim, the Plaintiffs will seek to preliminary enjoin the Final Rule to spare them the irreparable harm they are already facing and will continue to face in the future.

THE PARTIES

1. Plaintiff Alabama is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Alabama brings this suit through its attorney general, Steve Marshall, who is the chief legal officer for the State and is "authorized to institute and prosecute, in the name of the state, all civil actions and other proceedings necessary to protect the rights and interests of the state." Ala. Code § 36-15-12.

2. Plaintiff Alaska is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Alaska brings this suit through its Attorney General, Treg R. Taylor. He is authorized by Alaska law to sue on the State's behalf.

3. Plaintiff Arkansas is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Arkansas brings this suit through its attorney general, Tim Griffin. General Griffin is authorized to "maintain and defend the interests of the state in matters before the United States Supreme Court and all other federal courts." Ark. Code Ann. § 25-16-703.

4. Plaintiff the State of Florida is a sovereign State and has the authority and responsibility to protect its sovereign interests and the health, safety, and welfare of its citizens. As the State's Chief Legal Officer, Attorney General Ashley Moody is authorized to represent the interests of the State in civil suits. § 16.01(4), (5), Fla. Stat.

5. Plaintiff State of Georgia is a sovereign state of the United States of America. Georgia sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens, businesses and employees. Georgia brings this suit through its Attorney General, Christopher Carr. He is the chief legal officer of the State of Georgia and has the authority to represent the State in federal court.

6. Plaintiff State of Idaho is a sovereign State of the United States of America. Idaho sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens. The Final Rule will harm Idaho and its citizens. Idaho brings this suit through its attorney general, Raúl Labrador, the State's chief legal officer. He is authorized by Idaho law to sue on the State's behalf under Idaho Code § 67-1401. His address is 700 W. Jefferson Street, P.O. Box 83720, Boise, Idaho 83720.

7. Plaintiff Indiana is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Indiana brings this suit through its attorney general, Theodore E. Rokita. He is authorized to "represent the state in any matter involving the rights or interests of the state." Ind. Code § 4-6-1-6.

8. Plaintiff Iowa is a sovereign state of the United States of America. Iowa sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Iowa brings this suit through its attorney general, Brenna Bird. She is authorized by Iowa law to sue on the State's behalf under Iowa Code § 13.2.

9. Plaintiff Kansas is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Kansas brings this suit through its attorney general, Kris W. Kobach. He is the chief legal officer of the State of Kansas and has the authority to represent Kansas in federal court. Kan. Stat. Ann. 75-702(a).

10. Plaintiff Commonwealth of Kentucky is a sovereign state of the United States of America. Russell Coleman is the duly elected Attorney General of the Commonwealth of Kentucky with the constitutional, statutory, and common-law authority to bring a suit on behalf of the Commonwealth and its citizens. *See* Ky. Rev. Stat §§ 15.020, 15.255(a), 15.260; *see also Commonwealth ex rel. Beshear v. Commonwealth ex rel. Bevin*, 498 S.W.3d 355, 362 (Ky. 2016).

11. Plaintiff Missouri is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Missouri brings this suit through its attorney general, Andrew Bailey. He is the chief legal officer of the State of Missouri and has the authority to represent Missouri in federal court. Mo. Rev. Stat. § 27.060.

12. Plaintiff Montana is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Montana brings this suit through its attorney general, Austin Knudsen. He is the chief legal officer of the State of Montana and has the authority to represent Montana in federal court. Mont. Rev. Code § 2-15-501.

13. Plaintiff Nebraska is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Nebraska brings this suit through its attorney general, Mike Hilgers. He is the chief legal officer of the State of

Nebraska and has the authority to represent Nebraska in federal court. Neb. Rev. Stat. § 84-203.

14. Plaintiff Oklahoma is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Gentner Drummond is the duly elected Attorney General for the State of Oklahoma. Being "the chief law officer of the state," OKLA. STAT. tit. 74, § 18, General Drummond is empowered "[to] appear for the state and prosecute and defend all actions and proceedings in any of the federal courts in which the state is interested as a party." *Id.* at § 18b(A)(2).

15. Plaintiff North Dakota is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Drew Wrigley is the Attorney General of North Dakota and is authorized to "[i]nstitute and prosecute all actions and proceedings in favor or for the use of the state." N.D.C.C. § 54-12-01(2).

16. Plaintiff South Carolina is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. South Carolina brings this suit through its attorney general, Alan Wilson. He is the chief legal officer of the state of South Carolina and has the authority to represent South Carolina in federal court. *State ex rel. Condon v. Hodges*, 349 S.C. 232, 239-40, 562 S.E.2d 623, 627 (2002) (the South Carolina Attorney General "may institute, conduct and maintain all such suits and *proceedings as he deems* necessary for *the enforcement of the laws of the State*, the *preservation of order*, and the *protection of public rights*.") (emphasis in original) (quoting *State ex rel. Daniel v. Broad River Power Co.*, 157 S.C. 1, 68, 153 S.E. 537, 569 (1929), *aff'd* 282 U.S. 187 (1930)).

17. Plaintiff South Dakota is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. South Dakota brings this suit through its Attorney General, Marty J. Jackley. He is the duly elected Attorney General of South Dakota with the authority, per SDCL 1-11-1(1), to prosecute and defend all actions, civil or criminal, in which the state is an interested party.

18. Plaintiff Utah is a sovereign State of the United States of America. It sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Utah brings this suit through its attorney general, Sean D. Reyes. He is the chief legal officer of the State of Utah and has the authority to represent Utah in federal court. Utah Const. art. VII, § 16; Utah Code § 67-5-1(1)(b).

19. Plaintiff Commonwealth of Virginia is a sovereign State of the United States of America. Jason Miyares, the Attorney General of Virginia, is authorized by statute to "represent the interests of the Commonwealth … in matters before or controversies with the officers and several departments of the government of the United States." Va. Code § 2-2.513.

20. Plaintiff State of West Virginia is a sovereign State of the United States of America. Patrick Morrisey is the Attorney General of the State of West Virginia. The Attorney General "is the State's chief legal officer," *State ex rel. McGraw v. Burton*, 569 S.E.2d 99, 107 (W. Va. 2002), and his express statutory duties include "appear[ing] as counsel for the state in all causes pending . . . in any federal court[] in which the state is interested," W. Va. Code § 5-3-2.

21. Plaintiff LeadingAge Kansas is a state trade association that has operated for 70 years with over 150 not-for-profit and mission driven aging services providers, including 116 nursing homes. LeadingAge Kansas represents a significant number of small, rural, and stand-

alone nursing homes who will not be able to absorb the cost of the Final Rule year-after-year as they continue to rely on historically underfunded Medicaid and Medicare reimbursement.

22. Among the nursing homes that are members of Plaintiff LeadingAge Kansas are Plaintiffs Dooley Center and Wesley Towers. These and others are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

23. Plaintiff Dooley Center is a 44-person licensed nursing facility located in Atchison, Kansas, that accepts Medicaid and private pay only. It cares for the retired Benedictine Sisters of Mount St. Scholastica. Its mission is "the care of the sick rank above and before all else, so they may truly be served as Christ." It is harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

24. Plaintiff Wesley Towers is a continuing care retirement community located in Hutchinson, Kansas. It currently has 185 employees and 300 residents, 50 of whom are cared for in its nursing home. It is harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

25. Plaintiff LeadingAge South Carolina is an association that represents 30 non-profit mission driven skilled nursing communities in South Carolina. These communities, which include Presbyterian Communities of South Carolina, Lutheran Homes of South Carolina, The Woodlands at Furman, Wesley Commons, Westminster Towers, Bishop Gadsden Episcopal Community, Saluda Nursing & Rehabilitation, The Cypress of Hilton Head, Park Pointe Village, The Seabrook of Hilton Head, Rolling Green Village, South

Carolina Baptist Ministries of Aging, and Still Hopes Episcopal Retirement Community, are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

26. Plaintiff LeadingAge Colorado is a statewide trade association that represents the continuum of senior living and aging services providers including not-for-profit nursing homes. It represents 12 nursing communities, including Eben Ezer Lutheran Care Center, which are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

27. Plaintiff LeadingAge Iowa is a trade association that represents not-for-profit aging services providers in Iowa, including 60 nursing homes, nearly half of which are located in this District. These members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

28. Plaintiff LeadingAge Maryland is a membership association representing not-for-profit aging services organizations in Maryland. It represents 30 nursing communities, with its members including Coffman Nursing Center, Fahrney Keedy Home and Village. These and other members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are impossible to meet without reducing services or further limiting access to care.

29. Plaintiff LeadingAge Michigan is a state trade association with over 200 not-for-profit and mission-driven aging services providers, including 51 nursing homes. These

members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

30. Plaintiff LeadingAge Minnesota is a state trade association that has over 1100 mission-driven aging services providers, including 239 nursing homes. These members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

31. Plaintiff LeadingAge Missouri is a membership association for 125 Missouri aging services providers, including 44 nursing homes. These members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

32. Plaintiff LeadingAge Nebraska is a statewide trade association supporting nursing home and other providers of long-term care services in Nebraska. It represents 47 nursing home providers, including Florence Home, which are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

33. Plaintiff LeadingAge New Jersey/Delaware is a state trade association with over 140 mission driven senior living and services provider members, including over 30 nursing communities. These members, including United Methodist Communities, are harmed by the Final Rule because of significant costs and mandatory staffing requirements are impossible to meet without reducing services or further limiting access to care.

34. Plaintiff LeadingAge Ohio is an association that represents 112 nonprofit, mission-driven skilled nursing communities in Ohio, with its member including Shepherd of the Valley communities in Poland, Boardman, Girard and Howland; Community First Solutions, which operates three facilities in Hamilton, Ohio. These and other members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

35. Plaintiff LeadingAge Oklahoma is a state trade association with over 100 not-for-profit and mission driven aging services providers, including 58 nursing homes. These and other members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

36. Plaintiff LeadingAge PA is an association representing more than 400 non-profit and mission-driven providers of senior services in Pennsylvania, with its membership encompassing 182 of the more than 600 skilled nursing facilities in Pennsylvania. These and others members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are impossible to meet without reducing services or further limiting access to care.

37. Plaintiff LeadingAge South Dakota Association of Healthcare Organizations ("SDAHO") is a state trade association serving South Dakota's hospitals, nursing homes, home health, hospice and assisted living providers through advocacy, education and quality integration. Its membership includes 57 hospitals, 47 nursing homes, 77 assisted living facilities, and approximately 18 home health and hospice providers. Many of its members,

including The Neighborhoods at Brookview in Brookings, SD, Bethesda Home of Aberdeen, South Dakota, and Winner Regional Healthcare Center in Winner, SD, are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

38. Plaintiff LeadingAge Southeast is a state trade association with over 250 mission driven communities. Their members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

39. Plaintiff LeadingAge Tennessee is a state trade association with 20 not-for-profit nursing home members serving the State of Tennessee. These members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are difficult if not impossible to meet without reducing services or further limiting access to care.

40. Plaintiff LeadingAge Virginia is a state trade association with over 90 mission driven provider members, including over 46 homes. These members are harmed by the Final Rule because of significant costs and mandatory staffing requirements that are impossible to meet without reducing services or further limiting access to care.

41. Defendant Xavier Becerra is the Secretary of Health & Human Services. Defendant Becerra oversees the Medicare and Medicaid programs and approved the Final Rule at issue in this litigation. *See* 89 Fed. Reg. at 41000. Defendant Becerra is sued in his official capacity.

42. Defendant United States Department of Health and Human Services ("HHS") is a federal agency organized under the laws of the United States. It is responsible for

administering federal healthcare policy and is the cabinet-level department of which the Centers for Medicare & Medicaid Services ("CMS") is a part.

43. Defendant CMS is a federal agency within HHS responsible for the federal government's administration of Medicare and Medicaid.

44. Defendant Chiquita Brooks-Lasure is the Administrator of CMS and is sued in her official capacity.

JURISDICTION AND VENUE

45. This Court has jurisdiction over this action under 28 U.S.C. § 1331 and has authority to grant the relief requested under the Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

46. The Court is authorized to set aside the challenged agency actions, postpone their effective date pending judicial review, hold them unlawful, grant preliminary and permanent injunctive relief, and award the declaratory and injunctive relief requested below. 5 U.S.C. §§ 705-06 (2018); 28 U.S.C. §§ 1361, 2201-02 (2018).

47. Venue is proper under 5 U.S.C. § 703 and 28 U.S.C. § 1391(e) because (1) Plaintiff State of Iowa and members of LeadingAge Iowa reside in this judicial district and no real property is involved in this action.

48. Plaintiffs are challenging a final agency action pursuant to 5 U.S.C. §§ 551(13) and 704 (2018).

BACKGROUND

A. Medicare and Medicaid Statutes

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

50. Medicare is a federal program that provides healthcare coverage to individuals 65 or older, as well as those with certain disabilities or conditions. *See* 42 U.S.C. § 1395c.

51. Medicaid, on the other hand, is a joint federal-state program offering healthcare coverage to low-income individuals. *See* 42 U.S.C. §§ 1396-1, 1396a.

52. Nursing homes that wish to participate in Medicare must comply with the statutory requirements for "skilled nursing facilities" ("SNFs") provided for at 42 U.S.C. § 1395i-3.

53. Those participating in Medicaid must meet similar requirements for "nursing facilities" ("NFs") set forth at 42 U.S.C. § 1396r.

54. Together, "skilled nursing facilities" covered under Medicare, and "nursing facilities" covered under Medicaid are often collectively referred to as "long-term care" ("LTC") facilities. *See, e.g*. 87 Fed. Reg. 22720, 22790 (Apr. 15, 2022). Referring to both types of facilities as LTCs is convenient because the statutory language for both Medicare and Medicaid requirements are largely parallel.

55. CMS has issued consolidated regulations applicable to all LTC facilities participating in either or both Medicare and Medicaid. *See e.g.* 42 C.F.R. § 483.1.

56. Under the Medicaid statute, a state may waive the staffing requirements for an LTC facility if it cannot meet them, provided certain conditions are met: (1) the LTC facility must demonstrate to the state that, despite diligent efforts, it was unable to recruit suitable personnel; (2) granting a waiver will not compromise the health or safety of the LTC facility's residents; (3) during times when an RN is unavailable, an RN must be able to respond to calls from the LTC facility; (4) the state agency must notify the state long term care ombudsman

about the waiver; and (5) the LTC facility must inform its residents and family about the waiver. *See generally* 42 U.S.C. § 1396r(b)(4)(C)(ii)(I)-(V).

57. Similarly, under the Medicaid statute, LTC facilities are addressed in 42 U.S.C. § 1396r(b)(4)(C), also entitled "Required nursing care." This section mandates that LTC facilities provide necessary services and activities to achieve or maintain the highest practical well-being of each resident. Both the Medicare and the Medicaid emphasize the importance of quality care.

58. LTC facilities participating in either Medicare or Medicaid are required to utilize the services of a registered professional nurse for "at least 8 consecutive hours a day, 7 days a week." *See* 42 U.S.C. § 1395i-3(b)(4)(C)(i) (Medicare); *accord id.* § 1396r(b)(4)(C)(i)(II) (Medicaid).

59. They are required to provide 24-hour licensed nursing services that are "sufficient to meet the nursing needs of their residents." *See* 42 U.S.C. § 1395i-3(b)(4)(C)(i) (Medicare); *accord id*. § 1396r(b)(4)(C)(i)(I) (Medicaid).

60. Under the Medicare statute, the Secretary of HHS is authorized to waive the requirement for LTC facilities to employ an RN for more than 40 hours per week if: (1) the facility is "located in a rural area where the supply of skilled nursing services is insufficient to meet the needs" of local residents; (2) "the facility has one full-time RN who is regularly on duty at the [LTC] for 40 hours [per] week"; (3) the LTC facility has patients whose physicians have indicated that they do not require an RN or physician for 48 hours, or it has arranged for an RN or physician to provide necessary services when the full-time nurse is unavailable; (4) "the Secretary provides notice of the waiver to the State long-term care ombudsman …"; and

(5) the facility that is granted the waiver notifies residents of the LTC facility and their families of the waiver. *See generally* 42 U.S.C. § 1395i-3(b)(4)(C)(ii)(I)-(V).

61. Waivers of staffing requirements under the Medicaid statute are subject to annual review by the State and Secretary of HHS. *Id.* If a state is found to regularly grant waivers without facilities making diligent efforts to meet staffing requirements, the Secretary "shall assume and exercise the authority of the State to grant waivers." *Id.*

62. Neither the Medicare nor Medicaid statutes grant the Secretary the authority to establish a uniform HPRD requirement across all LTC facilities, irrespective of the actual needs of their residents or the idiosyncrasies of each facility. Rather, these statutes require nursing services that "are sufficient to meet the nursing needs" of each facility's residents. *See* 42 U.S.C. § 1395i-3(b)(4)(C)(i); *accord id.* 42 U.S.C. § 1396r(b)(4)(C)(i)(I).

63. Neither statute authorizes the Secretary to impose standardized HPRD requirements for RN staffing at every LTC facility across the country, regardless of their residents' specific needs or the idiosyncrasies of each LTC facility. *Id.*

64. Neither statute authorizes the Secretary to impose standardized HPRD requirements for NA staffing at every LTC facility across the country, regardless of their residents' specific needs or the idiosyncrasies of each LTC facility. *Id.*

65. Neither statute authorizes the Secretary to alter or increase the hour requirement for LTC facilities to employ the services of a registered professional nurse beyond "at least 8 consecutive hours a day, 7 days a week." *Id.*

B. Statutory and Regulatory History of Nursing Staff Requirements

66. For over fifty years, Congress has been at the helm of deciding the requisite staffing requirements for nursing homes participating in Medicare and Medicaid. In 1972,

Congress amended the Social Security Act to declare that all LTC facilities participating in Medicare or Medicaid provide "24-hour nurse service[s] which is sufficient" to meet patient needs, including employing at least one registered professional nurse full-time. Pub. L. No. 92-603, § 278, 86 Stat. 1329, 1424-27 (1972).

67. The amendments also introduced nurse-staffing waiver provisions for rural facilities under specific conditions. *See id.* § 267, 86 Stat. at 1450.

68. The Department of Health, Education and Welfare (predecessor of HHS), through its Social Security Administration ("SSA"), proposed regulations in 1973 that aligned with these statutory requirements. *See* 38 Fed. Reg. 18620 (July 12, 1973).

69. At the same time, during the notice-and-comment period, the SSA received public input urging it to deviate from Congress's flexible (qualitative) approach for a staffing requirement that all nursing homes implement a rigid (quantitative) nurse-to-patient ratio. *See* 39 Fed. Reg. 2238, 2239 (Jan. 17, 1974).

70. Despite calls for these specific nurse-to-patient ratios, the SSA rejected such a uniform approach, citing the variability in facility needs and the potential negative impacts of arbitrary staffing quotas. *Id*.

71. SSA reasoned that "the variation from facility to facility in the composition of its nursing staff, physical layout, patient needs and the services necessary to meet those needs precludes setting [a specific ratio]." *Id*. Moreover, "[a] minimum ratio could result in all facilities striving only to reach that minimum and could result in other facilities hiring unneeded staff to satisfy an arbitrary ratio figure." *Id*.

72. Later, in 1980, HHS took over the administration of Medicare and Medicaid services. It proposed a "general revision" of the regulation governing the participation of LTC facilities in the Medicare and Medicaid programs. *See* 45 Fed. Reg. 47368 (July 14, 1980).

73. However, HHS declined to implement any specific staffing ratios, but rather "retain[ed] the language in the existing regulations" that mirrored those statutes which called for "adequate staff to meet patient needs" *Id*. at 47371; *see also id*. at 47387 (requiring "24-hour nursing service with a sufficient number of qualified nursing personnel to meet the total nursing needs of the patient," and a registered nurse working full time for 7 days a week).

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

75. Congress further refined nursing home legislation by introducing waiver provisions and commissioning studies to analyze staffing requirements. These studies aimed to "determine the appropriateness of establishing minimum caregiver to resident ratios" for LTC facilities. *See* Pub. L. No. 101-508, §§ 4008(h), 4801(a), 104 Stat. 1338 (1990)).

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

77. In 2016, CMS once again dismissed the push for mandatory staffing ratios in LTC facilities and for the 24/7 RN requirement. *See* 81 Fed. Reg. 68688, 68754-56 (Oct. 4, 2016).

78. It concluded that a "one-size-fits-all approach" to staffing was not only "inappropriate[,]" but also that "mandatory ratios" and a "24/7 RN presence" were concerning. *Id*. at 68754-56, 68758; *see also* 80 Fed. Reg. 42168, 42201 (July 16, 2015) (emphasizing the importance of taking resident acuity levels into account").

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

80. CMS determined that the "focus" of its regulations "should be on the skill sets and specific competencies of assigned staff to provide the nursing care a resident needs rather than a static number of staff or hours of nursing care." 80 Fed. Reg. at 42201. And "establishing a specific number of staff or hours of nursing care could result in staffing to that number rather than to the needs of the resident population." *Id.*

81. CMS also found that having a 24/7 RN requirement "could negatively impact the development of innovative care options, particular[ly] in smaller, more home-like settings," and that "geographic disparity in supply could make such a mandate particularly challenging in some rural and underserved areas." 81 Fed. Reg. at 68755.

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

83. Because of the variation in LTC facility needs across the country, LTC facility minimum staffing requirements are handled differently across states. As CMS acknowledged,

there is "widespread variability in existing minimum staffing standards" adopted by 38 States and the District of Columbia. *See* 89 Fed. Reg. at 40880.

THE FINAL RULE

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

85. In doing so, the administration directed CMS to conduct a research study to determine the level and type of staffing needed to ensure safe and quality care. *Id.*

A. The Abt Study

86. In response to this directive, CMS contracted with a private firm, Abt Associates, to perform a "mixed-methods Nursing Home Staffing Study" as a party of CMS's goal of identifying a minimum staffing requirement.[2] The goal was to issue proposed rules by February 2023 and establish minimum standards for staffing adequacy. *See Supra*, White House Fact Sheet.

87. However, the truncated Abt Study was "conducted on a compressed timeframe" with data collected between June of 2022 through December of 2022. Abt Study at xix. Strikingly, "the short duration reflect[ed] the time-sensitive nature of the study and CMS's timeline for proposing a minimum staffing requirement in support of the Presidential initiative." *Id.*

[1] The White House, *FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes* (Feb. 28, 2022), available at https://tinyurl.com/3626wt8k
[2] Abt Associates, *Nursing Home Staffing Study: Comprehensive Report* (June 2023) ("Abt Study") at viii, available https://tinyurl.com/b2ehy528

88. The study was completed and published in June of 2023. Consistent with the decades of prior practice and contrary to the directive of the Biden-Harris Administration, the Abt Study did "not identif[y] a minimum staffing level to ensure safe and quality care." Abt Study at 115.

89. According to the study, if a minimum staffing level was to be implemented, "[n]ursing homes [would] face barriers to hiring, primarily [with] workforce shortages and competition from staffing agencies." *Id*. at xi; *see also*, *e.g*., *id*. at xii, xiv, 19, 31-32, 115.

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

91. Nowhere in the study did Abt Associates conclude that a minimum staffing requirement would result in *definitive* benefits. The Abt Study provides data for only "*potential* minimum staffing requirement benefits" and for "potential barriers to and unintended consequences of [an] implementation." Abt Study at 121 (emphasis added).

92. Nowhere in the study did Abt Associates conclude that a federally mandated minimum staffing requirement would *actually* provide better healthcare outcomes for nursing home residents. Rather, the reviewed literature "underscored" that there was no "clear eviden[tiary] basis for setting a minimum staffing level." Abt Study at xi.

93. Moreover, the staffing study did not find the implementation of a federally mandated minimum staffing requirement to be feasible without considering factors such as

variations in resident acuity, ongoing staffing shortages, compliance costs, and the diverse circumstances affecting quality patient care. *Id.* at 32.

94. That is not surprising given CMS's past positions that rejected calls to impose a one-size-fits-all approach. *See e.g.* 39 Fed. Reg. 2238, 2239 (Jan. 17, 1974) (explaining that the variation in patients' needs is a valid basis to reject setting a specific staff-to-patient ratio); 45 Fed. Reg. 47368, 47371 (July 14, 1980) (rejecting nursing staff ratios or minimum number of nursing hours per patient day because of the lack of conclusive evidence supporting the implementation of a minimum staffing requirement); 52 Fed. Reg. 38583, 38586 (Oct. 16, 1987) (explaining that a 24-hour nursing requirement would be impractical and that a nurse staffing requirement should be sensitive to the "patient mix") ; 80 Fed. Reg. 42168, 42201 (July 16, 2015) ("We believe that the focus should be on the skill sets and specific competencies of assigned staff to provide the nursing care a resident needs rather than a static number of staff or hours of nursing care that does not consider resident characteristics such as stability, intensity and acuity and staffing abilities including professional characteristics, skill sets and staff mix."); 81 Fed. Reg. 68688, 68755 (Oct. 4, 2016) ("[w]e do not agree that we should establish minimum staffing ratios at this time . . . [t]his is a complex issue and we do not agree that a 'one-size-fits-all' approach is best . . . [o]ur approach would require that facilities take into account the number of residents in the facility, those residents' acuity and diagnosis.").

95. As a result, the Abt Study never came to a definitive conclusion that supported a national, one-size-fits-all approach to minimum staffing requirements that the Biden-Harris Administration was hoping to achieve.

96. Rather, there was no "specific evidence" that a minimum nursing staff level could be feasibly implemented. *Id*. at 111. Troublingly, the study disregarded the ongoing "national health care staff shortages" and "current hiring challenges" that present barriers to nursing homes—which would make compliance with a new federal staffing requirement impractical. *Id*. at xxi.

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

B. Promulgation of the Final Rule

98. In lockstep with marching orders from the Biden-Harris Administration, CMS issued a proposed rule in September of 2023 that introduced new minimum staffing standards for LTC facilities. *See* 88 Fed. Reg. 61352 (Sept. 6, 2023).

99. Despite the 46,000 public comments—some of which informing CMS that the proposed rule exceeded CMS's statutory authority, contravened Congress's considered decision to keep flexible staffing standards, and failed to consider the barriers nursing homes would face with compliance—CMS published the Final Rule in May of 2024. *See Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting*, 89 Fed. Reg. 40876 (May 10, 2024).

100. CMS claims that the minimum staffing standard is supported by "literature evidence, analysis of staffing data and health outcomes, discussions with residents, staff, and industry." *See* 89 Fed. Reg. at 40877.

101. Citing the inconclusive and truncated six-month Abt Study, CMS claims that this was enough to conclude that an overly-broad and onerous staffing requirement was necessary. *See* 89 Fed. Reg. at 40881, 40877.

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

103. Notwithstanding the variability across the minimum staffing requirements different states employ, the inconclusive determination of the Abt Study, or the consistent rejection of a one-size-fits-all staffing requirement for over fifty years, CMS published the Final Rule.

104. CMS asserts that "various provisions" across 42 U.S.C. §§ 1395i-3 and 1396r contain "separate authority" to impose the Final Rule. *See* 89 Fed. Reg. at 40879, 40890-9.

1. The Secretary may impose "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." 42 U.S.C. § 1395i-3(d)(4)(B); *accord id*. § 1396r(d)(4)(B).

2. An LTC facility "must provide services and activities to attain or maintain the highest practicable physical, mental, and psychological well-being of each resident in accordance with a written plan of care." 42 U.S.C. § 1395i-3(b)(2); *accord id*. § 1396r(b)(2).

3. An LTC facility "must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident." 42 U.S.C. § 1395i-3(b)(1)(A); *accord id*. § 1396r(b)(1)(A).

C. The Final Rule's Provisions

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

106. *First*, the Final Rule *triples* the required hours per day of RN services. Both the Medicare and Medicaid statutes require that LTC facilities "[u]se the services of [an RN] for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1395i-3(b)(4)(C)(i); *accord id.* § 1396r(b)(4)(C)(i). But the Final Rule requires LTC facilities to have an RN "onsite 24 hours per day, for 7 days a week that is available to provide direct resident care" ("24/7 requirement"). 89 Fed. Reg. at 40997.

107. *Second,* the Final Rule abandons the flexible, qualitative statutory requirement that LTC facilities "provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1395i-3(b)(4)(C)(i); *accord id.* § 1396r(b)(4)(C)(i). Instead, the Final Rule now requires that "[t]he facility must meet or exceed a minimum of 3.48 hours per resident day ('HPRD') for total nurse staffing," which must include a "minimum of 0.55 [HPRD] for registered nurses," and a "minimum of 2.45 [HPRD] for nurse aides." 89 Fed. Reg. at 40996.

108. Before publication of the Final Rule, federal regulations mirrored Congress's *qualitative* statutory requirements to keep nursing staff available 24-hours per day. *See* 42 C.F.R. § 483.30.

109. Those regulations never specified a *quantitative* staffing requirement. *Id.*; *Cf.* 89 Fed. Reg. 40876, 40996-97. But by departing from the flexibility of both the Medicare and Medicaid statutes, the Final Rule now requires national compliance from LTC facilities "regardless of the individual facility's resident case-mix." 89 Fed. Reg. at 40877.

110. Regarding the statutory waivers, the Final Rule permits Medicare participants to qualify for a statutory waiver of the 24/7 RN requirement, but not the HPRD requirements. *Id.* at 40997-98.

111. The Final Rule also permits Medicaid participants to qualify for the statutory waiver concerning the new 24/7 RN requirement and 0.55 RN HPRD requirement, but not for the 3.48 total nurse HPRD nor 2.45 NA HPRD requirements. *Id.* at 40997.

112. The Final Rule proposes a "hardship exemption," ostensibly allowing partial relief from the 24/7 requirement and minimum HPRD requirements. *Id.* at 40998. However, this exemption is riddled with stringent criteria that make it virtually unattainable for most facilities to achieve.

113. To qualify for a "hardship exemption," the facility must establish that it meets *all four* regulatory requirements: (1) proving a significant local shortage of health care staff; (2) demonstrating unsuccessful recruitment efforts despite offering competitive wages; (3) documenting financial expenditures on staffing relative to revenue; and (4) qualified facilities must publicly disclose their exemption status. *Id.* at 40998.

114. This façade of an exemption is not only limited in scope, but explicitly departs from the statutory waiver criteria already laid out by Congress. Even *if* granted on the case-by-case determination, *see* 89 Fed. Reg. at 40886, the exemption only provides an 8-hour reprieve from the 24/7 RN requirement, leaving facilities with the requirement to staff for a minimum of 16 hours per day, 7 days per week. *Id*. at 40998.

115. Even the narrow allowance of a "hardship exemption" can still be denied if a facility is designated as a "Special Focus Facility," or those with recent staffing-related

citations. *Id*. Ultimately, LTC facilities currently struggling with staffing recruitment or retention will be incapable of qualifying for even a "hardship exemption."

D. CMS Fails to Explain the Final Rule

116. In the Final Rule, CMS fails to explain why it implemented the 24/7 requirement and departed from the statutory requirements of both the Medicare and Medicaid Acts that only require onsite RN services for only 8 hours per day, 7 days a week (hereinafter "8/7 requirement").

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

118. CMS fails to explain how it determined its 3.48, 0.55, or 2.45 HPRD requirements. It claims that the 3.48, 0.55, and 2.45 HPRD levels "were developed using case-mix adjusted data sources." 89 Fed. Reg. at 40877.

119. CMS claims that the 0.55 and 2.45 levels, but not the 3.48 level, were discussed during the notice of proposed rulemaking. *See* 88 Fed. Reg. 61352 (Sept. 6, 2023); 89 Fed. Reg. at 40891.

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

121. However, the Abt Study does not substantiate these specific levels. Moreover, a "review of existing literature" does not provide a valid evidentiary basis for establishing these requirements.

122. CMS also fails to establish how other data assessments support the published staffing levels.

123. CMS provides no rationale for the 3.48 HPRD requirement in either the notice of proposed rulemaking or the Final Rule, aside from vaguely stating it was developed using "case-mix adjusted data sources." 89 Fed. Reg. at 40877. This explanation departs from those used to establish other staffing levels in the notice of proposed rulemaking.

124. Moreover, CMS's minimum staffing ratios require LTC facilities to ignore the variability in resident acuity and needs across different facilities. Some facilities with higher acuity residents may need increased staffing, while others with lower acuity residents may not require an RN present 24/7. CMS fails to explain why requiring facilities with lower acuity residents to maintain higher staffing than needed is necessary for increasing quality of care.

125. CMS's rationale for the Final Rule is premised on truncated data that does not accurately capture the staffing realities in nursing homes. The Final Rule requires the use of Payroll Based Journaling ("PBJ") data to monitor and enforce the HPRD and 24/7 requirements. *See* 89 Fed. Reg. at 40882-83.

126. However, PBJ data fails to accurately account for the specific periods when LTC staff are working and need to comply with the Final Rule. For instance, if an LTC facility employs three RN's who each work 8-hour dayshifts but no overnight shifts, it would appear on paper that they meet the 24/7 requirement. But in reality, they are not. CMS thus fails to explain how PBJ data is an accurate metric of tracking compliance.

127. CMS fails to account for the ongoing shortage of nursing staff across the country—one that will surely be exacerbated by CMS's mandate that will make compliance virtually impossible in rural areas.

128. Instead of addressing the reality of the nationwide workforce shortage, CMS would rather throw $75 million to help "increase the [LTC] workforce" that it "expects" will be used for "tuition reimbursement." 89 Fed. Reg. 40885-86. This $75 million is only a miniscule fraction of what is *needed* to comply or alleviate many of the affected LTC facilities. Moreover, $75 million does not address the foundational problem.

129. Ultimately, CMS's explanation for the determination of these levels lacks transparency and does not adequately explain how such arbitrary figures and standards were determined.

HARM TO THE PLAINTIFFS

A. Financial Burden

130. The Final Rule imposes a monumental financial burden on LTC facilities, with costs (conservatively) projected to exceed $5 billion per year after the Final Rule is fully implemented. 89 Fed. Red. at 40970, tbl. 22; *see id.* at 40949. Outside studies point that number even higher—upwards of $7 billion per year by some estimates. *Id.* at 40950.

131. All of Plaintiff States' LTC facilities that receive Medicare and Medicaid will incur financial costs with the implementation of this Final Rule.

132. LTC facilities in Kansas are a prime example of how the Final Rule creates a daunting financial burden.

133. The total cost for Kansas nursing facilities to comply with the Final Rule's minimum staffing requirement—in the first year alone—ranges between $64 million and $92.7 million, with an average cost of $211,905 per facility.

134. In Indiana, the Indiana Health Coverage Program and Indiana PathWays for Aging provide coverage for long-term care services provided to eligible members with an

applicable level-of-care determination. CMS estimates that complying with the 24/7 RN Requirement will cost over $10.9 million annually in Indiana. 89 Fed. Reg. at 40962, tbl. 18. Statewide, CMS estimates that complying with this rule will cost Indiana long-term care facilities $151.2 million. *Id.* at 40984, tbl. 28. Much of this cost will be passed on to health plans, like Indiana Health Coverage Program and Indiana PathWays for Aging. So Indiana will face increased costs to cover long-term care services.

135. Plaintiff LeadingAge Kansas represents a significant number of small, rural, and stand-alone nursing homes who will be unable to absorb the incessant compliance costs.

136. LTC facilities operated by LeadingAge Kansas have historically relied on underfunded Medicaid and Medicare reimbursement while serving senior citizens in their communities who can already ill afford escalating costs of healthcare.

137. The estimated financial burden caused by the Final Rule will also include costs for both employing new staff and the use of contracted nursing agency workers—which is significantly more expensive.

138. For example, the average contracted RN rate is estimated at $72 per hour, while the average W2 RN employee rate is around $40 per hour. The averaged contracted NA rate is $38 per hour, while the average W2 NA employee rate is around $19 per hour.

139. For LeadingAge South Carolina, each LTC facility is estimated to have to pay $550,818 in compliance costs, which will potentially close most facilities.

140. Wesley Commons, one of LeadingAge South Carolina's LTC facilities, had to hire two additional RNs to comply with the Final Rule—incurring costs of $14,650, excluding night and weekend shifts.

141. Additionally, for compliance with the Final Rule, it reinstated two full-time nursing assistants to meet the HPRD requirement—adding an additional $66,560 per year.

142. These changes were necessary to comply with the Final Rule, despite previously meeting both state and federal requirements. Moreover, to retain and recruit more staff due to the new requirements, Wesley Commons increased pay, costing an additional $164,428 per year.

143. Facilities in rural areas that are operated by LeadingAge South Carolina will struggle to compete with urban LTC facilities.

144. For example, South Carolina Baptist Ministries of Aging paid over $1.25 million in 2022 to staffing agencies. In 2024 alone, and in order to come into compliance with the Final Rule, it paid an additional $500,000 to staffing agencies ahead of time to come into compliance.

145. Another LTC operated by LeadingAge South Carolina—The Woodlands at Furman—had to raise its pay rates by over 20% in the past year.

146. It is now forced to compete with private hospital systems that are continuously raising their RN and NA pay rates. Thus, the Final Rule's staffing mandate has had the downstream effect of creating a market where LTC facilities will have to limit their offerings or even shut their doors to elderly patients who need care.

147. The financial strain, along with inadequate Medicaid reimbursement rates, threatens many LTC facilities with closure, especially in rural communities with thin operating margins.

148. CMS has allocated only $75 million for nursing program tuition reimbursement—far less than what is needed. The Final Rule's cost burden will affect providers, private facilities, and Plaintiff States' taxpayers.

149. For example, 60 percent of nursing home residents in Kansas are on Medicaid. Since the COVID-19 Pandemic, Kansas lost 1,273 nursing home beds and 47 facilities closed or reduced services. Thus, the Final Rule will place a crippled LTC industry in dire straits.

B. Administrative Burdens

i. Staffing Issues

150. Not only is the Final Rule costly, but compliance will impact an overwhelming majority of LTC facilities across the country. Indeed, even by CMS's own estimate, more than 79 percent of LTC facilities in the United States will have to find additional staff just to comply with the new minimum-staffing requirements. 89 Fed. Reg.at 40877. This "exceed[s] the existing minimum staffing requirements in nearly all states." *Id*.

151. By CMS's estimates, LTC facilities across the country will have to hire almost 15,906 additional RNs to meet the 24/7 RN requirement and 0.55 RN HPRD requirement. 89 Fed. Reg. at 40958, 40977-80.

152. Additionally, LTC facilities will have to hire 77,611 NAs to meet the 2.45 NA HPRD requirement and the 3.48 total nurse HPRD requirement. *Id*. Hiring 90,000 new staff to fall in compliance with the Final Rule is practically impossible when LTC facilities are already experiencing staffing shortages, recruitment issues, and employment retention.

153. Kansas is a prime example of how the Final Rule's adverse effects will irreparably harm Plaintiffs. According to CMS data, the state of Kansas will need an

additional 230 RNs to comply with both the 24/7 Requirement and 0.55 RN HPRD requirement for LTC facilities. *See* 89 Fed. Reg. at 40059, 40077-79.

154. CMS has already indicated that 109 LTC facilities are out of compliance with the 24/7 RN requirement. 89 Fed. Reg. at 40062. Furthermore, Kansas will have to hire an additional 523 NAs to comply with the Final Rule's HPRD ratios. *See id.* at 40077-79.

155. Nearly 85,000 Kansans live in areas with only one LTC facility within a 30-minute drive, and the closure of such facilities would significantly increase travel time, creating a lack of access to care and essential services.

156. Additionally, with the aging population in Kansas projected to grow by 208,000 by 2036, the capacity to provide adequate care will be severely strained if more facilities are forced to reduce capacity or close entirely.

157. LTC facilities in Kentucky, according to the CMS data, will need to hire an additional 185 RNs and to comply with both the 24/7 requirement and the 0.55 RN HPRD requirement. See 89 Fed. Reg. 40965, 40977-80.

158. Furthermore, CMS estimates that Kentucky facilities will need to hire an additional 1336 NA staff just to comply with the Final Rule's HPRD ratios. *See id.* at 40977-80.

159. CMS data estimates that 211 LTC facilities in Kentucky do not currently meet the Final Rule's staffing requirements.

160. The Kentucky Association of Health Care Facilities, which represents skilled nursing facilities and personal care homes in Kentucky, estimates that only 6% of nursing homes currently have sufficient nursing staff to comply with all the Final Rule's requirements. Yet, a workforce survey report by the Kentucky Hospital Association predicted a worsening

shortage of nursing staff available in Kentucky for LTCs to hire. *See* Morgan Watkins, *New studies show scope of Kentucky's health care worker shortage, as a coalition promotes solution*s, available at https://perma.cc/XLT5-TMR9.

161. Most of Montana consists of health professional shortage areas (HPSAs). Many of these LTC facilities are located in small towns or remote areas of Montana and likely have difficulty hiring RNs or contracting for visiting nursing staff to meet the minimum staffing requirements in the Final Rule.

162. LTC facilities in South Carolina, according to CMS data, will need to hire an additional 159 RNs to comply with both the 24/7 requirement and the 0.55 RN HPRD requirement. *See* 89 Fed. Reg. 40958, 40978-80.

163. Furthermore, South Carolina facilities will need to hire an additional 1,045 NA staff just to comply with the Final Rule's HPRD ratios. *See id.* at 40978-80. However, these numbers are low.

164. Based on LeadingAge South Carolina's data, facilities in South Carolina will need to hire 411 additional RNs and over 1170 NAs to meet the minimum staffing ratio provision in the Final Rule.

165. South Carolina is also projected to have the 4th largest nurse shortage by 2030. The additional hiring necessitated by the Final Rule will thus make compliance virtually impossible for LTC facilities.

166. According to the South Carolina Workforce Publication on Nursing, 53% of RNs work in hospital settings, whereas only 4.4% of RNs work in LTC settings.

167. Virginia's HPRD requirement, which goes into effect on July 1, 2025, is more than ten percent less than the Final Rule's requirement. Senate Bill No. 1339, 2023 Gen

Assemb., Reg. Sess. (Va.), https://tinyurl.com/c3f58meh (to be codified at Va. Code § 32.1-127(B)(32)) (requiring nursing homes "to provide at least 3.08 hours of case mix-adjusted total nursing staffing hours per resident per day on average").

168. Accordingly, any kind of required increase in staffing will have to account for (1) the national shortage in the healthcare labor force, and (2) the detraction of nurses from hospital settings. Ultimately, detrimental negative externalities cascade from the Final Rule and jeopardize the health care system, state agencies, and state hospitals.

ii. Enhanced Facility Assessment ("EFA")

169. The Final Rule's EFA implemented on August 8, 2024, requires providers to conduct a comprehensive evaluation of their facility, residents, staff, and resident families to determine staffing and other needs. 89 Fed. Reg. 40881, 40906.

170. Specifically, the Final Rule mandates LTC facilities to ensure the "active involvement" of direct care staff and their representatives, and to "solicit and consider input" from residents, their representatives, and family members. *Id*. at 40908. LeadingAge Kansas has requested guidance from the state survey agency contracted by CMS to carry out healthcare surveys of nursing home providers in Kansas on this provision but did not receive adequate guidance.

171. The Final Rule requires facilities to "review and update" the EFA at least annually, without clear guidance on when updates are "necessary"—thus, leading to potential civil penalties. *Id*. at 40999.

172. LTC facilities must also create "contingency planning," despite already having emergency plans in place. *Id*. at 41000. Overall, the EFA imposes significant administrative burdens and vague requirements that could result in fiscal penalties.

173. Furthermore, staff hours and costs for the EFA vary facility-to-facility. For LeadingAge Kansas members like Wesley Towers and the Dooley Center, the initial EFA ranged from 16 hours to 89 hours.

174. The estimated cost for each update to comply with the assessment ranges from $400 to $600. The Final Rule's vague language requiring continual updates means that costs can quickly escalate.

175. Most importantly, the significant amount of time needed for the EFA detracts from the essential administration and direct resident care necessary for quality and safety. The EFA is a significant burden on staff because it diverts time away from direct resident care to maintain overburdensome compliance updates.

176. CMS estimates the cost at $4,955 per facility, *see* 89 Fed. Reg. at 40939, but that number is woefully low. The Final Rule requires EFAs conducted on all LTC facilities without considering the acuity and needs of the residents to determine staffing levels or evaluate unique circumstances. These factors, coupled with the lack of clear guidance and the risk of civil penalties, significantly contribute to the administrative burden imposed by the Final Rule.

C. Harm to Plaintiff States

177. Many Plaintiff States have their own state-run nursing homes.

178. For example, Arkansas has a state-operated 310-bed psychiatric nursing home, the Arkansas Health Center, which would be required to comply with these new minimum staffing quotas. See Ark. Code Ann. § 25-10-401.

179. Idaho has at least five state-run nursing homes, all which receive Medicaid payments. Four of the nursing homes are run by the Idaho Division of Veterans Services, and one is run by the Idaho Department of Health and Welfare.

180. Montana operates several LTC facilities that receive CMS fund and that would be subject to CMS regulations.

181. West Virginia's Department of Health Facilities operates four nursing homes: Hopemont Hospital, John Manchin, Sr. Health Care Center, Lakin Hospital, and Welch Community Hospital. *See* West Virginia Department of Health Facilities, https://tinyurl.com/3ykbt2tw (last visited Oct. 4, 2024). Altogether, West Virginia's state-run nursing homes have 312 beds. *See id.*

182. Those States facilities would incur the same harm as any LTC as noted above.

183. Non-State-run nursing homes would incur the same harm as any LTC as noted above. The resulting burdens may result in nursing homes closing, causing harm to state citizens.

184. Alaska is largely a frontier and rural state, with uniquely difficult workforce shortage challenges. According to a recent report, "hospital-based registered nurses had a vacancy rate of 21%, and it took an average of 118 days to fill a vacant position. Alaska is competing with the rest of the country for a limited number of healthcare workers. Projections indicate Alaska is expected to have the most significant shortages moving forward of any state. In 2022, Alaska programs graduated fewer than 900 healthcare workers in key positions, while the number of healthcare workers needed for those positions was 3,232. Travel nurses can be used to meet short-term staffing needs; however, this solution comes at a higher cost. In 2023, traveling registered nurses in Alaska earned 57% more pay on average than non-

traveling RNs." Alaska Hospital & Healthcare Association, *2023 Alaska Healthcare Workforce Analysis*, 1 (Dec. 2023), https://www.alaskahha.org/_files/ugd/ab2522_bde54b435a474ca48101c58d9239da21.pdf.

185. The Final Rule's 24/7 RN requirement will exacerbate the nursing workforce shortage.

186. The Final Rule's requirements disincentivize nursing homes from accepting Medicaid and Medicare, placing vulnerable Alaskans at risk of losing access to needed care.

187. The State of Alaska provides licensing oversight for LTCs. The Final Rule would impose additional financial costs and resource burdens on state agencies monitoring compliance and reviewing waivers under section 483.35(f).

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

189. Although this requirement does not take effect until four years after the Final Rule is published, it will impose costs on States well before that. The Final Rule acknowledges as much by estimating the cost to the States in *year one* to be $183,851. *Id.*

CLAIMS FOR RELIEF

COUNT ONE

(APA – Lack of Statutory Authority)

190. Plaintiffs re-allege and incorporate by reference the preceding allegations as though fully set forth herein.

191. Under the APA, a court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

192. CMS, like all administrative agencies, is a "creature[] of statute," and accordingly "possess[es] only the authority that Congress has provided." *Nat'l Fed'n of Indep. Bus. v. Dep't of Labor*, 595 U.S. 109, 117 (2022); *see also, e.g.*, *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act . . . unless and until Congress confers power upon it.").

193. The Final Rule exceeds CMS's statutory authority in violation of the APA, 5 U.S.C. § 706(2)(C) in multiple ways.

A. The 24/7 RN Requirement

194. Congress has already established the minimum amount of RN staffing necessary to participate in Medicaid or Medicare: 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).

195. The Final Rule ignores this by stating an LTC "must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week." 89 Fed. Reg. at 40997.

196. CMS acknowledges that the statutory provisions establishing the 8/7 requirement for RN staffing do not authorize it to adopt the 24/7 RN requirement. *See* 89 Fed. Reg. at 40891.

197. CMS nevertheless asserts that "various provisions" elsewhere in §§ 1395i-3 and 1396r contain "separate authority" for this novel requirement, *id.* at 40879, 40890-91, pointing to provisions stating that: (1) The Secretary may impose "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary," 42 U.S.C. § 1396r(d)(4)(B), *accord* 42 U.S.C. § 1395i-3(d)(4)(B); (2) An LTC facility "must provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care," 42 U.S.C. § 1396r(b)(2), *accord* 42 U.S.C. § 1395i-3(b)(2); and (3) An LTC facility "must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident." 42 U.S.C. § 1396r(b)(1)(A); *accord* 42 U.S.C. § 1395i-3(b)(1)(A).

198. The only provision that arguably allows authority for CMS to engage in rulemaking is 42 U.S.C. § 1396r(d)(4)(B), *accord* 42 U.S.C. § 1395i-3(d)(4)(B), that requires LTCs to "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." (emphasis added).

199. That statutory provision is in a broader subsection that refers to "[r]equirements relating to *administration and other matters*." *See* 42 U.S.C. § 1396r(d), *accord* 42 U.S.C. § 1395i-3(d) (emphasis added).

200. Drilling down further the subsection right above this rulemaking authority CMS latches onto is entitled "Miscellaneous." *See* 42 U.S.C. § 1396r(d)(4), *accord* 42 U.S.C. § 1395i-3(d)(4).

201. Finally, the specific statutory subsection relied on for authority is entitled "other" and refers to "other requirements relating to the health and safety…as the Secretary may find necessary." 42 U.S.C. § 1396r(d)(4)(B), *accord* 42 U.S.C. § 1395i-3(d)(4)(B).

202. The best reading of the only statutory authority CMS relies on for rulemaking is that it is related to administrivia for the health and safety of LTC patients that the rest of the Medicare and Medicaid statute does not already cover.

203. Congress covered the mandatory hours for nurse staffing for LTCs in a separate statutory provision and as such, there is no universe where they gave authority to CMS to alter that through rulemaking in a "miscellaneous" statutory provision.

204. None of the other general provisions CMS relies on allows it to impose a 24/7 statutory requirement either when a more specific statute only requires 8/7 nursing services. That's because "[g]eneral language" in one part of a statute "will not be held to apply to a matter specifically dealt with in another part of the same enactment." *E.g.*, *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645-46 (2012) (quoting *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932)).

205. Yet that is what the Final Rule does. Even CMS recognizes that the Final Rule "revises" the statutory 8/7 RN requirement codified at 42 U.S.C. §§ 1395i-3(b)(4)(C)(i) and 1396r(b)(4)(C)(i) by replacing it with CMS's 24/7 RN requirement. *See* 89 Fed. Reg. at 40898.

206. Congress did not leave that decision open for CMS to make. CMS lacks statutory authority to impose the 24/7 RN requirement, and the Final Rule must be set aside. *See* 5 U.S.C. § 706(2).

B. The HPRD Requirements

207. The same is true for the Final Rule's HPRD requirements. Congress carefully considered whether to enact quantitative staff-to-patient ratios for LTC facilities, and it chose not to do so.

208. Instead, Congress opted for a qualitative standard, leaving quantitative staff-to-patient ratios to the states: LTC facilities must provide nursing services "sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i); *accord* § 1395i-3(b)(4)(C)(i).

209. The Final Rule unlawfully substitutes CMS's current policy views for Congress' considered judgment. Instead of accommodating the wide variation of resident needs in different states, the Final Rule inflexibly mandates that each facility in each state meet an arbitrary numerical staffing threshold: "[a] minimum of 3.48 hours per resident day for total nurse staffing[,] including but not limited to—(i) [a] minimum of 0.55 hours per resident day for registered nurses; and (ii) [a] minimum of 2.45 hours per resident day for nurse aides." 89 Fed. Reg. at 40996.

210. Once again, CMS does not rely on § 1395i-3(b)(4)(C) or § 1396r(b)(4)(C) as authority for these new requirements.

211. And once again, CMS invokes the Secretary's "miscellaneous" authority to make "other" rules that Congress did not already cover for the health and safety of residents, as well as provisions requiring LTC facilities to "provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident," and "promote

maintenance or enhancement of the quality of life of each resident." 89 Fed. Reg. at 40879, 40890-91; *see* 42 U.S.C. §§ 1395i-3(b)(1)(A), (b)(2), (d)(4)(B); 1396r(b)(1)(A), (b)(2), (d)(4)(B).

212. But none of those general provisions authorizes CMS to impose nationwide HPRD requirements for RNs, NAs, and total nursing staff. CMS's general authority over Medicare and Medicaid does not permit it to modify "matter[s] specifically dealt with in another part of the same enactment." *RadLAX Gateway Hotel*, 566 U.S. at 646; *see also* 42 U.S.C. § 1302(a) (the Secretary may not promulgate regulations that are "inconsistent with" statutory requirements).

213. Congress carefully considered what staffing levels to require from LTC facilities, and it decided to require that each facility maintain staffing levels "sufficient to meet the nursing needs of its residents." 42 U.S.C. §§ 1396r(b)(4)(C), 1395i-3(b)(4)(C).

214. CMS cannot utilize general authority to supersede Congress' judgment with its own arbitrary numerical requirements. Simply put, CMS does not have the authority to override Congress' judgment.

C. Major Questions Doctrine

215. The Final Rule also flunks the Major Questions Doctrine. The history of Congress' actions in this area, the "breadth of the authority" CMS now asserts, and "the economic and political significance" of that asserted authority confirm that CMS does not have the power to impose these new staffing mandates. *West Virginia v. EPA*, 597 U.S. 697, 721 (2022).

216. CMS proposes to revamp the entire nursing home industry to the tune of *at least* $43 billion dollars in compliance costs. The actual cost is likely much higher. The Supreme

Court has held that $50 billion qualifies as a Rule of vast economic significance. *Alabama Association of Realtors v. Department of Health and Human Services*, 594 U.S. 758, 764 (2021).

217. Beyond the costs, the breath of authority CMS now asserts is monumental. The Final Rule would fundamentally alter the landscape of the nursing home industry in a manner that impacts 97% of all nursing homes and will put many of them out of business. Furthermore, it would exceed the minimum staffing requirements for nursing homes in "nearly all states." 89 Fed. Reg. 40,877.

218. Finally, because Congress only required 8/7 staffing requirements and allowed flexibility for LTCs based on the needs of their facilities, states have moved to fill that void. The Final Rule acknowledges that 38 states and the District of Columbia have adopted their own staffing standards that vary between them. *See* 89 Fed. Reg. 40,881.

219. "When an agency claims the power to regulate vast swaths of American life, it not only risks intruding on Congress's power, it also risks intruding on powers reserved to the States." *West Virginia*, 597 U.S. at 744. (Gorsuch, J. concurring). CMS has "intruded" on powers traditionally reserved to the States by forcing this staffing rule on them.

220. When the major questions doctrine is triggered, as it is in this case, "clear authorization" and not some "vague statutory grant" is required in order for a court to find it lawful. *Id.* at 732.

221. CMS fails this test because they rely *exclusively* on a vague statutory grant and do not come close to clear authorization as the Final Rule *conflicts* with a separate Congressional statute.

222. The Final Rule flunks the Major Questions Doctrine and should be set aside.

D. Constitutional Doubt

223. If Congress truly gave CMS the authority to implement a regulation that costs at least $43 billion to comply with and overrides another one of its provisions, then it supplies no intelligible principle to guide how that power should be exercised.\

224. If CMS' interpretation was accepted as the one Congress intended it would present serious nondelegation concerns. *See Kentucky v. Biden*, 23 F.4th 585, 607, n.14 (6th Cir. 2022). ("If the government's interpretation were correct—that the President can do essentially whatever he wants so long as he determines it necessary to make federal contractors more 'economical and efficient'—then that *certainly* would present non-delegation concerns.")

225. The constitutional-doubt canon requires this Court to interpret the Rule to avoid these severe constitutional problems.

226. As the Supreme Court has explained, its "application of the nondelegation doctrine principally has been limited to the interpretation of statutory texts, and, more particularly, to giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional." *Mistretta v. United States*, 488 U.S. 361, 373, n.7 (198

227. The Supreme Court thus reads statutes with this principle in mind, *see, e.g.*, *Gundy v. United States*, 139 S.Ct. 2116 (2019), and this Court should do the same.

COUNT TWO

(APA – Contrary to Law)

228. Plaintiffs re-allege and incorporate by reference the preceding allegations as though fully set forth herein.

229. The Final Rule is not in accordance with law in violation of the APA, 5 U.S.C. § 706(2)(A). Even if CMS had *some* authority to set staffing requirements through vague statutory provisions, it could not utilize that limited authority to contradict what Congress had already put into place.

230. "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001). The Final Rule is a crude attempt by CMS to play sorcerer.

A. The 24/7 RN Requirement

231. Congress has already established the minimum amount of RN staffing necessary to participate in Medicaid or Medicare: 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). The Final Rule rewrites this statutory requirement in two ways.

232. *First*, it triples the hours of mandatory RN staffing. It does this by replacing the 8/7 RN requirement enacted by Congress with a mandate that all LTC facilities "must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week." 89 Fed. Reg. at 40997.

233. As noted above, Congress only requires 24-hour nursing staff sufficient to meet the needs of nursing home patients. 42 U.S.C. §1396r(b)(4)(C)(i)(I)

234. This indicates that there are at least *some* situations where Congress did not expect nursing homes to require 24-hour nursing staff without seeking a waiver.

235. By requiring 24-hour nurse staffing for *all* nursing homes, CMS has directly contradicted the statute it claims to interpret. This they cannot do.

236. *Second*, the Final Rule replaces the statutorily set scope of services to be rendered by RNs. It does so by changing the requirement to "use the services of" an RN, including in administrative or supervisory roles, with a new requirement to have an RN "available to provide direct resident care." *Id.*

237. The Final Rule effectively rewrites this statutory provision to fit the views of CMS. This is an attempt to play sorcerer which the agency cannot do.

B. The HPRD Requirements

238. Under existing law, each LTC facility must provide nursing services "sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i); *accord* § 1395i-3(b)(4)(C)(i). The States are then free to set their own HPRD requirements. As CMS acknowledges, "38 States and the District of Columbia have minimum nursing staffing standards" for nursing homes. 89 Fed. Reg. at 40880.

239. But instead of accommodating the wide variation of resident needs in different states, the Final Rule inflexibly mandates that each LTC facility nationwide must meet an arbitrary numerical staffing threshold: "[a] minimum of 3.48 hours per resident day for total nurse staffing[,] including but not limited to—(i) [a] minimum of 0.55 hours per resident day for registered nurses; and (ii) [a] minimum of 2.45 hours per resident day for nurse aides." 89 Fed. Reg. at 40996.

240. Because the Final Rule's nationwide one-size-fits-all HPRD requirements contradicts Congress's intended flexibility for LTC facility nursing services, the Final Rule is not in accordance with law and must be set aside. *See* 5 U.S.C. § 706(2).

COUNT THREE

(APA – Arbitrary and Capricious Agency Action)

241. Plaintiffs re-allege and incorporate by reference the preceding allegations as though fully set forth herein.

242. Under the APA, a court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

243. The Final Rule is arbitrary and capricious in violation of the APA, 5 U.S.C. § 706(2)(A).

244. The APA's arbitrary-and-capricious standard requires agency action to be "reasonable and reasonably explained." *E.g.*, *Texas v. United States*, 40 F.4th 205, 226 (5th Cir. 2022) (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). This standard "is not toothless"; instead, "it has serious bite." *Id.*

245. The court "must set aside any action premised on reasoning that fails to account for relevant factors or evinces a clear error of judgment." *Id.* Failing to account for costs is failure to consider an important part of the problem. *Michigan v. EPA*, 576 U.S. 743, 752-53 (2015). ("Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions.")

246. And when an agency changes a longstanding policy, it must "show that there are good reasons for the new policy" and "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars,*

LLC v. Navarro, 579 U.S. 211, 221-22 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

247. By promulgating the Final Rule, CMS violated these requirements.

A. Sharp Departure from Past Practice

248. Over the past half century, CMS and its predecessors have consistently declined to deviate from the plain text of the Social Security Act by requiring nursing homes to provide "a specific ratio of nursing staff to patients." 39 Fed. Reg. at 2239 (In 1974, the Social Security Administration declined to adopt such a nationwide ratio requirement); *see also e.g.*, 45 Fed. Reg. at 47371 (In 1980, HHS expressly declined to propose "any nursing staff ratios or minimum number of nursing hours per patient per day.").

249. In 1986, an HHS-commissioned study concluded that "prescribing simple staffing ratios clearly is inappropriate."[3]

250. In 2002, the Secretary of HHS informed Congress that, after studying the issue for several years, it was not recommending the imposition of minimum-staffing ratios on LTC facilities.[4]

251. Most recently, in 2016, CMS again rejected requests to adopt minimum-staffing rules, reiterating that it is not reasonable to adopt "a 'one size fits all' approach" toward LTC facilities. 81 Fed. Reg. at 68755; *see id.* at 68754-56, 68758.

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[3] *See* Inst. of Med., *Improving the Quality of Care in Nursing Homes* 102-03 (Mar. 1986), https://archive.ph/KFNCi.

[4] Letter from Tommy G. Thompson, Sec'y of Health & Human Servs., to J. Dennis Hastert, Speaker of House of Representatives 1 (Mar. 19, 2002) ("Thompson Letter"), reprinted in *Office of Asst. Sec'y for Planning & Evaluation, Dep't of Health & Human Servs., State Experiences with Minimum Nursing Staff Ratios for Nursing Facilities: Findings from Case Studies of Eight States* app. 1 (Nov. 2003), https://archive.ph/wip/KQWPt.

252. With that longstanding position in view, CMS failed to provide a reasoned explanation for departing from it, especially when the study they utilized to justify the mandates did not provide sufficient evidence for it. This is arbitrary and capricious.

B. Failure to Consider Reliance Interests

253. In addition to failing to reasonably explain its sharp departure from prior practice, CMS also failed to consider reliance interests in its decision-making.

254. Longstanding policy has left decisions on staffing primarily up to the states. And States responded by crafting their own staffing requirements. Both States and LTCs have relied on this flexibility for decades.

255. State Medicaid rates for nursing home services vary from $170 per day to over $400 per day. AHCA Cmt.6. Some States have a relatively steady supply of RNs and NAs, while other States are facing a massive shortage. *See, e.g.*, 89 Fed. Reg. at 40957, 40976; 81 Fed. Reg. at 6755 (noting "geographic disparity in supply" of nursing staff).

256. Rather than "highlight[ing] the need for national minimum-staffing standards," the "widespread variability in existing minimum staffing standards" adopted by 38 States and the District of Columbia underscores that "different local circumstances . . . make different staffing levels appropriate (and higher levels impracticable) in different areas of the country." *Compare* 89 Fed. Reg. at 40880, *with* AHCA Cmt.6.

257. By imposing rigid nationwide requirements that "exceed the existing minimum staffing requirements in nearly all States," 89 Fed. Reg. at 40877, CMS not only ignored Congress but also state governments whose state-law minimum staffing requirements reflect local conditions.

258. Arkansas sets a general HPRD monthly standard lower than the Final Rule and does not establish specific quotas for RNs and NAs. See Ark. Code Ann. § 20-10-1402(a)(2) (requiring "direct care services by direct care staff equivalent to at least three and thirty-six hundredths (3.36) Average Direct Care Hours Per Resident Day").

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

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

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

262. South Carolina requires each nursing home to have one RN on call, but not on site, whenever residents are present in the facility. S.C. Code Ann. Regs. 61-17.

263. And South Carolina's HPRD requirement for FY 2024-2025 is less than half of that required by the Final Rule. S.C. Gen. Approp. Bill § 31.18 (requiring South Carolina nursing homes to provide "one and sixty-three hundredths (1.63) hours of direct care per resident per day from the non-licensed nursing staff" and requiring nursing homes to "maintain at least one licensed nurse per shift for each staff work area.") (https://tinyurl.com/3kjw4mtv).

264. West Virginia requires each nursing home in the State to have an RN on duty in the facility for at least eight consecutive hours, seven days a week. W. Va. Code R. § 64-13-8.14.4. If there is not an RN on duty, West Virginia law requires an RN to be on call. *Id.* § 64-13-8.14.5. West Virginia also requires nursing homes to provide at least "2.25 hours of nursing personnel time per resident per day." *Id.* § 64-13-8.14.1.

265. CMS concedes that its 24/7 RN requirement imposes a one-size-fits-all requirement, 89 Fed. Reg. at 40908. And CMS acknowledges that "more than 79 percent of nursing facilities nationwide" cannot meet the new requirements with their current staff, but its own findings belie the notion that anywhere close to 79 percent of U.S. nursing homes are failing to meet "minimum baseline standards for safety and quality." 89 Fed. Reg. at 40887.

266. Yet CMS's own survey process indicates that "roughly 95 percent of facilities" are already "providing 'sufficient nursing staff'" without the new requirements. AHCA Cmt.25.

267. CMS's explanation for abandoning its decades-old rejection of one-size-fits-all staffing requirements boils down to this: Some LTC facilities are chronically understaffed,

and "evidence demonstrates the benefits of increased nurse staffing in these facilities." 89 Fed. Reg. at 40881; *see id.* at 40893-94.

268. The general proposition that increased staffing in understaffed facilities can lead to better outcomes is not a reasonable consideration of the reliance interests of both states and LTCs who have had flexibility for decades. Such a failure is arbitrary and capricious.

C. Failure to Consider Important Aspects of the Problem

269. The Final Rule is arbitrary and capricious for another reason as well: It fails to consider important aspects of the problems, and it does so in two ways.

270. *First*, it fails to consider the possibility that it is virtually impossible for LTCs to comply with the Final Rule.

271. As detailed in various comments on the proposed rule, it will be nearly impossible for many LTC facilities to implement CMS's new minimum-staffing requirements because of the inadequate supply of RNs and NAs. *See* AHCA Cmt.1-2, 5, 11-13, 18; LeadingAge Cmt.1-2, 4; THCA Cmt.1-2.

272. Even CMS acknowledges the new requirements "exceed the existing minimum staffing requirements in nearly all States" and will require increased staffing "in more than 79 percent of nursing facilities nationwide." 89 Fed. Reg. at 40877.

273. And CMS estimates that LTC facilities will need to hire an additional 15,906 additional RNs to meet the 24/7 RN requirement and 0.55 RN HPRD requirement (an increase of about 11.8%), plus an additional 77,611 NAs to meet the 2.45 NA HPRD requirement and 3.48 total nurse HPRD requirement (an increase of about 17.2%). *See id.* at 40958, 40977-80.

274. Those increases are unattainable at a time when many LTC facilities are already experiencing extreme difficulty finding qualified RNs and NAs to fill vacant positions, and when staffing shortages are expected only to worsen. *See, e.g.*, AHCA Cmt.5; LeadingAge Cmt.1. Put simply, "staffing mandates do not create more caregivers, nor do they drive caregivers to work in long term care." AHCA Cmt.1.

275. The Final Rule also irrationally discounts the vital role of LPNs/LVNs, who hold nearly 230,000 jobs in LTC facilities across the country and undisputedly "provide important services to [their] residents." 89 Fed. Reg. at 40881; *see* AHCA Cmt.6; LeadingAge Cmt.2.

276. As commenters pointed out, the Final Rule creates an incentive for LTC facilities "to terminate LPN/LVNs and replace them with . . . [less qualified] nurse aides" in order to meet the 2.45 NA HPRD requirement.

277. CMS recognized this problem in both the proposed rule and the Final Rule, but concluded that "[a] total nurse staffing standard will guard[] against" it. 89 Fed. Reg. at 40893; *see* 88 Fed. Reg. at 61366, 61369.

278. But that's wrong. For example, a facility that already provides high-quality care through average staffing of 0.55 RN HPRD, 1.25 LVN/LPN HPRD, and 1.7 NA HPRD would satisfy the 3.48 total nurse HPRD requirement but would need an additional 0.75 NA HPRD to satisfy the 2.45 NA HPRD requirement.

279. The Final Rule thus pressures LTC facilities to replace experienced LPNs/LVNs with less-qualified new hires to meet CMS's arbitrary quota of 2.45 NA HPRD.

280. The Final Rule does not deny that there are not nearly enough RNs and NAs available to enable the 79 percent of LTC facilities that are not presently in compliance with the agency's new mandates.

281. CMS asserts that the Final Rule's phase-in period will "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. 40894.

282. But delaying the deadline for compliance does nothing to fix the underlying problems. Regardless of whether it goes into effect tomorrow or two or three years from now, the Final Rule is a multi-billion-dollar unfunded mandate that many LTC facilities will have no realistic way to meet. And there is no reason to think that the shortage of RNs and NAs will ease over the next two to three years.

283. In fact, it is projected to become even worse, as "hundreds of thousands are expected to retire or leave the health care profession entirely in the coming years." AHCA Cmt.5; *see id.* at 2 ("The phase-in provisions are frankly meaningless considering the growing caregiver shortage."); LeadingAge Cmt.7 (similar).

284. CMS says that it "fully expect[s] that LTC facilities will be able to meet [the Final Rule's] requirements," 89 Fed. Reg. at 40894, but it fails to cite any evidence to support this wishful thinking.

285. Moreover, the staggered implementation timeframe risks "pit[ting] urban and rural areas against each other as staff are first recruited away from rural areas to fulfill the needs of urban nursing homes, then 1-2 years later rural areas are scrapping to bring staff back." LeadingAge Cmt.7.

286. Finally, CMS's "hardship exemption" process is a wholly inadequate response to the staffing shortage and economic constraints facing LTC facilities.

287. For one thing, such exemptions are available only to facilities that have been surveyed and cited for failure to meet the new staffing standards—and "facilities cannot

request" (or receive) "a survey specifically for the purpose of granting an exemption." 89 Fed. Reg. at 40902.

288. Thus, instead of being able to proactively explain why it should be entitled to an exemption, facilities that cannot meet CMS's arbitrary requirements will face a perpetual risk of being sanctioned for non-compliance. *See* AHCA Cmt.6, 33-34; LeadingAge Cmt.6 (criticizing CMS's approach as "unnecessarily punitive").

289. In all events, the waivers are "no solution for the ongoing nationwide shortage in nursing staff" or the lack of funds available to implement the new requirements. AHCA Cmt.7.

290. CMS repeatedly emphasizes that the hardship exemption is meant for "limited circumstances," 89 Fed. Reg. at 40894, and that many facilities in areas of the country with severe shortages of available RNs and NAs would not qualify for an exemption because there are so many "other requirements" that must be met "to obtain an exemption." *Id.* at 40953.

291. *Second*, the Final Rule fails to reasonably consider the staggering costs, which underscores its arbitrary and capricious nature.

292. According to CMS, the Final Rule will cost over $5 billion per year to implement once fully phased in, *see* 89 Fed. Reg. at 40949, 40970. Other estimates place the costs as high as $7 billion per year, *see id.* at 40950.

293. The Final Rule does not provide any additional funding for Medicare or Medicaid, so CMS "assume[s] that LTC facilities . . . will bear the[se] costs." *Id.* at 40949.

294. And LTC facilities are in no position to take on this huge financial burden. AHCA Cmt.5; LeadingAge Cmt.1-2; THCA Cmt.3. Almost 60 percent of LTC facilities already have negative operating margins; more than 500 LTC facilities closed over the course of the

COVID-19 pandemic; and the costs associated with these new staffing mandates would likely force many more facilities to close. AHCA Cmt.5; *see* LeadingAge Cmt.1-2.

295. CMS's imposition of this massive, unfunded staffing mandate, despite the ongoing workforce crisis and economic realities, is neither "reasonable" nor "reasonably explained." *Cf. Texas*, 40 F.4th at 226.

296. It instead simply touts a new initiative that seeks to encourage people to pursue careers in nursing by "investing over $75 million in financial incentives such as tuition reimbursement." 89 Fed. Reg. 40894.

297. But this "one-time workforce effort" is "a drop in the bucket compared to the funding that will be needed to train [the] additional nursing staff" necessary to meet the new mandates. AHCA Cmt. 23; LeadingAge Cmt.1-2. It "is not going to fix the workforce crisis," and it does practically nothing to offset the $5 billion to $7 billion per year in costs that the Final Rule imposes on LTC facilities. AHCA Cmt.23; LeadingAge Cmt.1-2.

298. Additionally, LTC facilities are experiencing financial harms now. The Final Rule's EFA, implemented on August 8, 2024, requires providers to conduct a comprehensive evaluation of their facility, residents, staff, and resident families to determine staffing and other needs.

299. This assessment imposes a significant burden on LTC facilities. CMS estimates the cost of the EFA to be around $4,955 per facility, but that number is likely low.

300. The Final Rule also requires each facility to "review and update that assessment, as necessary, and at least annually." The facilities lack further guidance as to when such updates are "necessary," imposing a further burden of continuously updating a plan or being subject to potential civil penalties.

301. The EFA also requires facilities to create "contingency planning," even though the facilities already are required to have emergency plans for, among other things, staffing issues.

302. In total, the EFA imposes hours upon hours of additional work and significant administrative burdens on the facilities and subjects them to vague requirements that could result in steep civil penalties.

303. The Final Rule is arbitrary and capricious agency action and must be set aside.

PRAYER FOR RELIEF

1. Plaintiffs pray for the following relief from the Court:

2. A declaration, pursuant to 28 U.S.C. §2201, that the 24/7 RN requirement exceeds CMS's statutory authority and is arbitrary, capricious, or otherwise not in accordance with the law in violation of the APA.

3. A declaration, pursuant to 28 U.S.C. §2201, that the HPRD requirements exceed CMS's statutory authority and are arbitrary, capricious, or otherwise not in accordance with the law in violation of the APA.

4. A declaration, pursuant to 28 U.S.C. § 2201, that the enhanced facility assessment exceeds CMS's statutory authority and is arbitrary, capricious, or otherwise not in accordance with the law in violation of the APA.

5. An order vacating and setting aside the 24/7 RN requirement and permanently enjoining Defendants from taking any action to enforce that requirement.

6. An order vacating and setting aside the HPRD requirements and permanently enjoining Defendants from taking any action to enforce those requirements.

7. An order vacating and setting aside the enhanced facility assessment requirement and permanently enjoining Defendants from taking any action to enforce that requirement.

8. Any costs and reasonable attorneys' fees to which Plaintiffs may be entitled by law.

9. Any further relief that the Court deems just and proper.

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