

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

STATE OF TEXAS and §
LUBBOCK INDEPENDENT SCHOOL §
DISTRICT, §
Plaintiff, §

CIVIL ACTION No. 5:21-CV-300

v. §

XAVIER BECERRA, in his official §
capacity as Secretary of Health and §
Human Services, *et al.,* §
Defendants. §

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING
ORDER AND PRELIMINARY INJUNCTION

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INTRODUCTION

After months of choosing to “encourage” Head Start programs to ask staff, contractors, and volunteers to receive the COVID-19 vaccination, Defendants, at the direction of President Biden, moved the goalposts, and now conclude that nothing less than a 100% vaccination rate is acceptable. The decision to mandate vaccinations for every staff member, contractor, and volunteer in Head Start was uninformed, illogical, without statutory authority, and in violation of procedures established by law. Defendants also suddenly mandated that all individuals two years old and older be masked wherever Head Start services are provided. Congress never authorized Defendants to mandate vaccinations and masks for individuals who work at, volunteer at, or contract with Head Start programs (under the guise of merely “modifying program performance standards”).

In their rush to push out the Vaccine Mandate and the Mask Mandate—notwithstanding the lack of statutory authority to do so—Defendants failed to follow the statutorily mandated procedures for adopting such a rule—procedures that would have demonstrated the harm the Vaccine Mandate and the Mask Mandate will cause and are causing to Head Start Programs, the children who attend and their families, as well as the staff, contractors, and volunteers who work there.

Defendants’ decision to implement this Interim Final Rule,¹ effective immediately, was also arbitrary and capricious on numerous levels. Requiring mandatory vaccinations at this time, many months after COVID-19 vaccines were first available in Texas, would disrupt the status quo—which for the duration of the pandemic has been to encourage, but not compel, vaccinations (and

¹ 86 Fed. Reg. 68,052 (Nov. 30, 2021) (November 30, 2021) (entitled “Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs”) (adopting 26 C.F.R. §§ 1302.47(b)(5)(vi) (Mask Mandate); .93(a)(1), (2) (Vaccine Mandate for staff and contractors); .94(a) (Vaccine Mandate for volunteers) (attached as Exhibit 1).

routine testing) and masks. To radically alter the playing field now will have devastating effects on the State of Texas.

The implementation of Defendants' mandates will lead to an immediate reduction in the availability of Head Start services in Texas. Head Start programs are faced with the termination of staff, contractors, and volunteers—or having their funds cut off if they fail to submit. Injunctive relief is necessary to prevent these harms.

Defendants' mandates are unlawful, and Defendants should be enjoined from implementing them.

I. FACTUAL BACKGROUND

A. The Head Start program

Head Start is a federal grant program that provides funding to school districts, nonprofits, and other community educational providers. Head Start programs promote the school readiness of infants, toddlers, and preschool-aged children from low-income families.²

Head Start programs are available at no cost to children from low-income families from birth to age 5.³ Families and children experiencing homelessness, and children in the foster care system are also eligible.⁴ Preschool students whose attendance is funded via Head Start grant funding are often in preschool classrooms with other students whose attendance is funded by either state funds, district funds, or parent tuition.⁵ Overall, Head Start programs deliver services

² Head Start Programs, Office of Head Start (Nov. 3, 2020), <https://www.acf.hhs.gov/ohs/about/head-start>

³ *Id.*

⁴ *Id.*

⁵ See Exhibit 3 at ¶ 2 (Declaration of LISD Superintendent Dr. Kathy Rollo); see also Exhibit 9 at ¶ 4 (Declaration of LISD Coordinator of Early Childhood Education and Head Start Director Kathy Pearson).

through 1,600 agencies in local communities, and provide services to more than a million children every year, in every U.S. state and territory.⁶

The purpose of Head Start is to “promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development—(1) in a learning environment that supports children’s growth in language, literacy, mathematics, science, social and emotional functioning, creative arts, physical skills, and approaches to learning; and (2) through the provision to low-income children and their families of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary.”⁷

The Office of Head Start provides grants to Head Start agencies in Texas and throughout the country. Head Start programs are operated by several types of entities, including independent school districts. Staff employed by Head Start programs are not federal employees.

According to the United States Department of Health and Human Services’ Tracking Accountability in Government Grants System website, HHS awarded a total of \$842,280,184 in grants to Texas Head Start programs in fiscal year 2021.⁸

B. Reaction to COVID-19

As explained in the Office of Head Start’s May Guidance (Log No. ACF-PI-HS-21-04, Issuance Date: 05/20/2021),⁹ beginning in Spring 2020, the Office of Head Start allowed virtual and remote services for children as “an interim strategy in the presence of an emergency or disaster.”¹⁰ “Virtual” means “services for children provided through technology,” and “remote”

⁶ *Supra*, n.2.

⁷ 42 U.S.C. § 9831.

⁸ Exhibit 2.

⁹ Attached as Exhibit 5.

¹⁰ Exhibit 5 at 2.

means “services provided via the delivery of supports and resources, such as educational materials or food boxes.”¹¹ Nonetheless, “Almost one third of children served in Head Start programs before the pandemic — approximately 250,000 — have not received any services to date.”¹²

The May Guidance announced that it was time for Head Start to return to in-person services.¹³ Virtual and remote services were no longer approved beginning in January 2022.¹⁴

Importantly, the May Guidance did not require that staff, contractors, or volunteers returning to in-person services be vaccinated, and did not even mention masks, let alone a mandate to wear them.

C. The Head Start Interim Final Rule, the Vaccine Mandate, and the Mask Mandate

1. Defendants’ unreasonable, rushed timeline

On September 9, 2021, President Biden unveiled his “new plan to require more Americans to be vaccinated” by imposing “new vaccination requirements.”¹⁵ One of his announced mandates would “require all of nearly 300,000 educators in the federal paid program, Head Start program,” to get vaccinated.¹⁶

¹¹ *Id.* at 1.

¹² *Id.* at 3.

¹³ *Id.* at 1 (“The Office of Head Start has supported the implementation of virtual and remote services over the past 13 months. However, they are not an acceptable replacement for in-person comprehensive services.”).

¹⁴ Exhibit 5 at 2 (“Programs should build toward full enrollment and provide comprehensive services for all enrolled children as soon as possible,” and that the OHS “Beginning January 2022, [OHS] will reinstate pre-pandemic practices for tracking and monitoring enrollment.”).

¹⁵ Joseph Biden, Remarks by President Biden on Fighting the Covid-19 Pandemic (Sept. 9, 2021), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/>.

¹⁶ *Id.*; see also Covid-19 and the Head Start Community, <https://eclkc.ohs.acf.hhs.gov/about-us/coronavirus/vaccination-head-start-staff> (last visited Dec. 5, 2021).

On November 11, 2021—only 19 days before the Interim Final Rule—Stephanie Shine, the Executive Director of Texas Tech University’s Center for Early Head Start, emailed Jennifer Cobbs, an employee of the Administration for Children and Families, seeking guidance for the announced vaccine mandate.¹⁷ Cobbs wrote back the next day, stating that no guidance had yet been issued, but “Please remember that ultimately the Interim Final Rule (IFR) *is what you are expected to follow once published.*”¹⁸ Shine emailed back, asking for more explicit guidance, and noting, “We are in a tight timeframe to terminate and hire staff given the holidays.” Cobbs responded:

I understand and appreciate your diligence in seeking clarification as many other programs have raised similar questions and concerns. However at this time, I must reiterate; if staff refuse to receive a COVID- 19 vaccination and or If [sic] staff do not get fully vaccinated by January 2022, they can no longer be employed with the Head Start program. Staff must be fully vaccinated by January 2022 to remain employed with the Head Start program.

She also wrote:

[T]he vaccination requirement will be reviewed during OHS monitoring aa [sic] OHS will be making adjusts to its monitoring protocol to include staff vaccinations requirements as part of a review of personnel records. I hope this helps to ensure your program develops polices that align to the federal mandate around vaccination requirement for 2022.¹⁹

On November 29, 2021—one day before the Interim Final Rule—Defendants sent a Power Point to Head Start programs throughout the nation announcing that an Interim Final Rule would be issued on November 30.²⁰ According to Defendants’ Power Point, “[The Interim Final Rule] is the implementation of the Biden Administration’s COVID-19 action plan announcement on

¹⁷ Exhibit 4.

¹⁸ *Id.* (emphasis in original).

¹⁹ *Id.*

²⁰ Exhibit 6 at 3.

September 9, *Path out of the Pandemic*.”²¹ The Power Point described the Vaccine Mandate and the Mask Mandate.²² It noted that the Mask Mandate is effective immediately upon the publication of the Interim Final Rule.²³ Defendants’ Power Point also noted, “The compliance date for the vaccination requirement is January 31, 2022. This means staff, certain contractors and volunteers must have their second dose in a two-dose series, or first dose in a single-dose by January 31, 2022.”²⁴

2. The Interim Final Rule’s actual requirements

On November 30, 2021, Defendants, at the direction of President Biden, issued the Interim Final Rule with its Vaccine Mandate and Mask Mandate.²⁵

Vaccine Mandate for staff and Contractors. The Interim Final Rule adds paragraphs (a)(1) and (2) to 45 C.F.R. § 1302.93:

- (1) All staff, and those contractors whose activities involve contact with or providing direct services to children and families, must be fully vaccinated for COVID-19, other than those employees:
 - (i) For whom a vaccine is medically contraindicated;
 - (ii) For whom medical necessity requires a delay in vaccination; or
 - (iii) Who are legally entitled to an accommodation with regard to the COVID-19 vaccination requirements based on an applicable Federal law.
- (2) Those granted an accommodation outlined in paragraph (a)(1) of this section must undergo SARS-COV-2 testing for current infection at least weekly with those who have negative test results to remain in the classroom or working directly with children. Those with positive test results must be immediately

²¹ *Id.* at 2.

²² *Id.* at 4–15.

²³ *Id.* at 7.

²⁴ *Id.* at 14.

²⁵ 86 Fed. Reg. 68,052 (November 30, 2021).

excluded from the facility, so they are away from children and staff until they are determined to no longer be infectious.

86 Fed. Reg. at 68,101.

The new paragraphs require staff and contractors to be vaccinated, and to get tested weekly if granted an accommodation against being vaccinated. No such requirement existed in the prior version.

Vaccine Mandate for Volunteers. The Interim Final Rule revises paragraph (a) of 45 C.F.R. § 1302.94 to read as follows:

- (a) A program must ensure volunteers have been screened for appropriate communicable diseases in accordance with state, tribal or local laws. In the absence of state, tribal, or local law, the Health Services Advisory Committee must be consulted regarding the need for such screenings.
 - (1) All volunteers in classrooms or working directly with children other than their own must be fully vaccinated for COVID-19, other than those volunteers:
 - (i) For whom a vaccine is medically contraindicated;
 - (ii) For whom medical necessity requires a delay in vaccination; or
 - (iii) Who are legally entitled to an accommodation with regard to the COVID-19 vaccination requirements based on an applicable Federal law.
 - (2) Those granted an accommodation outlined in paragraph (a)(1) of this section must undergo SARS-CoV-2 testing for current infection at least weekly with those who have negative test results to remain in the classroom or work directly with children. Those with positive test results must be immediately excluded from the facility, so they are away from children and staff until they are determined to no longer be infectious.

86 Fed. Reg. at 68,101.

The new paragraphs require volunteers to be vaccinated, and to get tested weekly if granted an accommodation against being vaccinated. No such requirement existed in the prior version.

Despite Defendants' assertions to the contrary, the Vaccine Mandate, as currently written in the Code of Federal Regulations, (1) applies immediately, (2) requires staff, contractors, and volunteers to immediately be "fully vaccinated," and (3) does not provide a January 31, 2022 deadline.²⁶ And to the extent the Interim Final Rule's preamble addresses (1) through (3), even to the extent that a compliance period is provided, a preamble is not an enforceable agency explanation and "is inherently suspect in light of the [Defendants'] failure to offer interested parties notice or opportunity for comment . . . without providing a reasoned explanation." *Wyeth v. Levine*, 555 U.S. 555, 577 (2009).

Defendants can choose to enforce the mandates at any time. Moreover, Defendants acknowledge that "fully vaccinated" means "2 weeks after [a] second dose in a 2-dose series" and "2 weeks after a single-dose vaccine."²⁷

In practice, this means that a staff person who takes the two-dose series cannot be "fully vaccinated" by the announced date of January 31 unless the staff person receives the second shot by January 16, 2022, which means that the first shot must be received three weeks earlier, by **December 27, 2022**, for the Pfizer shot, and four weeks earlier, by **December 20, 2022**, for the Moderna shot.²⁸

²⁶ 26 C.F.R. §§ 1302.93(a)(1) (staff and contractors); 1302.94(a)(1) (volunteers). The Interim Final Rule does mention a January 31, 2022 deadline in reference to receiving a "final dose of a primary vaccination" as "me[eting] the vaccination requirement." But this "flexibility" "applies only to the initial implementation of this [Interim Final Rule] and has no bearing on ongoing compliance." 86 Fed. Reg. at 68,062. Despite this "flexibility" in the Interim Final Rule preamble, the actual, enforceable regulations have no such provisions.

²⁷ Exhibit 2 at 14.

²⁸ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/second-shot.html>.

This results in an unreasonably short timeline for a person to fully contemplate a major medical decision. And the unreasonable timeline is even more apparent considering the medical treatment must be weighed against potential job loss, and potentially loss of a career, if the medical mandate is not complied with.

Mask Mandate. The Interim Final Rule adds paragraph (b)(5)(vi) to 45 C.F.R. § 1302.47(b)(5):

- (vi) Masking, using masks recommended by CDC, for all individuals 2 years of age or older when there are two or more individuals in a vehicle owned, leased, or arranged by the Head Start program; indoors in a setting when Head Start services are provided; and for those not fully vaccinated, outdoors in crowded settings or during activities that involve sustained close contact with other people, except:
 - (A) Children or adults when they are either eating or drinking;
 - (B) Children when they are napping;
 - (C) When a person cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with Disabilities Act; or
 - (D) When a child's health care provider advises an alternative face covering to accommodate the child's special health care needs.

86 Fed. Reg. at 68,101.

The new paragraph requires masking. No such requirement existed in the prior version.

Defendants' November 29, 2021 Power Point also states, "[The Office of Head Start] will monitor this requirement [the Vaccine Mandate and the Mask Mandate] in the same way it monitors other health and safety requirements including in the Head Start Program Performance

Standards. Programs need to have a way to document vaccination status and those records need to be available for the purpose of monitoring.”²⁹

3. The Interim Final Rule’s harmful consequences

The Vaccine Mandate forces local Head Start programs, including the programs operated by Texas Tech University and the Lubbock Independent School District (“LISD”), to choose between ignoring the Mandate and risking the cancellation of grant funding,³⁰ cancelling the program and depriving children of Head Start services, or forcing their staff, contractors, and volunteers to comply with an illegal federal mandate that violates their constitutional rights, while dealing with the inevitable fallout from the resulting resignations that will damage the program. Defendants’ Power Point acknowledges, “Staff vaccination requirements may result in the loss of some staff because they will not get the COVID-19 vaccine.... Programs are encouraged to assess staff vaccination levels and to plan for vacancies as soon as possible to allow recruitment for needed staff.”³¹

The Mask Mandate likewise forces Head Start programs to make similar choices. And it also forces Americans with children in Head Start to choose between complying with the illegal mandate and allowing staff to force their children to wear masks, or withdrawing their children

²⁹ Exhibit 6 at 20.

³⁰ Head Start does cancel grants for failure to comply with Head Start rules. *See, e.g.,* Michelle Manzione, Tom Roussey, Brad Bell, *\$6.3 million grant terminated for Head Start program in PG County for reported misconduct*, ABC 7 News, Aug. 17, 2016 <https://wjla.com/amp/news/local/grant-terminated-for-pg-countys-head-start-program-after-failure-to-correct-deficiencies>; Topher Sanders, Urban League officially terminated from running Head Start program, Florida Times-Union, Aug. 21, 2013 <https://amp.jacksonville.com/amp/15818972007>. Of note, funding can be cut off without notice “if there is an emergency situation, such as a serious risk [of] harm to staff or participants’ health and safety.” 45 C.F.R. § 1304.4(a).

³¹ Exhibit 6 at 32.

from the program. Defendants' Power Point also acknowledges, "Staff vaccination requirements may result in the loss of some staff because they will not get the COVID-19 vaccine.... Programs are encouraged to assess staff vaccination levels and to plan for vacancies as soon as possible to allow recruitment for needed staff."³²

D. Plaintiffs' lawsuit

On December 10, 2021, Plaintiffs filed this lawsuit. Plaintiffs now seek an immediate temporary restraining order against enforcement of the Interim Final Rule and a hearing on their motion for a preliminary injunction.

II. ARGUMENT

A plaintiff seeking a temporary restraining order or preliminary injunction must establish (1) "that he is likely to succeed on the merits," (2) "that he is likely to suffer irreparable harm in the absence of preliminary relief," (3) "that the balance of equities tips in his favor," and (4) "that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The first two factors, the likelihood of success on the merits and a showing of irreparable injury absent a stay, are the most critical. *E.T. v. Paxton*, No. 21-51083, 2021 WL 5629045, at *2 (5th Cir. Dec. 1, 2021).

The standards for securing a temporary restraining order or preliminary injunction are substantively the same. *Whole Woman's Health v. Paxton*, 264 F. Supp. 3d 813, 818 (W.D. Tex. 2017). To preserve the status quo, federal courts have regularly enjoined federal agencies from implementing and enforcing new regulations pending litigation challenging them. *See, e.g., Texas v. United States*, 787 F.3d 733 (5th Cir. 2015) (enjoining executive order inconsistent with

³² *Id.*

immigration statutes). Here, Plaintiffs the State of Texas and LISD satisfy each of the requirements for the issuance of a temporary restraining order and preliminary injunction.

Plaintiffs request that the Court issue a temporary restraining order that remains in effect until the Court can rule on Plaintiffs' motion for preliminary injunction. *See Forman v. Dallas Cnty., Tex.*, 193 F.3d 314, 323 (5th Cir. 1999) (explaining that “[a] temporary restraining order is a ‘stay put,’ equitable remedy that has as its essential purpose the preservation of the status quo while the merits of the case are explored through litigation.”).

A. Plaintiffs are likely to succeed on the merits of their claims.

“[O]ur system does not permit agencies to act unlawfully even in pursuit of desirable ends.” *Ala. Ass’n of Realtors v. Dep’t of Health & Human Servs.*, 141 S. Ct. 2485, 2490 (2021). The Interim Final Rule violates multiple provisions of the Administrative Procedure Act, the Head Start Act, and other federal statutes that unambiguously delineate Defendants’ rulemaking authority and the procedural requirements that govern that rulemaking. Texas is likely to succeed on the merits of its claims because the Interim Final Rule (1) exceeds Defendants’ statutory authority; (2) is arbitrary and capricious; (3) was adopted without compliance with procedures required by law; and (4) violates the Constitution.

Parts A.1 through A.10, below, are copied from Parts B through H, paragraphs 90 through 222, of the Argument section of Plaintiffs’ Complaint, with headings and subheadings appropriately renumbered.

1. The Interim Final Rule lacks statutory authority.

The Interim Final Rule was issued by the Office of Head Start, the Administration for Children and Families, and HHS. 86 Fed. Reg. at 68,052. The Office of Head Start is within the Office of Early Child Development, which is in the Administration for Children and Families,

which is in HHS. Those entities are federal agencies, or parts of federal agencies, subject to the requirements of the Administrative Procedure Act.

Under the APA, courts must “hold unlawful and set aside agency action” that is “not in accordance with law” or “in excess of statutory . . . authority[] or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

a. Congress did not authorize Defendants to mandate vaccinations or masks.

An agency may implement a rule only when Congress authorizes it to do so. “[A]n agency literally has no power to act ... unless and until Congress confers power upon it.” *La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986). Agency actions that do not fall within the scope of a statutory delegation of authority are *ultra vires* and must be invalidated.

Defendants cite 42 U.S.C. § 9836a(a)(1)(C), (D), and (E) as their authority for issuing the vaccine and mask mandate. 86 Fed. Reg. at 68,053. Those subsections provide: “The Secretary shall modify, as necessary, *program performance standards* by regulation applicable to Head Start agencies and programs under this subchapter, including (C) administrative and financial management standards; (D) standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate) ... [and] (E) such other standards as the Secretary finds to be appropriate [emphasis added].”

Section 9836a authorizes the Secretary to regulate “program performance standards,” it does not authorize defendants to mandate an invasive, permanent medical treatment for or mask mandates for Head Start program children, staff, contractors, and volunteers. Notably, it does not mention vaccinations or masking requirements at all.

b. Defendants do not have limitless authority to regulate health and safety within Head Start programs.

The Interim Final Rule’s “purpose ... is to protect the health and safety of Head Start staff, children, and families and to mitigate the spread of [COVID-19] in Head Start programs.” 86 Fed. Reg. at 68,053. Defendants assert that they have authority to mandate COVID-19 vaccination of staff, contractors, and volunteers because of the purported “statutory authority to protect the health and safety of Head Start participants and their families and ensure the continuation of services.” 86 Fed. Reg. at 68,063.

Defendants’ assertion that their authority to set appropriate health and safety standards for the conditions of Head Start facilities grants them unfettered authority to generally regulate the “health and safety” of staff, contractors, volunteers, and students is unfounded. 86 Fed. Reg. at 68,054.

“The Secretary’s administrative authority is undoubtedly broad. But it is not boundless.” *Merck & Co. v. United States Dep’t of Health & Hum. Servs.*, 962 F.3d 531, 537–38 (D.C. Cir. 2020) (citations omitted) (discussing authority of CMS, a division of HHS).

Defendants’ assertion of authority to issue a vaccine mandate under vague statutory language generally referencing health and safety creates a “serious danger,” if allowed to stand, that Defendants will “choose to broadly exert power in a variety of contexts.” *Cf. Am. Health Care Ass’n v. Burwell*, 217 F. Supp. 3d 921, 934–35 (N.D. Miss. 2016) (discussing an assertion of authority by CMS).

Permitting Defendants to exercise such boundless authority would render the separation-of-powers principles set forth in the United States Constitution meaningless.

Just this year, the Supreme Court rejected the assertion by a federal agency of such broad authority based on vague statutory language. The authority granted an agency by statute is not based on vague language in isolation but is informed by the context in which that language appears. *See Alabama Ass'n of Realtors*, 141 S. Ct. at 2488 (“The Government contends that the first sentence of § 361(a) gives the CDC broad authority to take whatever measures it deems necessary to control the spread of COVID-19, including issuing the moratorium. But the second sentence informs the grant of authority by illustrating the kinds of measures that could be necessary: inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles. These measures directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself.... Reading both sentences together, rather than the first in isolation, it is a stretch to maintain that § 361(a) gives the CDC the authority to impose this eviction moratorium.”).

Section 9836a authorizes Defendants to implement performance standards, but that authority is circumscribed by the statute’s context.

“Performance standards” is not defined in § 9836a. But “performance standards” is a plain and unambiguous term so the ordinary definition applies. *Carcieri v. Salazar*, 555 U.S. 379, 387 (2009) (“This case requires us to apply settled principles of statutory construction under which we must first determine whether the statutory text is plain and unambiguous. If it is, we must apply the according to its terms.”) (cleaned up).

Ordinarily, a “performance standard” is a threshold criterion to measure quality or acceptability of a required or contractual action.³³

Here, the Head Start program performance standards are standards to measure a program’s quality and conditions in terms of administration, facilities, and education. *See* 42 U.S.C. § 9836a (discussing performance standards concerning “service provided,” “education performance standards,” “administrative and financial management standards,” and “standards relating to the condition and location of facilities”).

Further, this understanding of the term “performance standards” is supported by the purpose of the Improving Head Start for School Readiness Act of 2007 (Pub. L. 110–134). The Act is intended to improve the current Head Start program by: (1) increasing competition among Head Start providers; (2) improving the coordination of early childhood delivery systems; (3) requiring stronger educational and performance standards for Head Start teachers and staff; and (4) requiring financial accountability to ensure that all funds are being used properly to serve the educational needs of the children. 2007 U.S.C.C.A.N. S17, 2007 WL 4984163 (Leg. Hist.).

³³ *See* STANDARD, Black’s Law Dictionary (11th ed. 2019) (“2. A criterion for measuring acceptability, quality, or accuracy <the attorney was making a nice living — even by New York standards>. — standard, *adj.*”); PERFORMANCE, Black’s Law Dictionary (11th ed. 2019) (“performance *n.* (16c) 1. The successful completion of a contractual duty”); *see also* Developing Performance Standards (opm.gov) <https://www.opm.gov/policy-data-oversight/performance-management/performance-management-cycle/planning/developing-performance-standards/> (“A performance standard is a management-approved expression of the performance threshold(s), requirement(s), or expectation(s) that must be met to be appraised at a particular level of performance.”); *see, e.g., Salmon v. Soc. Sec. Admin.*, 663 F.3d 1378, 1383 (Fed. Cir. 2011) (“Performance standard means the management-approved expression of the performance threshold(s), requirement(s), or expectation(s) that must be met to be appraised at a particular level of performance[.]”); *Wilson v. Dep’t of Health & Hum. Servs.*, 770 F.2d 1048, 1053 (Fed. Cir. 1985) (“A performance standard for this critical element defines minimally acceptable performance for this activity[.]”).

Defendants' authority is circumscribed by the context of the statute. "Performance standards" is not a term that authorizes unlimited wishes of Defendants. "Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). These subsections relate to "program performance standards." Although Defendants attempt to cram an elephant in a mousehole with this rule, authority to implement program performance standards does not extend to mandating an invasive medical procedure or mask mandates.

Compare if the CDC—which (unlike Defendants) has authority to "make and enforce such regulations ... necessary to prevent the introduction, transmission, or spread of communicable diseases," *Alabama Ass'n of Realtors*, 141 S. Ct. at 2487 (quoting 42 U.S.C. § 264(a))—cannot issue an eviction moratorium to control the spread of communicable diseases, *id.* at 2489, then Defendants, lacking similar authority, cannot regulate the medical treatment of staff or other individuals by mandating vaccinations.

Defendants' read of 42 U.S.C. § 9836a and vague reference in the Interim Final Rule to health and safety, "would give [Defendants] a breathtaking amount of authority." *Id.* at 2489. "It is hard to see what measures this interpretation would place outside [Defendants'] reach, and the Government has identified no limit in [this authority] beyond the requirement that [Defendants'] deem a measure 'necessary.'" *Id.* at 2489.

Defendants' assertion of such expansive authority under 42 U.S.C. § 9836a and vague reference in the Interim Final Rule to "health and safety," is unprecedented, "not in accordance

with the law,” “in excess of [its] statutory ... authority,” “in excess of statutory ... limitations,” and “short of [its] statutory right.” 5 U.S.C. § 706(2)(A), (C).

c. Defendants do not explain how the Vaccine Mandate and the Mask Mandate are authorized by section 9836a.

The 49-page Interim Final Rule does not explain or even mention how the amendments to 45 C.F.R. §§ 1302.047 (Mask Mandate), .093 (Vaccine Mandate for staff), or .094 (Vaccine Mandate for volunteers) might be justified as a program performance standard of any kind, let alone a program performance standard that is also an administrative standard, a financial management standard, or a standard relating to the location of facilities. And the amendments are not in fact any of those types of standards.

The Interim Final Rule contains one sentence which is seemingly intended to explain how the amendments to 45 C.F.R. §§ 1302.047, .093, and .094 announced in the Interim Final Rule are a “standard relating to the condition ... of facilities”: “The Secretary finds it necessary and appropriate to set health and safety standards for the condition of Head Start facilities that ensure the reduction in transmission of the SARS-CoV-2 and to avoid severe illness, hospitalization, and death among program participants.” 86 Fed. Reg. at 68,054. But by its terms, this sentence refers to “health and safety standards,” not to a “standard relating to the condition ... of facilities.” Moreover, health and safety requirements for employees, volunteers, and children simply are not standards about the condition of facilities. They are standards about the condition of people.

Thus, the amendments to 45 C.F.R. §§ 1302.047, .093, and .094 announced in the Interim Final Rule are not administrative standards, financial management standards, or standards relating to the condition or location of facilities—and Defendants do not even claim that they are. Thus, they are not in fact justified under 42 U.S.C. § 9836a(a)(1)(C) or (D).

The Interim Final Rule also does not explain or even mention how the amendments to 45 C.F.R. §§ 1302.047, .093, or .094 might be justified as an “other standard[] as the Secretary finds to be appropriate” under subsection (a)(1)(E). Subsection (a)(1)(E) cannot justify the Interim Final Rule—or anything else—because it violates the non-delegation doctrine. “The nondelegation doctrine bars Congress from transferring its legislative power to another branch of Government.” *Gundy v. United States*, 139 S. Ct. 2116, 2121 (2019). “[A] nondelegation inquiry always begins (and often almost ends) with statutory interpretation. The constitutional question is whether Congress has supplied an intelligible principle to guide the delegee’s use of discretion.” *Id.* at 2123. Subsection (a)(1)(E) does not contain such an intelligible principle. “Appropriate” is not an intelligible principle. Therefore, subsection (a)(1)(E) is unconstitutional and cannot justify the Interim Final Rule.

If Defendants’ logic is that the Vaccine Mandate and the Mask Mandate can be implemented because the Secretary can implement “other standards as the Secretary finds to be appropriate” under subsection (a)(1)(E), then the same logic would support the implementation of any “performance standard” Defendants might wish to impose on Head Start staff and children, such as mandating flu vaccines or weekly RSV testing. This would be limitless, unguided authority in violation of the non-delegation doctrine.

In addition to specifically citing 42 U.S.C. § 9836a(a)(1)(C), (D), and (E), Defendants also claim, “There are two primary reasons that [the Administration for Children and Families] decided to mandate vaccination and mask use.” 86 Fed. Reg. at 68,066. The first asserted “primary reason” will be discussed in the next section. The second asserted “primary reason” for the vaccine and mask mandate is:

Second, as discussed in this [Interim Final Rule], being fully vaccinated for COVID-19 and using a mask are two of the most effective mitigation strategies available to reduce transmission of COVID-19 [citing Centers for Disease Control and Prevention, “Science Brief: COVID-19 Vaccines and Vaccination,” September 15, 2021]. With this in mind, [the Administration for Children and Families] determined a federal requirement is necessary. While some agencies and localities have implemented vaccine and masking requirements, many have not. Additionally, vaccine uptake among Head Start staff has not been as robust as hoped for and has been insufficient to protect the health and safety of children and families receiving Head Start services. Combined, these factors leave certain children and families with fewer mitigation strategies in place to protect them than others. It is ACF’s responsibility to make sure the environment is as safe as possible for Head Start programs uniformly across all 1,600 grant recipients.

86 Fed. Reg. at 68,066.

This second “primary reason” is nothing but a naked assertion that something needs to be done, without any effort to justify the mandate with any statutory authority.

Although it does not say so, perhaps this second “primary reason” is supposed to be justified by subsection (a)(1)(E) (“such other standards as the Secretary finds to be appropriate”). If so, then it cannot stand because subsection (a)(1)(E) violates the non-delegation doctrine.

d. Congress did not authorize the scope of authority claimed by Defendants.

A vaccine mandate is distinct from requiring performance standards. It is a mandate that staff, volunteers, and contractors submit to a specific medical treatment. Likewise, weekly COVID-19 testing and mask mandates are distinct from performance standards. These requirements are not a measure of educational quality, or even of the quality of facilities from a health and safety standpoint. Further, although Defendants can implement performance standards concerning the condition of Head Start facilities, conditions of *facilities* are separate and distinct from conditions of *individuals*. Likewise, it boggles the mind to comprehend how a performance standard for an individual—a measure of meeting minimum thresholds of a required action, such

as an employee duty in an employment contract—can stretch to include minimum medical treatment requirements.

As stated above, the purpose of the Improving Head Start for School Readiness Act is to (1) increase competition among Head Start providers; (2) improve the coordination of early childhood delivery systems; (3) require stronger educational and performance standards for Head Start teachers and staff; and (4) require financial accountability to ensure that all funds are being used properly to serve the educational needs of the children.³⁴

This is reiterated in the purpose statement of the Act:

It is the purpose of this subchapter to promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development--

- (1) in a learning environment that supports children's growth in language, literacy, mathematics, science, social and emotional functioning, creative arts, physical skills, and approaches to learning; and
- (2) through the provision to low-income children and their families of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary.

42 U.S.C. § 9831.

Nowhere in the Act are Defendants authorized to mandate an invasive, permanent medical treatment for staff or any individuals or mandate mask-wearing and weekly COVID-19 testing. These are all medical mandates, not performance standards.

The authority Defendants rely on to implement the Interim Final Rule does not grant Defendants the authority sought to exercise via the Vaccine Mandate and the Mask Mandate.

“[T]he sheer scope of [Defendants] claimed authority ... would counsel against” Defendants’ broad view of their own authority. *Ala. Ass’n of Realtors*, 141 S. Ct. at 2489. The

³⁴ 2007 U.S.C.C.A.N. S17, 2007 WL 4984163 (Leg. Hist.).

Supreme Court “expect[s] Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance.” *Id.* (quotation marks omitted) (quoting *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014)). “That is exactly the kind of power that [Defendants] claim[] here.” *Id.*

Defendants assert that under the Head Start Vaccine Mandate, they “anticipate that the requirement that all Head Start staff get fully vaccinated for COVID-19 will induce a substantial portion of unvaccinated staff to get fully vaccinated.” 86 Fed. Reg. at 68,064. Defendants also “estimate that the regulation will induce a similar number, but smaller share, of unvaccinated Head Start volunteers to get fully vaccinated. *Id.*

Defendants estimate that over 820,000 staff, over 637,000 volunteers, and almost 2.6 million children will fall under the mandate. 86 Fed. Reg. at 68,077, 68,094.

Defendants estimate that the costs associated with the Head Start Vaccine Mandates will be up to \$71.42 million in turnover costs alone. *Id.* at 68,092. This does not include any costs training new volunteers, finding new contractors, or opening a new program because another shut down due to the mandate.

If Defendants can mandate medical treatment for 1.45 million individuals, 86 Fed. Reg. at 68,094, not including contractors, it “would give [Defendants] a breathtaking amount of authority,” and “[i]t is hard to see what measures this interpretation would place outside [Defendants’] reach.” *Ala. Ass’n of Realtors*, 141 S. Ct. at 2489.

Defendants’ authority does not extend to exercising powers of vast economic and political significance without limit as it attempts with the Head Start Vaccine Mandate.

“Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.” *Whitman*, 531 U.S. at 468.

* * *

There is no valid statutory authority for the Interim Final Rule. Defendants are not authorized to mandate vaccinations for its staff and volunteers or the wearing of masks for its staff and volunteers or the children and family members while they are at Head Start facilities.

The Court should set aside the Interim Final Rule. “The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be . . . not in accordance with law [or] in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

2. The Interim Final Rule is not simply an extension of preexisting regulations.

The first asserted “primary reason” for the Interim Final Rule is:

First, Head Start programs have a broad set of program performance standards that already include requirements for infection control, exclusion policies, cleaning, sanitizing and disinfecting. The requirement for staying home when sick is part of § 1302.47(b)(4)(i)(A); hand hygiene (handwashing) is included at § 1302.47(b)(6)(i); cleaning, sanitizing, and disinfecting is at § 1302.47(b)(2)(i); and physical distancing is part of § 1302.47(b)(4)(i)(A), which [the Office of Head Start] sees as a strategy for a program’s infection control practices) [sic]. In addition, § 1302.47(b)(1)(iii) states that facilities need to be ‘free from pollutants, hazards and toxins that are accessible to children and could endanger children’s safety,’ though it is difficult be [sic] overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.

86 Fed. Reg. at 68,066 (unmatched right parenthesis in original).

In other words, Defendants are asserting that rules in place before the Interim Final Rule “already include” various requirements, and those various requirements themselves justify the Vaccine Mandate and the Mask Mandate. This assertion would be more appropriate for an

interpretive rule, or an informal interpretation of Defendants' own regulations, neither of which must be formally promulgated. But the Interim Final Rule is neither, so this assertion is pointless.

Moreover, Defendants' characterizations of the rules relied upon in the first "primary reason" do not match the text of those rules.

45 C.F.R. § 1302.47(b)(4)(i)(A) states: "All staff with regular child contact have initial orientation training within three months of hire and ongoing training in all state, local, tribal, federal and program-developed health, safety and child care requirements to ensure the safety of children in their care; including, at a minimum, and as appropriate based on staff roles and ages of children they work with, training in [t]he prevention and control of infectious diseases." Contrary to Defendants' assertion, this provision does not include "[t]he requirement for staying home when sick" or "physical distancing." This is a staff training regulation.

45 C.F.R. § 1302.47(b)(6)(i) specifies: "All staff systematically and routinely implement hygiene practices that at a minimum ensure [a]ppropriate toileting, hand washing, and diapering procedures are followed." Contrary to Defendants' assertion, this is not a general "hand hygiene (handwashing)" requirement, but instead refers to cleaning up after urination and defecation.

45 C.F.R. § 1302.47(b)(2)(i) reads: "Indoor and outdoor play equipment, cribs, cots, feeding chairs, strollers, and other equipment used in the care of enrolled children, and as applicable, other equipment and materials meet standards set by the Consumer Product Safety Commission (CPSC) or the American Society for Testing and Materials, International (ASTM). All equipment and materials must at a minimum [b]e clean and safe for children's use and are appropriately disinfected." Contrary to Defendants' assertion, this provision is not a general

“cleaning, sanitizing, and disinfecting” requirement, but only requires that equipment be kept clean.

45 C.F.R. § 1302.47(b)(1)(iii) reads: “All facilities where children are served, including areas for learning, playing, sleeping, toileting, and eating are, at a minimum [f]ree from pollutants, hazards and toxins that are accessible to children and could endanger children’s safety.” Defendants comment, “it is difficult be [sic] overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.” 86 Fed. Reg. at 68,066. This comment shows that Defendants understand this requirement to concern “ventilation.” If Defendants are trying to justify the Vaccine and Mask Mandates on a theory that ventilation at Head Start facilities is somehow inadequate, that will not work. This rule requires that ventilation be adequate. It does not allow Head Start facilities to replace inadequate ventilation with vaccine and mask requirements. Thus, contrary to Defendants’ assertion, this rule cannot support the Vaccine and Mask Mandates.

In sum, Defendants’ assertion that “Head Start programs [already] have a broad set of program performance standards that already include requirements for infection control, exclusion policies, cleaning, sanitizing and disinfecting” is such an exaggeration of its legal authority that it is simply false.

Similarly, Defendants also claim, “The Head Start Program Performance Standards require children to be up to date on immunizations and their state’s Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) schedule (45 CFR 1302.42(b)(1)(i)). When children are behind on immunizations or other care, Head Start programs are required to ensure they get on a

schedule to catch up.” 86 Fed. Reg. at 68,059. This is false. 45 C.F.R. § 1302.42(b)(1)(i) actually states:

- (1) Within 90 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, with the exceptions noted in paragraph (b)(3) of this section, a program must:
 - (i) Obtain determinations from health care and oral health care professionals as to whether or not the child is up-to-date on a schedule of age appropriate preventive and primary medical and oral health care, based on: The well-child visits and dental periodicity schedules as prescribed by the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program of the Medicaid agency of the state in which they operate, immunization recommendations issued by the Centers for Disease Control and Prevention, and any additional recommendations from the local Health Services Advisory Committee that are based on prevalent community health problems;
 - (ii) Assist parents with making arrangements to bring the child up-to-date as quickly as possible; and, if necessary, directly facilitate provision of health services to bring the child up-to-date with parent consent as described in § 1302.41(b)(1).

Thus, Head Start programs are required to find out if children are up to date on “immunization recommendations issued by the Centers for Disease Control” and must “assist parents with making arrangements to bring the child up-to-date as quickly as possible,” *but only with parental consent*. This rule does not justify requiring children to wear masks without parental consent.

Moreover, even if existing regulations really did already require that children be up to date on vaccinations, that would neither justify the Vaccine Mandate for staff, and nor would it justify the Mask Mandate for children, especially for children under five who are too young to be

vaccinated. At a minimum, vaccine and masking requirements for state-run programs are part and parcel with states' authority,³⁵ not the federal government.

Defendants build on this false claim by further claiming, "It is equally important [as the false requirement that children to be up to date on immunizations] that the Head Start program itself is safe for all children, families, and staff. For this reason, the Head Start Program Performance Standards specify that the program must ensure staff do not pose a significant risk of communicable disease (45 CFR 1302.93(a))." In fact, that rule reads,

A program must ensure each staff member has an initial health examination and a periodic re-examination as recommended by their health care provider in accordance with state, tribal, or local requirements, that include screeners or tests for communicable diseases, as appropriate. The program must ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program that cannot be eliminated or reduced by reasonable accommodation, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

The rule thus refers to staff that already have a communicable disease that constitutes a disability, not to staff that might temporarily be infected by an airborne virus at some unspecified time in the future. This rule does not allow Head Start to require that its employees get vaccinated. It does not justify the Vaccine Mandate.

42 U.S.C. § 9842(a)-(b) reads:

Each recipient of financial assistance under this subchapter shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such financial assistance, the total cost of the project or undertaking in connection with which such financial assistance is given or used, the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an

³⁵ Defendants' own regulations acknowledge this. *See, e.g.*, 45 C.F.R. § 1302.42(b)(1)(i) (referring to the "Medicaid agency of the state in which they operate" and "the local Health Services Advisory Committee").

effective audit. The Secretary ... shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the financial assistance received under this subchapter.

Defendants cites to this as a basis for requiring that head start recipients collect and store records relating to the vaccination status of staff and volunteers. However, as seen by the statute's context, these provisions only authorize Defendants to collect information pertinent to auditing the amount and disposition of the financial assistance received by a recipient. This does not authorize the collection of medical records and documentation relating to the vaccination status of staff and volunteers. Whether staff are vaccinated or not is irrelevant to the amount and disposition of financial assistance proceeds received by a recipient.

In short, the Interim Final Rule cannot be justified as merely an extension of already existing regulations. And extending already existing regulations is not authority for a new regulation.

3. The Interim Final Rule is arbitrary and capricious.

“Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Defendants did not engage in reasoned decision-making, but instead acted arbitrarily and capriciously, in issuing the Interim Final Rule.

Defendants acted arbitrarily and capriciously by enforcing a vaccine mandate against Head Start staff, while there is no such mandate for staff in K through 12 schools. That decision makes no sense.

Defendants acted arbitrarily and capriciously by enforcing a vaccine mandate against Head Start staff, while the federal government does not enforce the vaccine mandate against federal employees.

Defendants acted arbitrarily and capriciously by ignoring or arbitrarily rejecting the adverse effects resulting from resignations of unvaccinated Head Start workers who do not want to be vaccinated, and the withdrawal of children from families who do not want to wear masks.

Defendants acted arbitrarily and capriciously by ignoring or arbitrarily rejecting the interests of Head Start workers who—for any number of varying personal reasons—do not want to take one of the currently authorized COVID-19 vaccines.

Defendants acted arbitrarily and capriciously by refusing to provide a testing option for Head Start employees who decline to take one of the available COVID-19 vaccines. Defendants know that OSHA provided this option in its recently struck down vaccine mandate for employers, but nonsensically assert:

Whereas OSHA allows employers to offer an option for testing and face coverings, this [Interim Final Rule] does not permit a testing and face coverings option for individuals without an approved vaccine exemption. The rationale for the difference is that [the Administration for Children and Families] is acting under statutory and regulatory standards that are different from OSHA's. In general, the Head Start Act requires standards for a safe environment for staff, children, and other participants.

86 Fed. Reg. at 68,061. The second sentence proves too much. Of course, they are different. But Defendants do not explain why the differences justify differing rules. The third sentence falsely

suggests that Defendants have the general power to do anything they want in the name of “safe environments,” while simultaneously falsely suggesting that OSHA has no authority over safe environments for workers.

Defendants acted arbitrarily and capriciously by refusing to provide an exemption to persons with natural immunity to COVID-19 because natural immunity is at least as effective as vaccination in preventing re-infection, transmission, and severe health outcomes.

Defendants acted arbitrarily and capriciously by basing its decision to issue the Interim Final Rule under a pretextual justification. *See Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019) (setting aside agency action as arbitrary and when “the evidence tells a story that does not match the explanation the Secretary gave for his decision” and “unlike a typical case in which an agency may have both stated and unstated reasons for a decision, here the [] rationale—the sole stated reason—seems to have been contrived.”). The true purpose of the vaccine and mask mandate was a political decision and an attempt to federalize public-health issues involving vaccination that belong within the States’ police power. According to Defendants,

The Secretary consulted with experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA. The Secretary considered the Office of Head Start’s past experience with the longstanding health and safety Head Start Program Performance Standards that have sought to protect Head Start staff and participants from communicable and contagious diseases. The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures. The Secretary finds it necessary and appropriate to set health and safety standards for the condition of Head Start facilities that ensure the reduction in transmission of the SARS-CoV-2 and to avoid severe illness, hospitalization, and death among program participants.

86 Fed. Reg. at 68,054. All these supposed reasons are pretextual. The real reason for the Interim Final Rule is because President Biden ordered it. “After the President voiced his displeasure with the country’s vaccination ate in September, the Administration pored over the U.S. Code in search of authority, or a ‘work-around,’ for imposing a national vaccine mandate.” *BST Holdings, L.L.C. v. Occupational Safety & Health Admin., United States Dep’t of Labor*, 17 F.4th 604, 612 (5th Cir. 2021).

Defendants acted arbitrarily and capriciously because their finding that the vaccine mandate is necessary was undermined by its delay in adopting it. Vaccines have been authorized for almost a year, yet Defendants did not impose this mandate until two months after it was instructed to do so by the President as part of his “six-point plan” to federalize public-health policy.

The Interim Final Rule is arbitrary and capricious because it mandates that if COVID-19 exists in *some* communities, then *all* communities where Head Start operates must continue universal masking. Staff, volunteers, and students are required to wear masks even if there are no COVID-19 cases in their community. Some Texas counties, such as McMullen, Kenedy, Sterling, and Borden, have not had a reported COVID-19 case in weeks or months.³⁶ The CDC considers these counties a “low” risk of community transmission of COVID-19.³⁷ The CDC only recommends that “unvaccinated people” in these counties “should wear a mask in public, indoor settings.”³⁸ The one-size-fits all interim rule requires staff, volunteers, and students to continue

³⁶ <https://covid.cdc.gov/covid-data-tracker/#county-view> (last accessed Dec. 8, 2021).

³⁷ *Id.*

³⁸ *Id.*; *but, see* <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html> (last visited on Dec. 8, 2021) (CDC recommending universal masking in k-12 schools regardless of vaccination status).

masking regardless of the recommendations by local health officials, and likely long after COVID-19 is no longer present in their communities. There is no end date or criteria for ending the universal mask mandate. So, as long as COVID-19 exists somewhere in the US, everyone in Head Start, regardless of where they are located, their vaccination status, and the conditions on the ground, must continue universal masking.

The Interim Final Rule is arbitrary and capricious because Defendants do not know how many staff and volunteers are already vaccinated. This cannot be overstated.

Defendants rely on a survey of 1,456 Head Start staff (out of the estimated 820,000 staff and volunteers impacted by the rule), and which included none of the one million volunteers, that was conducted between May and June 2021, and found that 73% of head start staff were vaccinated.³⁹ The study did not specify whether the respondents were fully or partially vaccinated. Critically, the study concluded that “Overall vaccine uptake among US child care providers [] was significantly higher than that of the US general adult population (65%) at the time of the survey.... Of those reporting having not yet received the COVID-19 vaccine, another 11.9% stated that they were ‘absolutely certain’ (5.0%) or ‘very likely’ (6.9%) to get vaccinated in the future, **suggesting that the final vaccine uptake among child care providers may settle around 90%.**”⁴⁰ The study assumed this vaccination rate would be achieved voluntarily, without a vaccine mandate. Defendants ignored the study’s conclusion and *chose to assume* that all of the Head Start respondents in the study were only partially, and not fully, vaccinated. Defendants admit that they

³⁹ Kavin M. Patel, M.D., et. al., *COVID-19 Vaccine Uptake Among US Child Care Providers*, *Pediatrics*, Nov. 1, 2021, <https://publications.aap.org/pediatrics/article/148/5/e2021053813/181547/COVID-19-Vaccine-Uptake-Among-US-Child-Care>.

⁴⁰ *Id.* (emphasis added).

have no other data to rely on in determining how many staff and volunteers are currently vaccinated. Similarly, they have no goal to achieve a sufficient number of vaccinations to protect the health and safety of staff and students, short of 100%. Yet, they cite to no data showing that a vaccination rate of 90%—or 80% or—70%—is not sufficient to protect the health and safety of the staff and students.

Instead, Defendants extrapolated the number from the study, which showed that Head Start staff were 12% more likely to get vaccinated than the general public. At the time the rule was published, 83.5% of adults were partially vaccinated, and 71.6% of adults were fully vaccinated.⁴¹ If Head Start staff are 12% more likely to get vaccinated, then seemingly when the rule was published, approximately 93.7% of Head Start staff are partially vaccinated and 80.2% are fully vaccinated. Defendants cite to no data showing that this is not a sufficiently high enough vaccination rate to protect students and staff. Instead, Defendants abruptly switch the modeling criteria by factoring in the percentage of adults likely to get vaccinated, whereupon they concluded that 77.9% of Head Start staff are currently vaccinated and this number will only rise to 79.8% by March 1, 2022, without regulatory action. There is no scientific basis for this conclusion.

Defendants are not tracking, and do not actually know, what the vaccination rate among Head Start staff and volunteers. Their reliance on a single survey of 1,456 staff from June 2021 is wholly insufficient to support a sweeping Vaccine Mandate. Even when relying on the survey, Defendants ignored the study's conclusions that 90% of child care workers would voluntarily get vaccinated; instead, coming up with a wholly speculative and pretextual model to achieve their

⁴¹ https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-pop18 (last visited Dec. 8, 2021).

desired outcome. Therefore, the rule is arbitrary and capricious because it is not rationally related to the evidence relied upon.

The Interim Final Rule is arbitrary and capricious because Defendants failed to consider conflicting evidence on masking children under 5 years of age. The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) specifically advise that "Children aged 5 years and under should not be required to wear masks. This is based on the safety and overall interest of the child and the capacity to appropriately use a mask with minimal assistance."⁴² Defendants wholly failed to consider contrary evidence, instead solely relying on the CDC's recommendations.

Defendants acted arbitrarily and capriciously by requiring that children ages two years old and older wear masks outdoors. Defendants failed to consider that outdoor transmissions are exceedingly rare.⁴³ Many experts believe that outdoor masking is misguided.⁴⁴ When masks are required in outdoor settings, kids may experience limitations in play, exercise tolerance, and socialization. In Spain, children six years of age and older are required to wear a mask at school. A recent study of students in the Catalonia region found that transmission rates were lower among unmasked three to five-year-olds compared to masked children over six.⁴⁵

⁴² <https://www.who.int/news-room/questions-and-answers/item/q-a-children-and-masks-related-to-covid-19> (last visited Dec. 8, 2021).

⁴³ Tim O'Donnell, *Is the CDC exaggerating the risk of outdoor COVID-19 transmission?*, Yahoo News, May 11, 2021, https://www.yahoo.com/entertainment/cdc-exaggerating-risk-outdoor-covid-135958591.html?soc_src=social-sh&soc_trk=ma.

⁴⁴ Vinay Prasad, M.D., M.P.H., *The Downsides of Masking Young Students Are Real*, the Atlantic, Sept. 2, 2021, <https://www.theatlantic.com/ideas/archive/2021/09/school-mask-mandates-downside/619952/>.

⁴⁵ Alonso, Sergio PhD, et. al., *Age-dependency of the Propagation Rate of Coronavirus Disease 2019 Inside School Bubble Groups in Catalonia, Spain*, The Pediatric Infectious Disease Journal, Nov. 2021,

Defendants cite *no scientific evidence* that children under five are better protected by masking. The data it relies on all involved adults and older children.

The Interim Final Rule is arbitrary and capricious because it failed to consider evidence that doesn't support masking children between the ages of two and five, and it is arbitrary and capricious because it is not rationally related to the evidence relied upon that involved adults and older children.

Defendants also acted arbitrarily and capriciously by repeatedly relying on CDC guidelines to justify the Interim Final Rule⁴⁶ because CDC Guidelines are merely nonbinding recommendations and have never otherwise been imposed on Head Start programs.

The Mask Mandate is arbitrary and capricious because Defendants entirely failed to consider an important aspect of the problem—namely, that many Head Start participants go to school with children who are not in Head Start. Defendants acknowledge that the majority of its participants are from poor families and are disproportionately members of minority communities. 86 Fed. Reg. at 68,055–56. The Mask Mandate essentially means the “poor kids” in Head Start are stigmatized by having to wear masks, while others in school do not, creating the perception that the Head Start kids are dirty or contagious, and could subject them to playground taunts, ridicule, and isolation, and severely impact their self-esteem. The Mask Mandate is arbitrary and capricious because it failed to consider these psychosocial and developmental impacts.

The Mask Mandate is arbitrary and capricious because Defendants entirely failed to consider an important aspect of the problem—namely, the effectiveness of masking in preventing

https://journals.lww.com/pidj/Fulltext/2021/11000/Age_dependency_of_the_Propagation_Rate_of.2.aspx.

⁴⁶ See, e.g., 86 Fed. Reg. at 68,054 at n.28, 30; 68,059 at n.78; 68,060 at n.81.

the spread of COVID-19 when mixing masked and unmasked children. In Texas, students who are not in Head Start are not required to wear a mask. Defendants failed to consider whether masking is an effective method of preventing the spread of COVID-19 when masked students are mixed unmasked students.

Defendants acted arbitrarily and capriciously by justifying the Mask Mandate with a study that does not justify the Mask Mandate. According to the Interim Final Rule, a “study found that implementing and monitoring adherence to recommended mitigation strategies, such as mask use, can reduce risk for SARS-COV-2 transmission in Head Start settings. It also showed that Head Start and Early Head Start programs that successfully implemented CDC-recommended guidance for childcare programs were able to continue offering safe in-person learning.” 86 Fed. Reg. at 68,056. But the study says:

Multiple strategies were implemented simultaneously, including training teachers and encouraging caretakers to adhere to SOPs and mitigation strategies; instituting flexible medical leave policies for staff members; providing and requiring use of masks for all staff members and children; and supervising handwashing and hand-sanitizing for children (Box). **Variations regarding methods for screening the health of staff members and children were noted**; among these methods, self-administered temperature checks upon arrival were most frequently reported for staff members. **Screening for signs and symptoms of illness upon arrival was most frequently reported for children. Mask policies for children varied**, and exemptions for children aged <2 years and those with special health care and education needs were allowed. All programs reported increased cleaning and disinfecting or sanitizing of high-traffic areas, high-touch surfaces, and toys. Five programs reported increasing cleaning and disinfecting of bedding and improving ventilation. **Guidance from public health or education agencies and state or local mandates were the factors most commonly reported to influence decisions about SOP adjustments....** The findings in this report are subject to at least two limitations ... study outcomes could not be attributed to implemented mitigation strategies.⁴⁷

⁴⁷ Coronado F, Blough S, Bergeron D, et al., *Implementing Mitigation Strategies in Early Care and Education Settings for Prevention of SARS-CoV-2 Transmission — Eight States, September–October 2020*, MMWR Morb Mortal Wkly Rep, Dec. 11, 2020, DOI: <http://dx.doi.org/10.15585/mmwr.mm6949e3> (emphasis added).

This study fails to show that mask use “can reduce risk for [COVID-19] transmission in Head Start settings because “[m]ask policies for children varied.” The most common strategy was screening for signs of illness, not mask use. Yet the Interim Final Rule does not allow screening for signs of illness as an alternative to masking.

Defendants acted arbitrarily and capriciously by justifying the Mask Mandate with another study that does not justify the Mask Mandate. According to the Interim Final Rule, “[C]ounties without school mask requirements experienced larger increases in pediatric COVID-19 case rates after the start of school compared to counties that had school mask requirements.” 86 Fed. Reg. at 86,056. It cites a study⁴⁸ which said, “The findings in this report are subject to at least four limitations. First, this was an ecologic study, and causation cannot be inferred. Second, pediatric COVID-19 case counts and rates included all cases in children and adolescents aged <18 years; later analyses will focus on cases in school-age children and adolescents. Third, county-level teacher vaccination rate and school testing data were not controlled for in the analyses; later analyses will control for these covariates. Finally, because of the small sample size of counties selected for the analysis, the findings might not be generalizable.” 86 Fed. Reg. at 68,056 n.49. This study does not support the Mask Mandate.

Even if Defendants were authorized by statute or prior rules to promulgate the Interim Final Rule, which they are not, the Court would still have to set it aside for being arbitrary and capricious. “The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious [or] an abuse of discretion.” 5 U.S.C. § 706(2)(A).

⁴⁸ Budzyn SE, Panaggio MJ, Parks SE, et al., *Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements — United States, July 1–September 4, 2021*, MMWR Morb Mortal Wkly Rep 2021, Oct. 1, 2021, DOI: <http://dx.doi.org/10.15585/mmwr.mm7039e3>.

4. The Interim Final Rule was adopted in violation of the notice-and-comment requirement.

Defendants must comply with the notice-and-comment requirements of 5 U.S.C. § 553 before promulgating a rule. Subject to certain statutory exceptions not implicated here, a “[g]eneral notice of proposed rulemaking shall be published in the Federal Register.” 5 U.S.C. § 553(b). “After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.” 5 U.S.C. § 553(c). “The required publication or service of a substantive rule shall be made not less than 30 days before its effective date [with inapplicable exceptions].” 5 U.S.C. § 553(d).

Notice-and-comment procedures do not apply “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(3)(B).

The “good cause” exception should be read narrowly and “should not be used to circumvent the notice and comment requirements whenever an agency finds it inconvenient to comply.” *U.S. Steel Corp. v. U.S. E.P.A.*, 595 F.2d 207, 214 (5th Cir. 1979). Likewise, the “public interest” prong only met in “rare circumstances.” *Mack Trucks, Inc. v. E.P.A.*, 682 F.3d 87, 89 (D.C. Cir. 2012).

Defendants acknowledge that the Interim Final Rule is subject to notice-and-comment requirements, but assert that

a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to children from unvaccinated staff, continuing strain on the health care system, and known efficacy and safety of available vaccines, have persuaded us

that a vaccine requirement for Head Start staff, certain contractors, and volunteers is an essential component of the nation's COVID-19 response. Further, it would endanger the health and safety of staff, children and families, and be contrary to the public interest to delay imposing the vaccine mandate. Therefore, we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment procedures and to thereby delay the effective date of this [Interim Final Rule]. We find good cause to waive notice of proposed rulemaking under the APA.

86 Fed. Reg. at 68,059.

Defendants cannot show that notice and comment are impracticable and contrary to the public interest when it waited 82 days from the announcement of the rule on September 9, 2021, until publishing the rule on November 30, 2021. Defendants waited longer to publish the rule without comment than if it had simply noticed the rule and allowed comment.

The vaccines have been available for nearly a year, yet until this point, Defendants have sought only to “encourage” vaccination, presumably accepting that not all healthcare workers would choose to be vaccinated. And even when President Biden announced in September that Defendants needed a vaccine mandate, Defendants still waited more than sixty days before taking this emergency action. “Good cause cannot arise as a result of the agency’s own delay, because otherwise, an agency unwilling to provide notice or an opportunity to comment could simply wait . . . raise up the ‘good cause’ banner and promulgate rules without following APA procedures.” *Nat. Res. Def. Council v. NHTSA*, 894 F.3d 95, 114-15 (2d Cir. 2018). As the Fifth Circuit recently observed with respect to OSHA’s two-month delay in issuing its vaccine mandate, “The President announced his intention to impose a national vaccine mandate on September 9, 2021. OSHA issued the Mandate nearly two months later, on November 5, 2021, and the Mandate itself prominently features yet another two-month delay. One could query how an ‘emergency’ could prompt such a ‘deliberate’ response. *BST Holdings*, 17 F.4th at 612 n.11 (citation omitted).

Although delay is not conclusive, an agency's failure to act promptly is "evidence that a situation is not a true emergency." *Asbestos Info. Ass'n/N. Am. v. Occupational Safety & Health Admin.*, 727 F.2d 415, 423 (5th Cir. 1984).

In addition, the notice-and-comment procedures of the Administrative Procedure Act are designed to assure due deliberation. *Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 741 (1996). By alleging that notice and comment are "impracticable and contrary to the public interest," Defendants essentially say that, as of November 30, 2021, there is no need for further deliberation. Defendants would have us believe that the science became settled on that date. Millions of Americans and many Head Start programs believe otherwise, as evidenced by the over 1,000 comments that Defendants have already received (but not made available to the public for viewing). The "impracticable and contrary to the public interest" exceptions to notice-and-comment requirements do not apply to this case.

If Defendants had the authority to order Head Start staff to get certain medical care, which they do not, natural immunity is one obvious example of an issue that could have benefitted from deliberation. Defendants have not addressed—much less reasonably explained—why natural immunity should not be considered an adequate alternative to vaccination. Nor would it be possible to reasonably explain away this omission; by all indications, natural immunity confers superior resistance to COVID-19 than any of the currently available vaccines, and one in three Americans had COVID by the end of 2020.⁴⁹

⁴⁹ See, e.g., Meredith Wadman, *Having SARS-CoV-2 once confers much greater immunity than a vaccine—but vaccination remains vital: Israelis who had an infection were more protected against the Delta coronavirus variant than those who had an already highly effective COVID-19 vaccine*, Science, Aug. 26, 2021, <https://www.science.org/content/article/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-vaccination-remains-vital>; One in Three Americans Already Had

Similarly, if Defendants really had the authority they claim, another obvious issue that should be deliberated is testing and other best practices apart from vaccinations. Defendants have not addressed—much less reasonably explained—why other best practices in fighting the spread of COVID-19 could not be used in lieu of vaccination mandates. Nor would it be possible to reasonably explain away this omission; for example, testing has the advantage of providing relative certainty that an individual in the workplace is not infected with COVID-19, whereas vaccination does not provide that guarantee.

Because Defendants did not consider these and other issues, Defendants' error in failing to comply with notice-and-comment was not harmless. “[W]hen a party’s claims were considered, even if notice was inadequate, the challenging party may not have been prejudiced.” *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011). The flipside is that when claims are not considered, as in this case, prejudice is assumed. “absence of prejudice “must be clear” before applying harmless error. *Id.* at 933.

Defendants accept comments until December 30, 2021. 86 Fed. Reg. at 68,052. But “[n]or does accepting post-promulgation comments excuse compliance with APA procedures. We have previously found that parties will have a greater opportunity for influencing agency decision making if they participate at an early stage, when the agency is more likely to give real consideration to alternative ideas. If we allowed post-promulgation comments to suffice in this case, we would make the provisions of § 553 virtually unenforceable.” *Johnson*, 632 F.3d at 929 (citations omitted).

COVID-19 by the End of 2020, (Aug. 26, 2021), <https://www.publichealth.columbia.edu/public-health-now/news/one-three-americans-already-had-covid-19-end-2020>.

The importance of deliberation is evidenced by the number comments submitted in response to this rule. Currently, in just the week since the rule posted, there are over 1,200 public comments. A critical aspect of rulemaking is both the public and the agency being able to review the public comments submitted about the rule and its impact.

At the time of filing, these public comments are not available for the public to view. The reason they are not publicly available is because Head Start has not released them to the Federal Register to publish. This is highly unusual. Typically, public comments are immediately available to view online on the Federal Register website. Perhaps Defendants are deliberately being secretive, or perhaps they are merely taking their time in posting the comments. In either case, the public comments are critical to the court and public in assessing the Interim Final Rule and its impact. Head Start has received 1,578 comments to date. The number and rate of public comments demonstrates the level of public interest and illustrates the importance of going through the notice and comment period before enacting rules.

Defendants did not, and could not, demonstrate “good cause” to justify its failure to comply with its notice-and-comment obligations under the APA.

For all these reasons, Defendants’ promulgation of the Head Start Vaccine Mandate violated APA procedural requirements, and the Head Start Vaccine Mandate should be held unlawful and set aside.

Even if Defendants were authorized by statute or prior rules to make the Interim Final Rule, which they are not, the Court would still have to set it aside for failure to comply with notice-and-comment requirements in 5 U.S.C. § 553 without good cause. “The reviewing court shall hold

unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law.” 5 U.S.C. § 706(2)(D).

5. The Interim Final Rule is a major rule that was adopted in violation of the Congressional Review Act.

“Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing (i) a copy of the rule; (ii) a concise general statement relating to the rule, including whether it is a major rule; and (iii) the proposed effective date of the rule.” 5 U.S.C. § 801(a)(1).

A “major rule” cannot take effect until at least 60 days after Congress receives the report. 5 U.S.C. § 801(a)(3). A “major rule” is a “rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in an annual effect on the economy of \$100,000,000 or more.” 5 U.S.C. § 804(2).

Defendants acknowledge that “[t]he Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this action is a major rule because it will have an annual effect on the economy of \$100 million or more.” 86 Fed. Reg. at 68,063.

But “[n]otwithstanding section 801[,] any rule which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.” 5 U.S.C. § 808(2).

Defendants assert that they found

good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 552(d), 553(b)(B). For those same reasons [as found to exempt the Interim Final Rule from notice-and-comment under the APA], . . . we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this [Interim

Final Rule] under the [Congressional Review Act]. Therefore, we find there is good cause to waive the [Congressional Review Act's] delay in effective date pursuant to 5 U.S.C. § 808(2).

86 Fed. Reg. at 68,059.

For the same reasons that good cause does not exist to exempt the Interim Final Rule from notice-and-comment requirements in the APA, good cause does not exist for Defendants to evoke 5 U.S.C. § 808(2).

For the same reasons that skipping notice-and-comment rulemaking was not harmless error, skipping Congressional review was also not harmless error.

Even if Defendants were authorized by statute or prior rules to make the Interim Final Rule, which they are not, the Court would still have to set it aside for failure to comply with the Congressional Review Act. “The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law.” 5 U.S.C. § 706(2)(D).

6. The Interim Final Rule was adopted in violation of 42 U.S.C. § 9836a(a)(2).

According to the Interim Final Rule, the vaccine mandate and the mask mandate are “program performance standards” under 42 U.S.C. § 9836a(a)(1). As explained above, they are not. But even if they were, 42 U.S.C. § 9836a(a)(2)(A) requires that, in developing program performance standards, the Secretary “shall consult with experts in the fields of child development, early childhood education, child health care, family services (including linguistically and culturally appropriate services to non-English speaking children and their families), administration, and financial management, and with persons with experience in the operation of Head Start programs.”

According to the Interim Final Rule, Defendants did not do that. Instead, “[t]he Secretary consulted with experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA.” 86 Fed. Reg. at 68,054.

Moreover, there is no way to evaluate Defendants’ consultations because the agency did not say with whom they met, when they met, for how long, or what they discussed.

In addition, 42 U.S.C. § 9836a(a)(2)(B) requires the Secretary to take into consideration ten factors in developing program performance standards. According to the Interim Final Rule,

[t]he Secretary considered the Office of Head Start’s past experience with the longstanding health and safety Head Start Program Performance Standards that have sought to protect Head Start staff and participants from communicable and contagious diseases. The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures.

Id. None of these factors that Defendants say they considered are factors that they must consider under § 9836a(a)(2)(B).

For instance, § 9836a(a)(2)(B)(vi) requires Defendants to consider “guidelines and standards that promote child health services and physical development, including participation in outdoor activity that supports children’s motor development and overall health and nutrition.” The Interim Final Rule states, “The Office of Head Start notes that being outdoors with children inherently includes sustained close contact for the purposes of caring for and supervising children.” 86 Fed. Reg. at 68,060. Thus, children “participat[ing] in outdoor activity that supports children’s motor development” will be required to wear masks. Yet the Interim Final Rule does

not discuss how or whether wearing masks during “caring for and supervising children” will affect the beneficial aspects of such activity, in violation of § 9836a(2)(B)(vi).

Subsection (a)(2)(C)(2) requires Defendants to “ensure that [the] revisions in the [program performance] standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services required to be provided under such standards as in effect on December 12, 2007.” No such analysis appears in the Interim Final Rule.

Subsection (a)(2)(D) requires Defendants to “consult with Indian tribes, including Alaska Natives, experts in Indian, including Alaska Native, early childhood education and development, linguists, and the National Indian Head Start Directors Association on the review and promulgation of [program performance] standards.” The Interim Final Rule contains a “Tribal Consultation Statement” which states,

[The Administration for Children and Families] conducts an average of five tribal consultations each year for tribes operating Head Start and Early Head Start. The consultations are held in four geographic areas across the country: Southwest, Northwest, Midwest (Northern and Southern), and East. The consultations are often held in conjunction with other tribal meetings or conferences, to ensure the opportunity for most of the 150 tribes that operate Head Start and Early Head Start programs to attend and voice their concerns regarding service delivery. We complete a report after each consultation, and then we compile a final report that summarizes the consultations. We submit the report to the Secretary of Health and Human Services (the Secretary) at the end of the year. We invite public comment on this [Interim Final Rule] if there are concerns specific to Native communities and programs.

86 Fed. Reg. at 68,052. In other words, Defendants state only that they meet with Indians once a year. But § 9836a(a)(2)(D) requires consultation with Indians *before* issuing program performance standards, which the Interim Final Rule supposedly contains. It is not enough that Defendants have annual meetings with Indians. Defendants violated 42 U.S.C. § 9836a(a)(2)(D).

Defendants' multiple violations of § 9836a(a)(2) require the Interim Final Rule to be set aside. "The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

7. The Interim Final Rule was adopted in violation of the Treasury and General Government Appropriations Act of 1999.

Defendants admit that Section 654 of the Treasury and General Government Appropriations Act of 1999 (codified at 5 U.S.C. § 601 note) requires them to determine whether a policy or regulation may negatively affect family well-being. 86 Fed. Reg. at 68,062.

But they summarily dismiss the need for an impact assessment, reasoning "it is not necessary to prepare a family policymaking assessment ... because [the rule] will not have any impact on the autonomy or integrity of the family as an institution." *Id.*

First, the impact analysis is mandatory. Public Law 105-277, 5 U.S.C. § 601 note ("Before implementing policies and regulations that may affect family well-being, each agency *shall* assess such actions[.]") (emphasis added). Congress specifically required Defendants to include an impact analysis to assess any impact on family well-being. *Id.* Following Defendants' logic used in this Interim Final Rule, Defendants could subjectively determine that the analysis is not required as they see fit to conveniently circumvent the requirement. This directly undermines the statute and renders the impact analysis requirement moot.

Second, an impact analysis has specific requirements that agencies must meet. For example, the impact analysis

must assess such actions with respect to whether—(1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment;(2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the

action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

5 U.S.C. § 601 note. In addition to the other requirements concerning the impact analysis, Defendants wholly and completely ignored this requirement.⁵⁰

Third, Defendants limit the meaning of “family well-being” in contradiction to the actual text. Assessment of “family well-being” is not defined as an assessment of the impact “on autonomy or integrity of the family as an institution.” Instead, it is an assessment of “family well-being” and requires Defendants to assess the statutorily require factors.

Defendants failed to comply with this procedural requirement. Under the APA, a court must “hold unlawful and set aside agency action” that is found to be “not in accordance with law” or “without observance of procedure required by law.” 5 U.S.C. § 706(2)(A), (D).

⁵⁰ See also 5 U.S.C. § 601 note (“(d) Governmentwide family policy coordination and review.--(1) Certification and rationale.--With respect to each proposed policy or regulation that may affect family well-being, the head of each agency shall--(A) submit a written certification to the Director of the Office of Management and Budget and to Congress that such policy or regulation has been assessed in accordance with this section [this note]; and (B) provide an adequate rationale for implementation of each policy or regulation that may negatively affect family well-being. (2) Office of Management and Budget.--The Director of the Office of Management and Budget shall--(A) ensure that policies and regulations proposed by agencies are implemented consistent with this section; and (B) compile, index, and submit annually to the Congress the written certifications received pursuant to paragraph (1)(A). (3) Office of Policy Development.--The Office of Policy Development shall--(A) assess proposed policies and regulations in accordance with this section [this note]; (B) provide evaluations of policies and regulations that may affect family well-being to the Director of the Office of Management and Budget; and (C) advise the President on policy and regulatory actions that may be taken to strengthen the institutions of marriage and family in the United States.”).

8. The Interim Final Rule is an unconstitutional exercise of the Spending Power.

If 42 U.S.C. § 9836a(a)(1) authorized Defendants to enforce the Vaccine Mandate and the Mask Mandate, which it does not, then it would be an unconstitutional condition on the receipt of federal funds.

“[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously,” so “States [can] exercise their choice knowingly.” *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). The executive branch cannot impose conditions on spending that the Constitution would prohibit it from imposing directly, because that authority belongs to Congress. *See id.* at 17. Only *Congress* can condition the receipt of federal funds.

42 U.S.C. § 9836a(a)(1) does not authorize, let alone unambiguously impose, the Vaccine Mandate or the Mask Mandate. There is no nexus between grants to Head Start and vaccine and mask requirements. *South Dakota v. Dole*, 483 U.S. 203 (1987). Thus, the Vaccine Mandate and the Mask Mandate are not authorized under the Spending Clause.

9. The Interim Final Rule violates the Anti-Commandeering Doctrine.

“[T]he Federal Government may not compel the States to implement, by legislation or executive action, federal regulatory programs.” *Printz v. United States*, 521 U.S. 898, 925 (1997).

Even if the Vaccine Mandate and the Mask Mandate were valid, which they are not, they would unconstitutionally compel LISD and others, such as Texas Tech, to administer a federal regulatory program by forcing them to either fire their unvaccinated employees and fire and expel staff and children who do not wear mask or risk their Head Start funding.⁵¹

⁵¹ *See* Exhibit 4.

Forcing Head Start programs to comply with the Vaccine Mandate and the Mask Mandate under threat of the loss of all funding is unconstitutionally coercive; it is a gun to the head that compels Texas and other governmental entities such as LISD operating Head Start programs to participate against its will. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 580 (2012).

For all these reasons, the Interim Final Rule was adopted pursuant to an unconstitutional exercise of authority and must be held unlawful and set aside.

10. The Interim Final Rule violates the Tenth Amendment.

The structure of the U.S. Constitution and the text of the Tenth Amendment protect federalism.

The powers not delegated by the Constitution to the federal government are reserved to the States.

Through the Vaccine Mandate and the Mask Mandate, the federal government seeks to exercise power far beyond what was delegated to the federal government under the United States Constitution.

The power to impose vaccine mandates and mask mandates, to the extent that any such power exists, is a power reserved to the States.

“[T]he police power of a state” includes, above all, the authority to adopt regulations seeking to “protect the public health,” including the topic of mandatory vaccination. *Jacobson v. Massachusetts*, 197 U.S. 11, 24–25 (1905). These matters “do not ordinarily concern the national government.” *Id.* at 38.

By interfering with the traditional balance of power between the States and the federal government, Defendants violated the Tenth Amendment and structural principles of federalism.

For all these reasons, the Interim Final Rule was adopted pursuant to an unconstitutional exercise of authority and must be held unlawful and set aside.

B. Plaintiffs are likely to suffer irreparable harm in the absence of preliminary relief.

Plaintiffs will suffer irreparable harm from the Interim Final Rule absent preliminary relief from this Court. Implementation of the Interim Final Rule will cause Head Start programs in Texas to choose between (1) ignoring the Interim Final Rule and risking the cancellation of grant funding, (2) cancelling the program and depriving children of Head Start services, or (3) forcing their staff, contractors, and volunteers to comply with an illegal federal mandate that violates their constitutional rights, while dealing with the inevitable fallout from the resulting resignations that will damage the program.

1. Harm to Texas's and LISD's Head Start programs

Similarly, if LISD were to implement the Interim Final Rule's mandates, LISD's actions would be in direct violation of state law. *Compare* Interim Final Rule, *with* Exec. Order No. GA-38 (July 29, 2021),⁵² Exec. Order No. GA-39 (Aug. 25, 2021),⁵³ Exec. Order No. GA-40 (Oct. 11, 2021).⁵⁴ Under state law, "no governmental entity can compel any individual to receive a COVID-19 vaccine," but the Interim Final Rule requires LISD to compel staff, contractors, and volunteers to receive a COVID-19 vaccine. Exec. Order No. GA-39 (Aug. 25, 2021); Tex. Gov't Code

⁵² GA-38 is publicly available at https://gov.texas.gov/uploads/files/press/EO-GA-38_continued_response_to_the_COVID-19_disaster_IMAGE_07-29-2021.pdf (last visited Dec. 13, 2021).

⁵³ GA-39 is publicly available at https://gov.texas.gov/uploads/files/press/EO-GA-39_prohibiting_vaccine_mandates_and_vaccine_passports_IMAGE_08-25-2021.pdf (last visited Dec. 8, 2021).

⁵⁴ GA-40 is publicly available at https://gov.texas.gov/uploads/files/press/EO-GA-40_prohibiting_vaccine_mandates_legislative_action_IMAGE_10-11-2021.pdf (last visited Dec. 8, 2021).

§ 418.012 (The Governor’s “[e]xecutive orders, proclamations, and regulations have the force and effect of law.”).

Moreover, if LISD is required to implement the Interim Final Rule, it will inevitably lose teachers and students.⁵⁵ A survey of LISD teachers and teaching assistants who work with Head Start students revealed that at least 20 of them are not vaccinated.⁵⁶ If LISD were to lose those 20 teachers and teaching assistants, it would exacerbate already dire staffing issues at LISD and make it impossible for LISD to comply with Head Start student and faculty ratios.⁵⁷

At least one LISD Head Start teacher has already indicated he will seek alternative employment if he is required to be vaccinated for COVID-19.⁵⁸

Further, the breadth of the Interim Final Rule extends so far that LISD would even lose tuition-based students whose parents do not want their children to be required to wear masks—or their children’s teachers to be wearing masks.⁵⁹ LISD is already struggling to secure necessary staffing for all positions, and the wide-ranging scope of Defendants’ Mandate could impact not only teachers but also custodial and cafeteria staff.⁶⁰

In sum, implementation of the Interim Final Rule would result in a loss of both staff and funding to LISD.

⁵⁵ See Declaration of Allison Swafford attached as Exhibit 7; Declaration of David Gray attached as Exhibit 8.

⁵⁶ See Declaration of Kathy Pearson, attached as Exhibit 9.

⁵⁷ *Id.*

⁵⁸ See Exhibit 8 (Declaration of David Gray).

⁵⁹ See Exhibit 7 (Declaration of Allison Swafford).

⁶⁰ See Exhibit 9 (Declaration of Kathy Pearson).

2. Harm to Texas's sovereign interests

By purporting to preempt state laws, the Interim Final Rule harms Texas's sovereign interests in the enforcement of its laws—which include a ban on vaccine mandates and mask mandates.

In August 2021, Governor Abbott issued Executive Order GA-39, which in part ensured that individual medical autonomy was protected by providing that no governmental entity (including the LISD) could compel any individual to receive a COVID-19 vaccine administered under the emergency use authorization.

Recognizing that federal government overreach was impending and that the right to choose whether to take the vaccine could be stripped from all Texans, Governor Abbott issued GA-40 on October 11, 2021. GA-40 further protected personal liberty and autonomy and made it illegal for *any* entity in Texas (including the LISD) to compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objected to such vaccination “for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19.”

Governor Abbott and the State of Texas have made it clear to Texans: the decision whether to receive a vaccine should be free from governmental control. In response, millions of Texans have enthusiastically adopted best practices for public health and safety, including widespread uptake of the COVID-19 vaccine. So far in Texas, over 66% of the total Texan population eligible

for vaccines are fully vaccinated.⁶¹ Despite Texas’s diversity and largely rural character, Texas ranks above many states in vaccination rates—all without any government vaccine mandate.⁶²

In July 2021, Governor Abbott issued Executive Order GA-38, which provides in part that “[n]o governmental entity, including a ... school district, ... and no governmental official may require any person to wear a face covering or to mandate that another person wear a face covering[.]”

Nonetheless, according to the Interim Final Rule,

State and local laws that forbid employers in the State or locality from imposing vaccine requirements on employees directly conflict with this exercise of our statutory authority to protect the health and safety of Head Start participants and their families and ensure the continuation of services by requiring vaccinations for staff, certain contractors, and volunteers and universal masking. As is relevant here, this [Interim Final Rule] preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader grounds for exemptions than provided for by Federal law and are inconsistent with this [Interim Final Rule]. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule.

86 Fed. Reg. at 68,063. The Interim Final Rule’s claim to preemption of state and local laws directly attacks Texas’s ability to enforce its own laws.

The second factor (“a plaintiff is likely to suffer irreparable harm in the absence of preliminary relief”) weighs in favor of the State of Texas because when a statute is enjoined, the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its laws. *See, e.g., Abbott v. Perez*, 138 S. Ct. 2305, 2324 n.17 (2018) (“[T]he inability to enforce its

⁶¹ CDC COVID Data Tracker, <https://covid.cdc.gov/covid-data-tracker/#county-view> (last visited Dec. 13, 2021); Texas Coronavirus Vaccination Progress, <https://usafacts.org/visualizations/covid-vaccine-tracker-states/state/texas> (last visited Dec. 13, 2021).

⁶² *Id.*

duly enacted plan clearly inflicts irreparable harm on the State.”); *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (“Any time [a State is blocked] from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.”) When the State is blocked from implementing its laws, “the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its law.” *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013); *Coal. For Econ. Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997).

While this case centers on an executive order issued by the Governor under his emergency authority rather than enforcement of a statute enacted by the plenary legislative authority of the people, the same reasoning applies. *E.T. v. Paxton*, 2021 WL 5629045, at *6. In our system of federal courts representing the nation, subsisting side by side with 50 state judicial, legislative, and executive branches, appropriate consideration must be given to principles of federalism in determining the availability and scope of equitable relief. Here, as in *E.T. v. Paxton*, those principles counsel acknowledgement that Texas’s public officials are charged with carrying out Texas’s public policy, and enjoining those officials from carrying out Texas’s policy injures the state. *Id.*

C. The balance of equities favors Plaintiffs, and the injunction is in the public interest.

Next, in considering whether issuance of a stay pending appeal will substantially injure the other party, “the maintenance of the status quo is an important consideration in granting a stay.” *E.T. v. Paxton*, 2021 WL 5629045, at *7. LISD has never before been required to enforce a vaccine mandate against staff, constrictors, and volunteers, or a mask mandate against anyone. Moreover, GA-38, GA-39, and GA-40 have been in effect for months, so the Texas population has made and

continues to make decisions, personal or otherwise, relying on these orders. The balance of equities favors Plaintiffs.

“Once an applicant satisfies the first two factors, the traditional stay inquiry calls for assessing the harm to the opposing party and weighing the public interest. These factors merge when the Government is the opposing party.” *Nken v. Holder*, 556 U.S. 418, 435 (2009). Defendants will not be harmed by staying the Interim Final Rule. These factors favor in Plaintiffs’ favor.

In order to preserve the relative positions of the parties until a trial on the merits can be held, federal courts have regularly enjoined federal agencies from implementing and enforcing new regulations pending litigation challenging them. *See, e.g., Texas v. United States*, 787 F.3d 733 at 743, 768–69.

For those same reasons, injunctive relief is in the public interest. In addition to the economic and healthcare interests discussed, the liberty interests at stake here “are not reducible to dollars and cents.” *BST Holdings*, 17 F.4th at 618. “The public interest is also served by maintaining our constitutional structure and maintaining the liberty of individuals to make intensely personal decisions according to their own convictions—even, or perhaps *particularly*, when those decisions frustrate government officials.” *Id.* (emphasis in original).

III. CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs’ motion for a temporary restraining order to preserve the status quo until the Court has had an opportunity to rule on Plaintiffs’ motion for preliminary injunction, and grant Plaintiffs’ motion for preliminary injunction.

Respectfully submitted,

KEN PAXTON
Attorney General of Texas

BRENT WEBSTER
First Assistant Attorney General

GRANT DORFMAN
Deputy First Assistant Attorney General

SHAWN E. COWLES
Deputy Attorney General for Civil Litigation

/s/ Charles K. Eldred
CHARLES K. ELDRED
Special Litigation Counsel
Administration Law Division
State Bar No. 00793681
Charles.Eldred@oag.texas.gov

JOHNATHAN STONE
Assistant Attorney General
Civil Medicaid Fraud Division
State Bar No. 24071779

AMY L.K. WILLS
Assistant Attorney General
General Counsel Division
State Bar No. 24093379

Office of the Attorney General
Administrative Law Division
P.O. Box 12548, Capitol Station
(512) 936-1706 • fax (512) 320-0167
Austin, Texas 78711-2548

**ATTORNEYS FOR PLAINTIFF
STATE OF TEXAS**

THOMAS A. ALBRIGHT
Chief, General Litigation Division

/s/ Amy S. Hilton
AMY S. HILTON
Assistant Attorney General
General Litigation Division
State Bar No. 24097834
Amy.Hilton@oag.texas.gov

Office of the Attorney General
General Litigation Division
P.O. Box 12548, Capitol Station
Austin, Texas 78711-2548
(512) 936-1327 • fax (512) 320-0667

**ATTORNEYS FOR PLAINTIFF
LUBBOCK INDEPENDENT
SCHOOL DISTRICT**

CERTIFICATE OF CONFERENCE

We hereby certify that it was not possible to confer because we do not yet know who has been assigned to defend Defendants. Under Local Rule 7.1(b)(3), this motion is presumed to be opposed.

/s/ Charles K. Eldred /s/ Amy S. Hilton
Charles K. Eldred Amy S. Hilton

CERTIFICATE OF SERVICE

We certify that a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) on December 14, 2021. I further certify that a true and accurate copy of the foregoing document was served by mail on the following recipients on December 14, 2021:

United States Attorney's Office
Northern District of Texas
Lubbock Office
1205 Texas Ave., Suite 700
Lubbock, Texas 79401-40024

Xavier Becerra
Secretary of the United States Department of Health and Human Services
United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

JooYuen Chang
Principal Deputy Assistant Secretary
Administration for Children and Families
Mary E. Switzer Building
330 C Street, S.W.
Washington, D.C. 20201

Administration for Children and Families
Mary E. Switzer Building
330 C Street, S.W.
Washington, D.C. 20201

Katie Hamm
Deputy Assistant Secretary for Early Childhood Development
Office of Early Childhood Development
Administration for Children and Families
Mary E. Switzer Building
330 C Street, S.W.
Washington, D.C. 20201

Office of Early Childhood Development
Administration for Children and Families
Mary E. Switzer Building
330 C Street, S.W.
Washington, D.C. 20201

Bernadine Furtrell
Director
Office of Head Start
Administration for Children and Families
Mary E. Switzer Building
330 C Street, S.W.
Washington, D.C. 20201

Office of Head Start
Administration for Children and Families
Mary E. Switzer Building
330 C Street, S.W.
Washington, D.C. 20201

Joseph R. Biden
President of the United States
c/o U.S. Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530-0001

/s/ Charles K. Eldred /s/ Amy S. Hilton
Charles K. Eldred Amy S. Hilton