No. 21-14098

In the United States Court of Appeals for the Eleventh Circuit

STATE OF FLORIDA,

Plaintiff-Appellant.

v.

DEPARTMENT OF HEALTH & HUMAN SERVICES, ET AL.,

Defendants-Appellees.

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
No. 3:21-cv-2722-MCR-HTC

PETITION FOR INITIAL HEARING EN BANC

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Plaintiff-Appellant certifies that, to the best of its knowledge, the following is a complete list of interested persons:

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17. U.S. Centers for Medicare & Medicaid Services, *Defendant-Appellee*

18. U.S. Department of Health & Human Services, *Defendant-Appellee*

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RULE 35(b) & 11TH CIR. RULE 35-5 STATEMENT

I express a belief, based on a reasoned and studied professional judgment, that this appeal involves a question of exceptional importance: whether the Centers for Medicare and Medicaid Services (CMS) violated the Administrative Procedure Act (APA) when it mandated as a condition of participation in Medicare and Medicaid that participating facilities force millions of frontline healthcare workers to submit to COVID-19 vaccination.

/s/ Henry C. Whitaker
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STATEMENT OF THE ISSUES

1. Whether CMS has authority to mandate, as a condition of participation in Medicare and Medicaid, that participating facilities force millions of frontline healthcare workers to take a COVID-19 vaccine.

2. Whether CMS had good cause to skip notice and comment when imposing its mandate.

3. Whether CMS acted arbitrarily and capriciously when imposing its mandate.

4. Whether Florida meets the other factors for injunctive relief.

INTRODUCTION

"It is hard to imagine how a decision mandating vaccines for much of this nation's healthcare workforce—regardless of whether they have contact with a patient—does not constitute an agency decision of vast economic and political significance." *Florida v. HHS*, 2021 WL 5768796, at *24 (11th Cir. Dec. 6, 2021) (Lagoa, J., dissenting) (Dissent). Yet a divided panel of this Court has now said just that, holding that CMS may mandate COVID-19 vaccination for millions of frontline healthcare workers without clear statutory authority. *Id.* at *11–13 (majority op.).

The panel's fractured disposition contradicts decisions in two other circuits. District courts in the Fifth and Eighth Circuits enjoined CMS's mandate, one applying its injunction nationwide, *see Missouri v. Biden*, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021); *Louisiana v. Becerra*, 2021 WL 5609846 (W.D. La. Nov. 30, 2021), and those circuits have both denied the government a stay, *Missouri v. Biden*, No. 21-3725 (8th Cir. Dec. 13, 2021); *Louisiana v. Becerra*, 2021 WL 5913302, at *1 (5th Cir. Dec. 15, 2021).

Despite the panel's outlier decision, Florida was, until today, protected by the nationwide injunction issued by the Western District of Louisiana. The Fifth Circuit, however, narrowed that injunction to apply only to the States who sued. *Id.* Florida's

healthcare workers now face the immediate prospect of forced vaccination.[1] Florida therefore petitions for the en banc Court's expeditious intervention.

Because this case is time-sensitive and of vast importance, the en banc Court should hear this case in the first instance. The Court should then "alter" or "amend" the motion panel's decision, 11th Cir. R. 27-1(g), and grant an injunction pending appeal for the reasons discussed in Judge Lagoa's dissent and Florida's motion briefing (App. 200–32, 274–93). In the alternative, the Court should construe this petition as one for en banc review of Florida's motion, suspend its rule barring en banc petitions related to such motions, 11th Cir. R. 2-1 & 35-4, and grant an injunction pending appeal.[2]

COURSE OF PROCEEDINGS AND DISPOSITION OF THE CASE

On November 17, Florida challenged CMS's mandate under the APA and moved for a preliminary injunction in district court. App. 9–131. The district court denied the motion on November 20 without addressing the merits or even waiting for CMS to respond, holding only that Florida had not established irreparable harm. App. 132–43. On November 24, Florida noticed its appeal to this Court and moved in the

[1] After the Fifth Circuit's decision today, Florida consulted government counsel about whether CMS intends to enforce the rule in Florida. Counsel could provide no information about CMS's intentions.

[2] If the Court is not inclined to suspend its rule, a member of this Court may still call for en banc review of Florida's motion sua sponte. *See United States v. St. Hubert*, 918 F.3d 1174, 1181 (11th Cir. 2019) (Tjoflat, J., concurring in denial of rehearing en banc).

district court for an injunction pending appeal. App. 144–66. On November 27, the district court denied the motion again without addressing the merits. App. 167–76.

On November 29, Florida moved for an injunction pending appeal in this Court. App. 200–32. The district court then issued an unprompted "order in aid of the appeal" on December 1, in which explained for the first time its view that Florida had failed to satisfy each requirement for preliminary relief. App. 180–98. On December 3, CMS responded to Florida's Eleventh Circuit motion, App. 234–72, and Florida replied the same day, App. 274–93.

On December 5, a divided panel of this Court denied Florida's motion in a published decision. *Florida*, 2021 WL 5768796, at *17. Judges Rosenbaum and Jill Pryor found that Florida met none of the factors justifying injunctive relief. *Id.* at *11–17. Judge Lagoa dissented, finding that Florida met all of them. Dissent at *23–34.

STATEMENT OF FACTS

Medicare and Medicaid

Medicare and Medicaid are federal programs that pay medical expenses for certain individuals. CMS administers Medicare and partners with States to administer Medicaid. Dissent at *17.

To be eligible to receive payments from these programs, participating providers must agree to comply with federally imposed conditions of participation. *E.g.*, 42 U.S.C. §§ 1395cc(b)(2), 1396a(a)(33)(B), (36). CMS contracts with state health agencies to "survey" participating providers and ensure that they meet these conditions. 42 U.S.C.

§§ 1395aa(a), 1396a(a)(33)(B), (36). Florida is no exception—its Agency for Health Care Administration (AHCA) surveys participating providers on behalf of CMS. App. 100.

Current State of the Healthcare Industry

Reeling from the COVID-19 pandemic, the healthcare industry is facing the "worst U.S. health-care labor crisis in memory." App. 64. Frontline workers are experiencing unprecedented levels of exhaustion and fatigue, with almost 30% considering leaving the medical field and over 500,000 having done so already. *Id.*

These departures have put the healthcare industry on life support. In Florida, for instance, 92% of long-term-care facilities face a staffing crunch; for 75% of them, it is "the number one concern." App. 65. Florida's vacancy rate for nurses is also 11%. *Id.* And Florida's state-run healthcare agencies face similarly dire staffing shortages, which hinder their ability to provide adequate medical care. App. 103–13, 120–31.

A vaccine mandate threatens to exacerbate these grim circumstances. Officials at state-run healthcare facilities expect that many healthcare workers would resign rather than vaccinate. *Id.* And indeed, a recent study confirms these fears, reporting that 37% of unvaccinated workers would quit if their employers mandated vaccination or weekly testing, and 72% would quit were vaccination the only option. App. 66.

The Mandate

CMS issued its vaccine mandate as an interim final rule titled "Omnibus COVID-19 Health Care Staff Vaccination." 86 Fed. Reg. 61,555 (Nov. 5, 2021). The mandate directs most facilities participating in Medicare and Medicaid to require that covered

employees submit to COVID-19 vaccination unless they are eligible for an exemption otherwise established by law. *Id.* at 61,570–73. Whether employees take a single-dose or double-dose vaccine, they must, absent an exemption, receive their first shot by December 6 and must be fully vaccinated by January 4, 2022. *Id.* at 61,573. The December 6 date was pushed back because of the nationwide injunction, but as explained above, that injunction has been narrowed and no longer applies to Florida.

ARGUMENT & AUTHORITIES

This Court may grant initial hearing en banc. *See Jones v. Governor of Fla.*, 975 F.3d 1016, 1028 (11th Cir. 2020) (en banc). Once it does, it becomes the "merits panel" and may "alter, amend, or vacate" an earlier ruling on a motion. *See* 11th Cir. R. 27-1(g).

Alternatively, though the Court typically will not consider a petition for en banc review of a motion for injunction pending appeal, 11th Cir. R. 35-4(a), it may suspend this rule when warranted and proceed "as it deems appropriate," 11th Cir. R. 2-1. A member of this Court may also call sua sponte for en banc review of an order on a motion. *See United States v. St. Hubert*, 918 F.3d 1174, 1181 (11th Cir. 2019) (Tjoflat, J., concurring in denial of rehearing en banc).

No matter which path the Court chooses, it should consider these issues en banc and grant an injunction pending appeal.

A. This case presents a question of exceptional importance.

A confluence of factors makes this case one of remarkable significance.

First, the mandate is unprecedented. CMS has never before conditioned federal funding on vaccination. 86 Fed. Reg. at 61,567. Indeed, "no existing federal law expressly imposes vaccination requirements on the general population." Dissent at *30. So far as Florida can tell, the federal government has *never* compelled the widespread vaccination of the public. *Accord In re: MCP No. 165*, 2021 WL 5914024, at *18–20 (6th Cir. Dec. 15, 2021) (Bush, J., dissenting from denial of initial hearing en banc in challenge to OSHA's vaccine mandate).

Second, the mandate's scope is colossal. It has "near-universal applicability" to the healthcare industry, covering about 10 million employees. 86 Fed. Reg. at 61,573, 61,603. It also involves Medicare and Medicaid—two of the "largest federal program[s]" ever created. *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). The mandate thus "touches the lives of nearly all Americans." *Id.* at 1808. And given that even "minor changes" to the way these programs are administered "can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate," *id.* at 1816, a major change like the mandate promises consequences "of vast economic and political significance," Dissent at *24.

Third, the mandate tramples on the States' sovereign right to regulate the vaccination of their citizens—a traditional "part of [their] police power." *Id.* at *29; *cf. In re: MCP No. 165*, 2021 WL 5914024, at *6 (Sutton, C.J., dissenting from denial of initial hearing en banc). Indeed, the Biden Administration agreed just months ago that mandating vaccines is "not the role of the federal government." App. 25. Yet the

mandate purportedly preempts conflicting state laws, contrary to Florida's and Georgia's bans on inflexible vaccine mandates.[3] These sovereign injuries require "immediate correction." *Bristol Reg'l Women's Ctr., P.C. v. Slatery*, 988 F.3d 329, 344 & n.1 (6th Cir.) (Thapar, J., dissenting from refusal to stay an order invalidating state law and calling for initial en banc review), *vacated*, 994 F.3d 774 (6th Cir. 2021) (on initial en banc review).

Finally, given the mandate's aberrant intrusion into the privacy and autonomy of millions of Americans, it is "difficult to identify many other issues that currently have more political significance at this time." *Missouri*, 2021 WL 5564501, at *3. When agency action presents "issue[s] of such profound legal and political importance . . . the [C]ourt as a whole" should decide its legality. *Cf. Feldman v. Ariz. Sec'y of State*, 841 F.3d 791, 792 (9th Cir. 2016) (en banc) (Reinhardt, J., concurring in grant of rehearing en banc). Simply put, this is precisely the type of case for which initial en banc has "traditionally been utilized." *Mayor & City Council of Balt. v. Azar*, 799 F. App'x 193, 195 (4th Cir. 2020) (en banc) (Thacker, J., concurring in grant of initial en banc review of HHS's defunding of certain preconception services); *see also Int'l Refugee Assistance Project v. Trump*, 883 F.3d 233 (4th Cir. 2018) (en banc) (granting initial en banc review of agency action banning travel from certain countries); *Int'l Refugee Assistance Project v. Trump*, 857 F.3d 554 (4th Cir. 2017) (en banc) (same); *Bristol Reg'l Women's Ctr., P.C. v. Slatery*, 993

[3] Fla. Stat. §§ 381.00317, 112.0441; Ga. Exec. Order 05.25.21.01.

F.3d 489 (6th Cir. 2021) (en banc) (same for review of state law involving access to abortion).

B. The district court and motion panel rulings were wrong.

Both the district court and the motion panel found that Florida met none of the requirements for injunctive relief. But as Judge Lagoa explained, these rulings were mistaken; Florida meets every requirement.[4]

1. The mandate is contrary to law.

Courts must "hold unlawful and set aside agency action" that is "not in accordance with law," "in excess of statutory . . . authority," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C)–(D). Because the mandate violates multiple statutes, CMS has "gone beyond what Congress has permitted it to do." *City of Arlington v. FCC*, 569 U.S. 290, 298 (2013).

a) The mandate violates 42 U.S.C. § 1395.

The Medicare Act provides that no federal official may "exercise any supervision or control" over the "selection [or] tenure" of "any" healthcare "employee." 42 U.S.C. § 1395. The panel majority determined that the mandate does not violate this statute because it merely places conditions on optional funding. *Florida*, 2021 WL 5768796, at

[4] The standards for a preliminary injunction and an injunction pending appeal are identical: "(1) a substantial likelihood that [it] will prevail on the merits of the appeal; (2) a substantial risk of irreparable injury to the [movant] unless the injunction is granted; (3) no substantial harm to other interested persons; and (4) no harm to the public interest." *Florida*, 2021 WL 5768796, at *4.

*12. But Medicare and Medicaid are Spending Clause programs—federal action under these programs inherently involves conditions on optional funding. Section 1395 therefore must apply to overbearing funding conditions. And "[i]mposing a vaccination requirement with its concomitant penalties that include withholding funding from facilities that choose to employ or contract with nonvaccinated individuals certainly seems to fall within the plain meaning of the words 'supervision or control.'" Dissent at *31; *accord Louisiana*, 2021 WL 5609846, at *12.

b) CMS lacks statutory authority to issue the mandate.

The panel majority believed that several statutes specific to each regulated facility authorize CMS to impose the mandate, reasoning that these statutes permit CMS to promulgate "health and safety standards" for regulated facilities. *Florida*, 2021 WL 5768796, at *11–12. Putting aside that not all the statutes contain this "health and safety" language, *e.g.*, 42 U.S.C. § 1395x(iii)(3)(D)(i)(IV), that generic language provides nothing approaching the "clear statutory authorization" needed for a mandate of such "vast economic and political significance," Dissent at *24–25; *accord Missouri*, 2021 WL 5564501, at *2–4; *Louisiana*, 2021 WL 5609846, at *11; *cf. In re: MCP No. 165*, 2021 WL 5914024, at *6 (Sutton, C.J., dissenting from denial of initial hearing en banc).

c) The mandate violates 42 U.S.C. § 1395z.

Under § 1395z, CMS "shall consult with appropriate State agencies" in "carrying out [its] functions" relating to the "determination of conditions of participation" for many healthcare providers subject to the mandate. Though CMS admits that it did not

consult the States before issuing the mandate, 86 Fed. Reg. at 61,567, the panel majority found no statutory violation because, in its view, the statute imposes "no temporal requirement for the necessary consultation to occur *before* an interim rule is issued." *Florida*, 2021 WL 5768796, at *14 n.3.

But the statute does exactly that. It describes the required consultation as "relating to *determination* of conditions of participation." 42 U.S.C. § 1395z (emphasis added). A "determination" is "[t]he act of deciding something officially." *Determination*, Black's Law Dictionary (11th. ed. 2019). Consultation thus must come as the decision is being made, not afterward. The provision's title also confirms this meaning by referring to "[c]onsultation with State agencies . . . *to develop* conditions of participation." 42 U.S.C. § 1395z (emphasis added). Consultation only after the conditions have been set, as CMS did here, violates § 1395z. *Accord Louisiana*, 2021 WL 5609846, at *12.

2. CMS lacked good cause to bypass notice and comment.

An agency must provide notice of, and opportunity to comment on, rules that "affect individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979); 5 U.S.C. §§ 553, 706(2)(D). CMS did not do that here; instead, it invoked the "good cause" exception, which permits an agency to waive notice and comment when it finds for "good cause" that the process is "impracticable, unnecessary, or contrary to the public interest." 86 Fed. Reg. at 61,583. This is a demanding standard. *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012). CMS did not meet it. *Accord Louisiana*, 2021 WL 5609846, at *10; *Missouri*, 2021 WL 5564501, at *6–8.

The majority reasoned that "the urgency presented by the ongoing pandemic, the outbreaks associated with the Delta variant, and the oncoming influenza season" satisfied good cause. *Florida*, 2021 WL 5768796, at *14. But "we are two years into a global pandemic, with multiple, widely available vaccines and treatments that are only getting better. At this point . . . COVID-19, in and of itself, cannot constitute good cause to avoid notice and comment." Dissent at *27 (citation omitted); *cf. BST Holdings, LLC v. OSHA*, 2021 WL 5279381, at *3 & n.10 (5th Cir. Nov. 12, 2021).[5] To allow otherwise "would be to effectively repeal notice and comment requirements for the duration of the pandemic." Dissent at *27. And CMS's "own delay" in mandating vaccines despite their widespread availability and the months-long presence of the Delta variant undermines any claimed "urgency" here. *Id.* at *26; *cf. In re: MCP No. 165*, 2021 WL 5914024, at *10–11 (Sutton, C.J., dissenting from denial of initial hearing en banc).

3. The mandate is arbitrary and capricious.

Courts must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A). On this score, the majority ignored Florida's topline argument: To justify imposing its mandate on all facilities, "CMS 'extrapolated' the data from its long-term care facilities" without providing "similar evidence" for other covered facilities. Dissent at *28. Long-term-care facilities, however, are uniquely susceptible to COVID-19: They "make up less than 1 percent of the U.S. population"

[5] *Accord Florida v. Becerra*, 2021 WL 2514138, at *45 (M.D. Fla. June 18, 2021); *Regeneron Pharms., Inc. v. HHS*, 510 F. Supp. 3d 29, 48 (S.D.N.Y. 2020).

yet "accounted for 35 percent of all COVID-19 deaths during the first year of the pandemic." *Id.* (quotations omitted). It was thus unreasonable to rely on such skewed data to justify imposing an across-the-board vaccine mandate. *Id.*; App. 222–23; *accord Missouri*, 2021 WL 5564501, at *7–8; *Louisiana*, 2021 WL 5609846, at *14.

Rather than address this shortfall, the majority rejected Florida's arbitrary-and-capricious claim for two reasons, both mistaken.

First, the majority dismissed the argument that CMS failed to adequately consider a testing alternative and natural-immunity exemption, contending that Florida merely "seeks to substitute its views on epidemiology for [CMS's] judgment." *Florida*, 2021 WL 5768796, at *15. But Florida never claimed that these alternatives, if considered, must carry the day; Florida argued that CMS failed to "provide[] a satisfactory explanation" for rejecting these alternatives, as it must under the APA. Dissent at *29; App. 223–24. Indeed, CMS rejected a testing alternative "in a single sentence"—despite OSHA having included a testing alternative in its contemporaneously issued vaccine mandate—and its natural-immunity analysis was riddled with "contradictions." Dissent at *29; App. 223–24; *accord Missouri*, 2021 WL 5564501, at *8; *Louisiana*, 2021 WL 5609846, at *13.

Second, the majority rejected Florida's claim that CMS "failed to adequately consider the risk" that the mandate will "cause unvaccinated workers to flee the industry rather than submit to vaccination." *Florida*, 2021 WL 5768796, at *15. According to the majority, CMS did so when it considered evidence from some healthcare employers

that had "imposed vaccine mandates." *Id.* But locality-specific evidence provides no support for a nationwide vaccine mandate. *See Missouri*, 2021 WL 5564501, at *14 n.33. CMS's own sources recognize this, warning that attitudes toward vaccination differ across the country, and thus individual "circumstances" should "shap[e] whether and how [vaccine mandates] are implemented." *See* 86 Fed. Reg. at 61,566 n.128 (providing link). Worse still, the majority disregarded Florida's argument that CMS ignored a nationwide survey—published a week before the mandate—finding that 72% of unvaccinated workers would quit rather than vaccinate. App. 223–24.

CMS thus failed to sufficiently consider the risk that the mandate could aggravate an already-severe healthcare staffing shortage, leaving patients without adequate medical care in the process. *Missouri*, 2021 WL 5564501, at *10 n.15; *Louisiana*, 2021 WL 5609846, at *12–14; *accord* Dissent at *32–33.

C. Florida has suffered and will suffer irreparable harm.

At the gate, the majority ignored Florida's claim that, should it refuse to comply with the mandate, "the resulting loss of federal funding would lead to a reduction in patient care, i.e., services [Florida] would be unable to provide and receive revenue from, or a reduction in staff the agencies were able to employ." Dissent at *33. The loss of these services, patients, and employees "would not be recoverable, even if the mandate was held invalid." *Id.* Nor would the "heavy compliance costs" Florida would sustain because of the mandate, yet another harm the majority declined to address. *Id.*

Instead, the majority zeroed in on just three of Florida's injuries. It was wrong on all counts.

First, the majority reasoned that the mandate's preemptive effect inflicted no sovereign injury against Florida because "it is black-letter law" that federal preemption does not "invade" state sovereignty. *Florida*, 2021 WL 5768796, at *15 (citing *Hodel v. Va. Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 291 (1981)). But *Hodel* did not hold that federal preemption inflicts no harm on a State; it merely held that lawful federal preemption does not violate the Tenth Amendment. 452 U.S. at 291–92. At any rate, the majority all but conceded that the mandate inflicts irreparable sovereign harm if CMS "lacked the authority to issue" it. *Florida*, 2021 WL 5768796, at *15 n.4. Because there is "a substantial likelihood . . . that the mandate is unlawful," Florida has established irreparable harm. Dissent at *32.

Second, the majority dismissed Florida's claim that its agencies will lose healthcare workers because of the mandate, rejecting this harm as "speculative." *Florida*, 2021 WL 5768796, at *16. But as Judge Lagoa detailed, Dissent at *19–21, Florida provided substantial evidence that "the mandate will exacerbate the staffing shortages [Florida] face[s]" and will "result in disruptions in, and reductions to, the quality of patient care," *id.* at *33.

Finally, the majority dismissed Florida's claim that it could sue as parens patriae "for the many Floridians who work in healthcare and do not wish to receive a vaccine," seemingly asserting that a State may not sue the federal government as parens patriae

for their citizens. *Florida*, 2021 WL 5768796, at *16 (citing *Massachusetts v. Mellon*, 262 U.S. 447 (1923)). But *Mellon* does not apply when a State "assert[s] its rights under federal law," which Florida has here. App. 228.

D. The remaining factors favor Florida.

The majority asserted that the equities favored CMS because enjoining the mandate "would harm the public interest in slowing the spread of COVID-19 and protecting the safety" of patients. *Florida*, 2021 WL 5768796, at *17. But "as even CMS recognizes, there are 'major uncertainties' as to . . . vaccine effectiveness in preventing 'breakthrough' disease transmission from those vaccinated [and] the long-term effectiveness of vaccination." Dissent at *34. "Moreover, 'our system does not permit agencies to act unlawfully even in pursuit of desirable ends.'" *Id.* (quoting *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2490 (2021)). And since "there is a substantial likelihood that [Florida] will prevail on the merits . . . an injunction pending appeal" would "preserve the status quo" and avoid needlessly "exacerbating" already dangerous "healthcare staff shortages." *Id.*; *accord Louisiana*, 2021 WL 5913302, at *2 (concluding that preserving pre-mandate "status quo" was "an important equitable consideration" in denying CMS's motion to stay an injunction against the mandate (quotation omitted)).

CONCLUSION

For these reasons, the en banc Court should review this case, either on the merits or on review of Florida's motion for injunction pending appeal. And for the reasons

given in Judge Lagoa's dissent and Florida's motion briefing, the en banc Court should contemporaneously grant an injunction pending appeal.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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/s/ Henry C. Whitaker
Solicitor General

CERTIFICATE OF SERVICE

I certify that on December 16, 2021, I electronically filed this Petition for Initial Hearing En Banc with the Clerk of Court using the Court's CM/ECF system, which will send a notice of docketing activity to all parties who are registered through CM/ECF.

/s/ Henry C. Whitaker
Solicitor General