IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas, *Plaintiff*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*.	Civil Action No. 5:24-cv-00204-H

MEMORANDUM IN SUPPORT OF
PROPOSED INTERVENOR-DEFENDANTS' MOTION FOR LEAVE TO INTERVENE

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INTRODUCTION

Proposed Intervenor-Defendants, the City of Columbus, Ohio ("Columbus"), the City of Madison, Wisconsin ("Madison"), and Doctors for America ("DFA") (collectively, "Proposed Intervenors") move to intervene as of right as defendants under Rule 24(a) of the Federal Rules of Civil Procedure to protect their legal interests in upholding the two regulations at issue in this case. In the alternative, Proposed Intervenors seek permissive intervention under Rule 24(b).

Texas challenges two regulations promulgated by the Department of Health and Human Services (the "Department") under the Health Insurance Portability and Accountability Act ("HIPAA"), Appx. 0037 (Pub. L. 104-191, 110 Stat. 1936). Texas alleges they exceed the Department's statutory authority and are arbitrary and capricious, an abuse of discretion, and not in accordance with law, all in violation of the Administrative Procedure Act. Appx. 0162 (5 U.S.C. § 706(2)). Texas asks this Court to declare both violative of the APA and vacate and set them aside.

The first challenged rule, the *Standards for Privacy of Individually Identifiable Health Information*, is a 24-year-old regulation that serves as the foundation for medical privacy nationwide. Appx. 0164 (65 Fed. Reg. 82462-01 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164)) (the "2000 Privacy Rule"). If it were vacated, it would drastically increase levels of medical mistrust, inhibit the ability of health care providers to protect the confidentiality of patient information, impair the ability of public health authorities to protect the public health, and throw the nation's health care system into chaos.

The Department promulgated the second challenged rule, the *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, to provide heightened protections for sensitive medical information sought to investigate the provision and reception of lawful reproductive health care. Appx. 0776–934 (89 Fed. Reg. 32976-01 (Apr. 26, 2024) (codified at 45 C.F.R. pts. 160,

164) (the "2024 Rule") (both rules together, the "Privacy Rules"). The 2024 Rule offers providers and their patients additional critical assurances and protections at a time when patients are increasingly concerned about the confidentiality of their discussions with and treatment by health care providers.

Proposed Intervenors are entitled to intervene as of right to defend both Privacy Rules. The Rules regulate health care providers such as the public health departments of the City of Columbus and the City of Madison and, in the case of DFA, its members. They are vital for protecting patient confidentiality and, in turn, ensuring that patients trust their clinicians and that their clinicians can provide them with needed medical care. And fostering trust and honesty between clinicians and their patients is essential to overall public health: accurate data allows providers and public health departments to identify and address troubling public health trends. Proposed Intervenors' motion is timely; absent successful intervention, Proposed Intervenors' interests will be impaired by the relief Texas seeks; and these unique interests cannot be adequately defended by the federal government, both because Proposed Intervenors and the government have divergent interests in this litigation and because the government is unlikely to defend the Privacy Rules after President-Elect Donald J. Trump takes office. In the alternative, Proposed Intervenors should be permitted to intervene.

"Federal courts should allow intervention where no one would be hurt and the greater justice could be attained." *Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015) (quoting *Sierra Club v. Espy*, 18 F.3d 1202, 1205 (5th Cir. 1994)). These two principles dictate one result here: the Court should grant Proposed Intervenors' motion.

PROPOSED INTERVENORS

City of Columbus, Ohio. Proposed Intervenor City of Columbus is a municipal corporation organized under Ohio law. *See* Appx. 0936 (Ohio Const. art. XVIII § 1). Columbus has all the

powers of local self-government and home rule under the constitution and laws of the State of Ohio, which are exercised in the manner prescribed by the Charter of the City of Columbus. Columbus's public health department, Columbus Public Health, operates HIPAA-covered clinics, expends significant resources ensuring HIPAA compliance by its relevant staff, and provides a wide range of health care services on behalf of its residents, including sexual and reproductive health care. Because Columbus Public Health relies on HIPAA protections to preserve trust between its clinicians and patients as well as to protect the public health, the City of Columbus opposes Plaintiff's efforts to erode the privacy protections in the HIPAA Rules.

City of Madison, Wisconsin. Proposed Intervenor City of Madison is a municipal corporation organized under Wisconsin law. *See* Appx. 1023–29 (Wis. Stat. Ch. 66.0201–03). Madison has all the powers of local self-government and home rule under the constitution and laws of Wisconsin, which are exercised in the manner prescribed in the ordinances of the City of Madison. Madison's public health department, Public Health Madison and Dane County,[1] operates as a HIPAA-covered entity, expends significant resources ensuring HIPAA compliance by its relevant staff, and provides a wide variety of health care services to its residents, including sexual and reproductive health care. Because Public Health Madison and Dane County relies on HIPAA protections to preserve trust between its clinicians and patients as well as to protect the public health, the City of Madison also opposes Plaintiff's efforts to erode the privacy protections in the HIPAA Rules.

Doctors for America. Proposed Intervenor DFA is a nonpartisan, nonprofit organization comprised of more than 27,000 physicians, medical students, and other health professionals across the country, representing all medical specialties. DFA members are subject to HIPAA, and they

[1] The City of Madison jointly operates Public Health Madison and Dane County with Dane County.

rely on the law's protections to help preserve the physician-patient relationship and maintain trust with their patients. Because trust between providers and their patients is a critical component to delivering effective care, DFA vehemently opposes Plaintiff's efforts to erode the privacy protections in the Privacy Rules.

LEGAL STANDARD

Rule 24(a) of the Federal Rules of Civil Procedure governs intervention of right and requires intervention be granted where (1) the motion to intervene is timely; (2) the movant claims an interest relating to the property or transaction that is the subject of the action; (3) the disposition of the action may impair or impede the movant's ability to protect that interest; and (4) the movant's interest is inadequately represented by the existing parties to the suit. Fed. R. Civ. P. 24(a)(2); *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 305 (5th Cir. 2022); *Edwards v. City of Houston*, 78 F.3d 983, 999 (5th Cir. 1996) (en banc). These factors are "measured by a practical rather than technical yardstick." *Edwards*, 78 F.3d at 999 (internal quotation marks and citation omitted); *see Brumfield v. Dodd*, 749 F.3d 339, 341 (5th Cir. 2014) ("Rule 24 is to be liberally construed."); *NBIS Constr. & Transp. Ins. Servs. v. Kirby Smith Mach., Inc.*, No. 5:20-CV-182-H, 2021 WL 4227787, at *1 (N.D. Tex. Apr. 8, 2021) (citation omitted) ("The inquiry is a flexible one, and a practical analysis of the facts and circumstances of each case is appropriate."). While would-be intervenors bear the burden of establishing all four elements, that burden is "minimal." *Texas*, 805 F.3d at 661.

Federal Rule of Civil Procedure 24(b) allows a court to permit intervention where the movant makes a timely motion and "has a claim or defense that shares with the main action a common question of law or fact," Fed. R. Civ. P. 24(b)(1)(B), taking into consideration "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights," Fed. R. Civ. P. 24(b)(3).

ARGUMENT

Proposed Intervenors satisfy all requirements for intervention as of right and, accordingly, are entitled to intervene. Alternatively, Proposed Intervenors should be permitted to intervene, as their motion is timely, their defense of the Privacy Rules shares common questions of law and fact with this case, and their intervention will not delay or prejudice the existing parties' rights.

I. Proposed Intervenors are entitled to intervention as of right.

a. Proposed Intervenors' motion is timely.

Whether a motion to intervene is timely is assessed on (1) the length of time the movant waited to file after knowing its interests were unlikely to be protected; (2) the prejudice to existing parties resulting from any delay in the movant's filing; (3) the prejudice to the movant that would result if intervention were denied; (4) and the existence of any other unusual circumstances weighing for or against timeliness. *Stallworth v. Monsanto Co.*, 558 F.2d 257, 263–66 (5th Cir. 1977). Courts do not assess these factors in a rote manner. They are "a framework and not a formula," and a motion may be timely even where all factors do not weigh in favor of timeliness. *John Doe No. 1 v. Glickman*, 256 F.3d 371, 376 (5th Cir. 2001).

On all counts relevant here, Proposed Intervenors' motion is timely.[2]

First, start with an easy metric: Motions, such as this one, made before a trial or final judgment are generally considered timely. *See John Doe No. 1 v. Glickman*, 256 F.3d 371, 378 (5th Cir. 2001); *Edwards v. City of Houston*, 78 F.3d 983, 1001 (5th Cir. 1996) ("[M]ost of our case law rejecting petitions for intervention as untimely concerns motions filed after judgment was entered in the litigation."); *Alliance for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-CV-223-Z, 2024 WL 1260639, at *2 (N.D. Tex. Jan. 12, 2024).

[2] No unusual factors militate against timeliness here. *Stallworth*, 558 F.2d at 266.

Proposed Intervenors seek to join this case in its still early stages, and before anything of substance has occurred, because the government—obligated to consider a diverse array of interests in defense of this rule—cannot adequately represent the more specific interests of Proposed Intervenors in this litigation. *See infra* Section I(d).

Proposed Intervenors have another reason to intervene at this time: The statements and actions of leaders in the incoming administration have made it apparent that, following the change in presidential administration on January 20, 2025, the federal government will likely cease defending the challenged regulations and will not adequately represent Proposed Intervenors' interests moving forward. *See infra* Section I(d). This anticipated change in defensive posture is something that Proposed Intervenors have been able to glean as the incoming administration has moved from election to office—announcing cabinet nominees and firming up its policy agenda. *See* Appx. 1415 (Texas's Memo. In Support of Mot. to Intervene at 4, *Commonwealth of Pennsylvania et al. v. Devos et al.*, 1:20-cv-01468 (D.D.C. Jan. 19, 2021), ECF No. 130-1) ("The motion is timely because it was filed close in time to the change in circumstances requiring intervention: President-elect Biden's inauguration on January 20."); *Cook County v. Mayorkas*, 340 F.R.D. 35, 45 (N.D. Ill. 2021), aff'd sub nom. *Cook County v. Texas*, 37 F.4th 1335 (7th Cir. 2022) (noting that until the end of the "administration that soon would leave office, Texas could count on [the federal agency] to defend the challenged regulation").

Second, intervention will not cause any prejudice to the existing parties as a result of "delay." *Edwards*, 78 F.3d at 1002. Proposed Intervenors move before any responsive pleading has been filed. The only activity in this litigation so far has been on a proposed schedule for the resolution of the case, with which Proposed Intervenors intend to comply. Proposed Intervenors concurrently file a proposed dispositive motion—on the date the Court had originally ordered the

existing parties to file theirs—to avoid disruption to the briefing schedule. *See* ECF No. 15, Order Granting Motion to Enter Briefing Schedule and Hold Defendants' Deadline to Respond to Complaint In Abeyance. If this motion is granted, no deadlines will need to be moved, no portions of the litigation that have already occurred will need to be rehashed or delayed, and no discovery will be disrupted. *See Wal-Mart Stores, Inc. v. Texas Alcoholic Beverage Comm'n*, 834 F.3d 562, 565–66 (5th Cir. 2016); *NBIS Constr. & Transp. Ins. Servs.*, 2021 WL 4227787, at *1 ("Here, the second factor weighs in favor of timeliness because no deadlines will need to be moved, no additional discovery will be necessary, and no delay will occur, and, therefore, the parties will not be prejudiced by [the applicant's] intervention."); *Alliance for Hippocratic Med.*, 2024 WL 1260639, at *3 ("Any delay in filing a motion to intervene 'cause[s] no prejudice whatsoever' where, during the period in question, 'the parties to [the] litigation did nothing except anticipate and prepare to address' arguments to be presented later on." (quoting *Edwards*, 78 F.3d at 1002)).

Third, by contrast, Proposed Intervenors' interests will be severely prejudiced if intervention is denied at this juncture. Without intervention, Proposed Intervenors will lose out on the "legal rights associated with formal intervention," such as the ability to brief the issues, appeal, and raise objections to a settlement (and appeal a decision granting a settlement agreement). *See Espy*, 18 F.3d at 1207. And without the participation of Proposed Intervenors actively defending the rules at stake, a decision in this case could result in significant harm to Columbus, Madison, and DFA and its members, parties with interests that are not adequately defended by the federal government. *See infra* Section I(d).

b. The Proposed Intervenors have a legally protectable interest in this matter.

To intervene under Rule 24(a)(2), an intervenor must have a "direct, substantial, legally protectable interest in the proceedings." *Edwards*, 78 F.3d at 1004 (internal quotation marks and citation omitted). This requirement is less stringent than that of Article III standing. *Texas*, 805

F.3d at 659; *see Alliance for Hippocratic Med.*, 2024 WL 1260639, at *3 (citation omitted). Instead, the inquiry "turns on whether the intervenor has a stake in the matter that goes beyond a generalized preference that the case come out a certain way." *Id.* at 657. And where, as here, the case involves a public interest question, "the interest requirement may be judged by a more lenient standard." *Brumfield*, 749 F.3d at 344 (citation omitted) (noting that the en banc Fifth Circuit has compared the interest requirement to the "zone of interest" test in public law cases); *Alliance for Hippocratic Med.*, 2024 WL 1260639, at *4 (quoting *id.*).

Organizational intervenors may seek to intervene to protect the interests of their organization, and they may also seek to intervene to assert the "interests of their individual members." *Franciscan Alliance, Inc. v. Azar*, 414 F. Supp. 3d 928, 937 (N.D. Tex. 2019). DFA seeks to do both.

i. The Cities of Columbus and Madison and DFA's members are regulated by the Privacy Rules.

Parties, like the Cities of Columbus and Madison and DFA's members, plainly have an interest in a suit "challenging the regulatory scheme that governs" them. *Wal-Mart*, 834 F.3d 562; *see Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, No. 5:21-CV-071-H, 2022 WL 974335, at *5 (N.D. Tex. Mar. 31, 2022); *accord Michigan State AFL-CIO v. Miller*, 103 F.3d 1240, 1244–48 (6th Cir. 1997).

DFA's members include providers who themselves are "covered entities" subject to the Privacy Rules. Appx. 1429–30 (45 C.F.R. § 160.103); Appx. 0008 (Petrin Decl. ¶ 10). DFA's members are subject to both civil and criminal liability for violating HIPAA. *See* Appx. 1438–43 (42 U.S.C. § 1320d-5); Appx. 1444–45 (42 U.S.C. § 1320d-6(b)). They may also be subject to professional discipline for violating the patient privacy rules of the hospitals and practices in which they work. *See* Appx. 0008 (Petrin Decl. ¶ 11). And they expend significant time and money on

HIPAA compliance and training. *See* Appx. 0009 (Petrin Decl. ¶ 14); Appx. 0015 (Oller Decl. ¶ 14); *Texas*, 805 F.3d at 658 (citation omitted); *Wal-Mart*, 834 F.3d at 567–68.

Similarly, Columbus and Madison operate public health departments that are "covered entities" subject to the HIPAA rules. Appx. 1429–30 (45 C.F.R. § 160.103); Appx. 0018 (Mitchell Decl. ¶ 5); Appx. 0025 (Johnson Decl. ¶ 15); Appx. 0032 (Heinrich Decl. ¶ 15). Columbus Public Health and Public Health Madison and Dane County operate a number of outpatient clinics and treat thousands of patients each year. Appx. 0024 (Johnson Decl. ¶ 10); Appx. 0032 (Heinrich Decl. ¶ 10). They too spend a significant amount of time and money on HIPAA compliance and training. *See* Appx. 0018 (Mitchell Decl. ¶ 6); Appx. 0025 (Johnson Decl. ¶ 16); *Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, 2022 WL 974335, at *5 (N.D. Tex. Mar. 31, 2022) (citing *Texas*, 805 F.3d at 658). Columbus Public Health has already devoted staff time toward implementing the 2024 Rule. Appx. 0020 (Mitchell Decl. ¶ 14). "If the [Rules are] overturned, their time and money will have been spent in vain." *City of Houston v. Am Traffic Sols., Inc.*, 668 F.3d 291, 294 (5th Cir. 2012) (finding that proposed intervenors were sufficiently interested to justify mandatory intervention where architects of a successful campaign to change a city's charter sought to intervene in litigation that threatened to overturn the change).

That the public health departments of Columbus and Madison and DFA's members are regulated by the Privacy Rules gives them "real, concrete stake[s] in the outcome of this litigation." *Texas*, 805 F.3d at 661. No further inquiry is needed.

ii. The Cities of Columbus and Madison and DFA's members have an interest in the provider-patient relationship.

Proposed Intervenors' interests go beyond their status as regulated parties. They also have an interest in the challenged Privacy Rules because of their interest in maintaining and strengthening the provider-patient relationship by promoting trust between patients and providers.

As the Fifth Circuit has recognized, "[t]he doctor-patient relationship requires trust and confidentiality to facilitate the candid disclosure of sensitive health information." *Huntington Ingalls, Inc. v. Director, Office of Workers' Compensation Programs, U.S. Dep't of Labor*, 70 F.4th 245, 251 (5th Cir. 2023) (citation omitted).[3]

DFA members know first-hand how difficult it can be to build a relationship with a patient and how quickly a relationship can be fractured. *See* Appx. 0009 (Petrin Decl. ¶ 13); Appx. 0014–15 (Oller Decl. ¶¶ 9–12, 15). Patients have a "reasonable expectation" that the medical information they share with their providers will be used only to treat them. Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)). If patients believe their sensitive health information will be used by law enforcement for non-health care purposes, it endangers the very relationships that DFA members and all health care providers work so hard to build. *See* Appx. 0010 (Petrin Decl. ¶ 16); Appx. 0014 (Oller Decl. ¶ 12); Appx. 0789 (89 Fed. Reg. 32984 (Apr. 26, 2024)). This risk has only increased since the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), as patients find some health care banned, and providers and patients may face investigations into the legal treatment they provide and receive. *See* Appx. 0010 (Petrin Decl. ¶ 16); Appx. 0014 (Oller Decl. ¶ 12); Appx. 0789 (89 Fed. Reg. 32984 (Apr. 26, 2024)).

Patient trust is especially vital to the Columbus and Madison public health departments which serve as providers of last resort in their communities. Appx. 0025 (Johnson Decl. ¶ 19); Appx. 0031 (Heinrich Decl. ¶ 12). Many of the patients that Columbus Public Health and Public Health Madison and Dane County treat come from historically marginalized populations. Appx.

[3] For centuries, the patient-clinician relationship has been at the heart of medical practice. This relationship has an ethical foundation and is built on confidentiality, trust, and honesty. *See* Appx. 1446–52 (Am. Med. Ass'n, *Opinion 1.1.1: Patient-Physician Relationships*, Code of Medical Ethics (Aug. 2022), https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/1.1.1%20Patient-physician%20relationships--background%20reports_0.pdf).

0025 (Johnson Decl. ¶ 19); Appx. 0033 (Heinrich Decl. ¶ 22). "[M]edical mistrust—especially in communities of color or other communities that have been marginalized or negatively affected by historical and current health care disparities—can create damaging and chilling effects on individuals' willingness to seek appropriate and lawful health care for medical conditions that can worsen without treatment." Appx. 0789–90 (89 Fed. Reg. 32985 (Apr. 26, 2024)). Patients seek out care from Columbus Public Health and Public Health Madison and Dane County instead of a family physician to preserve their anonymity and avoid stigma that can be associated with particular statuses (e.g., sex work) or health conditions (e.g., sexually transmitted infections). *See* Appx. 0026 (Johnson Decl. ¶ 20); Appx. 0033 (Heinrich Decl. ¶ 23). Trust that their personal health information will remain confidential is paramount.

Preserving this relationship of trust between providers and their patients is an aim of the Privacy Rules. *See, e.g.*, Appx. 0169 (65 Fed. Reg. 82463 (Dec. 28, 2000)) (noting that "improv[ing] the quality of health care in the U.S. by restoring trust in the health care system among consumers, health care professionals, and the multitude of organizations and individuals committed to the delivery of care" is a "major purpose[]" of the 2000 Privacy Rule); Appx. 0781 (89 Fed. Reg. 32978 (Apr. 26, 2024)) (specifying that the 2024 Rule was necessary to "continue to protect privacy in a manner that promotes trust between individuals and health care providers" in light of the "changing legal landscape").

Strong privacy protections on patient medical information and the trust they engender between patients and their providers, in turn, allow Columbus Public Health, Public Health Madison and Dane County, and DFA's members to provide competent care and comport with their ethical obligations to do so. *See* Appx. 0009 (Petrin Decl. ¶ 13); Appx. 0014–15 (Oller Decl. ¶¶ 9, 11–13); Appx. 0019 (Mitchell Decl. ¶ 8); Appx. 0032 (Heinrich Decl. ¶ 17); Appx. 1453 (Am.

Med. Ass'n, *Opinion 3.1.1: Privacy in Health Care, Code of Medical Ethics*, https://code-medical-ethics.ama-assn.org/sites/amacoedb/files/2024-12/3.1.1.pdf (last visited Jan.16, 2025)). The provision of effective care depends on the sharing of sensitive health information, which will only happen where patients trust that their information will be kept confidential. Appx. 0009 (Petrin Decl. ¶ 13); Appx. 0014–15 (Oller Decl. ¶¶ 9–13); Appx. 0025 (Johnson Decl. ¶ 18); Appx. 0032–33 (Heinrich Decl. ¶ 20); *see* Appx. 0019 (Mitchell Decl. ¶ 9); Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)). When patients fear sharing their medical history or other relevant sensitive information with their providers, it risks misdiagnosis or mistreatment and puts patients' lives at risk. Put simply, "high-quality health care cannot be attained without patient candor." Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)).

As discussed, the Privacy Rules protect against that. More fundamentally, the provision of competent care is only possible where patients actually seek such care. Without robust privacy protections, patients may be afraid to seek certain health care because they are concerned about how their sensitive medical information will be used or shared. Appx. 0010 (Petrin Decl. ¶ 17); Appx. 0014 (Oller Decl.¶ 11); Appx. 0027 (Johnson Decl. ¶ 25); Appx. 0035 (Heinrich Decl. ¶ 29).

iii. The Cities of Columbus and Madison have an interest in the promotion of public health.

Columbus and Madison additionally have an interest in promoting the public health of their communities. Courts have long recognized the interest of local governmental bodies to protect public health. *See, e.g.*, *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 27 (1905)

("Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members.").

Protecting individual privacy while promoting public health is an express purpose of the Privacy Rules. Robust privacy protections engender accurate reporting and "[a]ccurate medical records assist communities in identifying troubling public health trends and in evaluating the effectiveness of various public health efforts." Appx. 0177 (65 Fed. Reg. 82467 (Dec. 28, 2000)). Put differently, "[b]arriers that undermine the willingness of individuals to seek health care in a timely manner or to provide complete and accurate health information to their health care providers undermine the overall objective of public health." Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)).

Columbus Public Health and Public Health Madison and Dane County are the public health authorities for their jurisdictions, responsible not just for treating individual patients but also for preventing disease and improving the overall health of their residents as a whole. *See* Appx. 0023 (Johnson Decl. ¶ 8); Appx. 0030 (Heinrich Decl. ¶ 7); Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)). The cities' ability to identify and address concerning health trends depends, in part, on the willingness of patients to seek care and be honest with public health department providers. Appx. 0026 (Johnson Decl. ¶ 22); Appx. 0034 (Heinrich Decl. ¶ 26). The cities' interest in vindicating

their public health mandates gives them sufficient interest in this litigation. *See Edwards*, 78 F.3d at 995.

iv. DFA will have to expend significant resources if either Privacy Rule is undone.

An organization satisfies Rule 24(a)(2)'s interest requirement where it "expend[s] significant resources" on efforts that may be impacted by the outcome of the proceedings. *La Union del Pueblo Entero*, 29 F.4th at 306. There is no question that DFA surpasses this threshold.

DFA spends significant resources advocating on behalf of providers for accessible, equitable health care at the local, state, and federal levels. It also works to increase the physician voice in health policy decisions. *See* Appx. 0007–08 (Petrin Decl. ¶¶ 7–8). In addition to advocating for legislative and regulatory change, DFA provides resources and trainings, including HIPAA-specific resources, for its members on legal and policy issues. *See* Appx. 0007–08 (Petrin Decl. ¶¶ 7–8). And in 2022, DFA co-founded the Reproductive Health Coalition—a group of more than a hundred health professional organizations—specifically focused on protecting access to reproductive care. Appx. 0009 (Petrin Decl. ¶ 9).

If either of the Privacy Rules were to fall, DFA would be required to expend significant resources advocating for increased privacy protections elsewhere (for example, at the state level) and educating and training its members on the reworked legal landscape. *See* Appx. 0010 (Petrin Decl. ¶ 17). "This interest goes beyond a purely 'ideological' reason for intervention and amounts to a 'direct' and 'substantial' interest in the proceedings." *La Union del Pueblo Entero*, 29 F.4th at 306.

c. Resolution of this action would practically impair and impede Proposed Intervenors' interests.

An intervenor must demonstrate that the disposition of the case "may, as a practical matter" impair or impede its ability to protect its interests. *Brumfield*, 749 F.3d. at 344. This threshold is low—a party "need only show that if [it] cannot intervene, there is *a possibility* that [its] interest could be impaired or impeded." *La Union del Pueblo Entero*, 29 F.4th at 307 (citing *Brumfield*, 749 F.3d at 344–45) (emphasis added).

It takes little imagination to see how a partial or complete resolution of the case in favor of Texas would impair Proposed Intervenors' interests. If either Privacy Rule is vacated, Proposed Intervenors will face severe costs, in both time and money, to understand and comply with the new legal landscape in which they operate. And patients' trust will be compromised, harming the provider-patient relationship, endangering Proposed Intervenors' ability to provide effective care to their patients, and undermining the public health missions of Columbus and Madison.

If Texas is afforded even part of its broad-sweeping requests for relief, Proposed Intervenors will be bound by the judgment. There will be no way to appeal or—depending on the grounds upon which this Court would hypothetically rule—advocate for the agency to revive the rules. *See Sierra Club v. Glickman*, 82 F.3d 106, 109 (5th Cir. 1196) ("[T]he *stare decisis* effect of an adverse judgment constitutes a sufficient impairment to compel intervention." (citing *Espy*, 18 F.3d at 1207)). And if the Proposed Intervenors are prevented from joining this litigation, they will have no other recourse—such as affirmative litigation—through which to vindicate their interests. *See Deus v. Allstate Ins. Co.*, 15 F.3d 506, 526 (5th Cir. 1994) ("Intervention generally is not appropriate where the applicant can protect its interests and/or recover on its claim through some other means." (citation omitted)). Precluding Proposed Intervenors from involvement in this

litigation would significantly impede and impair their abilities to protect the interests they have outlined.

d. The government's representation of Proposed Intervenors' interests is inadequate.

To make the "minimal" showing required for this factor, Proposed Intervenors need only demonstrate that the government's representation of their interests "*may* be inadequate," *Heaton v. Monogram Credit Card Bank of Georgia*, 297 F.3d 416, 425 (5th Cir. 2002) (emphasis added), which Proposed Intervenors can more than do here. Indeed, intervention has been permitted even in cases where the movant's interest "may diverge in the future, even though, at [the time of intervention] they appear to share common ground." *Id.*

Although adequacy of representation will be presumed (1) where the existing party is a government charged by law with representing a putative intervenor's interests; or (2) where the putative intervenor has the same "ultimate objective" as a party to the lawsuit, *Edwards*, 78 F.3d at 1005, the federal government is not entitled to either presumption of adequacy here. To begin, this case is not one in which the government defendants are "charged by law" with representing Proposed Intervenors' interests. *Id.* Although the Department has considered the interests of covered entities in crafting the Privacy Rules, *see, e.g.*, Appx. 0182 (65 Fed. Reg. 82471 (Dec. 28, 2000)), "there is no suggestion" that it is their "legal representative," *Brumfield*, 749 F.3d at 345*; see also Espy*, 18 F.3d at 1207–08. Moreover, if the government, as expected, imminently abandons its defense of either Privacy Rule, Proposed Intervenors and the existing defendants will not share the same ultimate goal of maintaining them.

If either presumption of adequacy did apply, Proposed Intervenors could easily rebut them. An intervenor overcomes the government-representative presumption by showing that the intervenors' interests are distinct from the existing governmental party and thus may not be

adequately represented by it. *La Union del Pueblo Entero*, 29 F.4th at 308 (citations and internal quotation marks omitted). An intervenor overcomes the same-objective presumption by showing "adversity of interest." *Id.* In this case, the same facts rebut both. *See Texas*, 805 F.3d at 662 (analyzing both under "adversity of interest").

Proposed Intervenors have outlined their specific interests in this case. *See* Section I(b) *supra*. The government's potential interests—in balancing patient privacy with the public interest in using health information and law enforcement needs, defending the integrity of its rulemaking process, managing its relationship with the states, and implementing the agenda of a new administration—are both broader and distinct. These competing interests are something the Department itself recognized in both Privacy Rules. *See, e.g.*, Appx. 0781 (89 Fed. Reg. 32978 (Apr. 26, 2024)) ("This final rule balances the interests of society in obtaining PHI for non-health care purposes with the interests of the individual, the Federal Government, and society . . . ."); Appx. 0527 (65 Fed. Reg. 82685 (Dec. 28, 2000)) ("The final rule seeks to strike a balance in protecting privacy and facilitating legitimate law enforcement inquiries."). These more extensive interests that the Department was obliged to consider at the rulemaking stage may lead to divergent legal strategies, such as a willingness to settle, agree to an injunction limited in scope, or not appeal relief ordered against it. *See Glickman*, 256 F.3d at 381 ("The USDA is a governmental agency that must represent the broad public interest, not just the [intervenors'] concerns.").

If that were not enough to overcome the presumption, the imminent change in administration "raises 'the possibility of divergence of interest' or a 'shift' during litigation." *W. Energy Alliance v. Zinke*, 877 F.3d 1157, 1169 (10th Cir. 2017) (citation omitted); *see Heaton*, 297 F.3d at 425 ("That the [intervenor's] interests and [existing party's] may diverge in the future, even though, at this moment, they appear to share common ground, is enough to meet the

[intervenor's] burden on this issue."). *Alliance for Hippocratic Med.*, 2024 WL 1260639, at *6 ("[I]n any event, 'it is enough' for the purposes of this factor that the Intervenors' broader interests 'may diverge' from Plaintiffs' interests 'in the future.'" (citing *Heaton* , 297 F.3d at 425)). This possibility alone satisfies the minimal requirement that the government's representation "may be" inadequate. *Espy*, 18 F.3d at 1207 (citing *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972)). Proposed Intervenors note abundant recent evidence that the incoming administration will abandon its defense of the challenged Privacy Rules. For example, the Nominee for Department Secretary, Robert F. Kennedy, Jr., has indicated his willingness to rescind Department regulations related to reproductive health care, including the 2024 Rule. *See* Appx. 1454–59 (Megan Messerly et al., *Anti-abortion groups have 2 asks. RFK Jr. is listening*, Politico (Nov. 20, 2024), https://www.politico.com/news/2024/11/20/anti-abortion-rfk-jr-00190552); Appx. 1460–64 (Tyler Arnold, *Trump's HHS nominee Robert F. Kennedy Jr. reassures pro-life senators with policy plans*, Catholic News Agency (Dec. 19, 2024), https://www.catholicnewsagency.com/news/261111/trump-hhs-nominee-robert-kennedy-jr-reassures-pro-life-senators) (noting that Kennedy has told Senators that he "will back certain pro-life policies if the Senate confirms him," and that abortion should go "back to the states").[4] Further,

[4] President-Elect Trump and his administration have demonstrated that they believe the federal government should not take any actions to protect access to abortion. *See* Appx. 1462 (Arnold, *supra*) (quoting Senator Tommy Tuberville as saying, "Basically, [Kennedy] and President Trump have sat down and talked about it and both of them came to an agreement," and "Roe v. Wade is gone, [abortion has] gone back to the states"). Within the past year, President-Elect Trump has indicated that he "would let red states monitor women's pregnancies," a sentiment completely diametric to the 2024 Rule's intent and Proposed Intervenors' interests. Appx. 1467 (Eric Cortellessa, *How Far Would Trump Go*, TIME (Apr. 30, 2024), https://time.com/magazine/us/6979410/may-27th-2024-vol-203-no-17-u-s/). Vice President-Elect Vance opposed the new rule from its inception, submitting a comment that makes many of the same arguments that Texas does here. *See* Appx. 1477–87 (Members of Congress, Comment on Proposed HIPAA Privacy Rule To Support Reproductive Health Care Privacy 9 (June 16, 2023), https://www.regulations.gov/comment/HHS-OCR-2023-0006-0171).

opposed similar HHS efforts to protect reproductive health information. Appx. 1490 (The Heritage Foundation, *Mandate for Leadership: The Conservative Promise* 497 (2023), https://tinyurl.com/55dbtvkx).[5]

Although the incoming administration has been less outspoken on the 2000 Privacy Rule, Texas's opposition to the 2000 Privacy Rule appears to be focused on provisions that it argues inhibit its ability to receive unlimited patient information pursuant to an administrative subpoena or investigative demands: requests that have increased following *Dobbs*. *See* Appx. 0792 (89 Fed. Reg. 32988 (Apr. 26, 2024)). Given the incoming administration's opposition to robust protections for reproductive care, its leaders may very well agree with Texas that the limits in the 2000 Privacy Rule overreach and also cease to defend that Rule.

Although Proposed Intervenors "cannot say for sure that the state's more extensive interests will *in fact* result in inadequate representation, . . . surely they might, which is all that the rule requires." *Brumfield*, 749 F.3d at 346 (emphasis in original).

II. Alternatively, this Court should permit Proposed Intervenors to intervene under Rule 24(b).

Federal Rule of Civil Procedure 24(b) provides that a court may permit intervention where an intervenor makes a timely motion and "has a claim or defense that shares with the main action a common question of law or fact," taking into consideration "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(1), (3). "The 'claim or defense' portion of Rule 24(b) . . . [is to be] construed liberally.'" *U.S. ex rel Hernandez v. Team Finance, LLC*, 80 F.4th 571, 577 (5th Cir. 2023) (quoting *Newby v. Enron*

[5] Although President-Elect Trump has endeavored to distance himself from Project 2025, he has since picked "major architects" of the blueprint for key posts in his next administration. Appx. 1491 (Amanda Becker, *How Trump's nominees could make Project 2025 a reality*, News from the States (Jan. 2, 2025), https://www.newsfromthestates.com/article/how-trump-nominees-could-make-project-2025-reality).

Corp., 443 F.3d 416, 422 (5th Cir. 2023)). On all counts, Proposed Intervenors should be permitted to intervene permissively if they are not entitled to under Rule 24(a)(2).

First, as explained above, Proposed Intervenors motion is timely. *See* Section I(a) *supra*. Although timeliness is analyzed with more scrutiny in the context of permissive intervention, *Rotstain v. Mendez*, 986 F.3d 931, 942 (5th Cir. 2021), Proposed Intervenors move to intervene promptly, before the matter proceeds substantively, to protect their interests. Second, Proposed Intervenors seek to take up the position (defending the Privacy Rules) and arguments that they believe the federal government will shortly abandon; their claims and defenses do not just share a common question of law or fact with the main action, they are practically identical. If the incoming administration does not abandon its defense of the rules, Proposed Intervenors' specific interests still easily satisfy this requirement. *See* Section I(b) *supra*. Lastly, intervention here would not cause any delay or prejudice, as this litigation is in its nascent stages. *See* Section I(a) *supra*.

CONCLUSION

For the foregoing reasons, Proposed Intervenors respectfully request that this Court grants their motion for leave to intervene under Rule 24(a), or, in the alternative, Rule 24(b).

Date: January 17, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Jennifer R. Ecklund
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IN THE UNITED STATES OF AMERICA
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas,

Plaintiff,

v.

United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services,

Defendants,

and

City of Columbus, Ohio; City of Madison, Wisconsin; and Doctors for America,

Intervenor-Defendants.

Civil Action No. 5:24-cv-00204-H

[PROPOSED] MEMORANDUM OF LAW IN SUPPORT OF INTERVENOR-DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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The cities of Columbus, Ohio, and Madison, Wisconsin, together with Doctors for America ("Intervenor-Defendants"), having moved for leave to intervene as defendants to protect their legal interests in upholding the two regulations at issue in this case pursuant to Fed. R. Civ. P. 24, by and through their undersigned counsel, respectfully submit this memorandum of law in support of their motion to dismiss, or in the alternative for summary judgment, against the above-captioned action in its entirety pursuant to Fed. R. Civ. P. 12(b)(1) and 56(a), and adopt and join in Defendants' arguments in support of, and motion for, dismissal and/or judgment. *See* Dkts. 19–20.

PRELIMINARY STATEMENT

The confidentiality of patient health information is a cornerstone of effective health care. Congress provided critical protection for patient privacy by enacting the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (Pub. L. 104–191, 110 Stat. 1936). In doing so, Congress expressly delegated to the Department of Health and Human Services ("HHS" or the "Department") the authority to "promulgate final regulations" containing "standards with respect to the privacy of individually identifiable health information," including specifically as it pertains to the "rights that an individual who is a subject of individually identifiable health information should have," "[t]he procedures that should be established for the exercise of such rights," and "[t]he uses and disclosures of such information that should be authorized or required." Appx. 561 (42 U.S.C. § 1320d–2 note (codifying Pub. L. 104–191, title II, § 264)). The Department promulgated the Privacy Rules consistent with this statutory authority, considering the relevant factors and acting well within its discretion, including with respect to both Privacy Rules that Texas purports to challenge, namely, the initial, broad-gauged 2000 Privacy Rule and the 2024 Rule, which strengthen protections for information about lawful reproductive care. *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82462-01 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164) (the

"2000 Privacy Rule"); *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) (the "2024 Rule" or the "Rule") (together, the "Privacy Rules").

The Privacy Rules challenged in this matter are essential to the provision of health care throughout the United States. Patients and clinicians alike rely on the protections afforded by the Privacy Rules to use and disclose information regarding patient health care efficiently, effectively, and confidentially. The Privacy Rules ensure that patient information—including sensitive information touching on the patient's symptoms, questions, fears, diagnoses, prognoses, test results, images, treatment, medical history, medication, wishes, and bills—remains confidential. When patient information does need to be disclosed—for example, when patients consult with multiple clinicians, submit bills to insurance, seek care across specialties, or even move to a new city—it is the Privacy Rules that ensure that information remains confidential. The 2024 Rule provides additional safeguards related to reproductive health care information, which is particularly sensitive and uniquely jeopardized by recent uncertainty arising from changes in law and the divergence of law between and among states. The Privacy Rules do not impede legitimate law enforcement: in fact, the Privacy Rules expressly provide exceptions to confidentiality when law enforcement has a legitimate basis to obtain confidential information and engages in the appropriate process. Intervenor–Defendants and the constituencies they represent and serve as municipalities or as clinicians are subject to and impacted by the Privacy Rules as detailed in their motion to intervene, as are all participants in the health care system who depend upon the Privacy Rules as the framework governing the transmission, maintenance, access, and disclosure of individually identifiable information regarding health care.

Texas's request to enjoin and set aside the Privacy Rules would be devastating for patients, providers, cities, and all those who participate in the health care system. Texas disregards both the text of the HIPAA statute directing the Department to implement the rules, and the text of the Privacy

Rules as issued. It has operated pursuant to the 2000 Privacy Rule for nearly 25 years without objecting to it as invalid under the Administrative Procedure Act ("APA"), and without identifying any particular instance of injury arising from compliance with its prerequisites for disclosure to law enforcement. Texas offers no meaningful argument that the Privacy Rules violate the APA—its ostensible legal claim—but rather argues that, as a policy matter, it has decided that it would like broader access to information than the Privacy Rules permit. It asks this Court to substitute its judgment—and Texas's policy objective—for Congress's duly-enacted legislation and the Privacy Rules promulgated and updated at its express direction. Texas's goal is to grant its law enforcement officials (and law enforcement officials across the country) access to records of ***lawful*** health care, without regard for the confidentiality of patient information or the clinician-patient relationship, without satisfying the legal prerequisites of showing a legitimate law enforcement exception, and without regard to the protections established by federal law. The Privacy Rules' exceptions already permit reporting to law enforcement when certain limited conditions are satisfied, but Texas's request would result in "open season" on patient records and eliminate the Privacy Rules' protections altogether, if this Court were to accede.

Texas's Complaint fails as a matter of law because it disregards the will of Congress as represented by the text of the governing HIPAA statute and the Privacy Rules themselves, including their explicit exceptions for law enforcement investigation, and ignores (although does not dispute) the Department's consideration of relevant factors and the applicable legal standards. Texas cannot overcome the stark record demonstrating as a matter of law that the 2000 Privacy Rule and 2024 Rule were issued consistent with the Department's statutory authority and that neither Privacy Rule is arbitrary and capricious.

The Complaint also fails for lack of jurisdiction because Texas brings its claims as to the 2000 Privacy Rule far too late, without even attempting to satisfy the threshold requirement of

standing. The Complaint's allegations of injury to the interests of the State of Texas are wholly conclusory and do not identify any concrete injury at all, let alone an injury sufficient to give rise to standing. Because Texas's challenge to the 2000 Privacy Rule relies on a claim of harm dating back to the 2000 Privacy Rule itself, it is decades too late, and time-barred.

For the reasons stated below and in the brief of the Department and individual Defendants (collectively, "Defendants"), this Court should dismiss Plaintiff's Complaint in its entirety, and enter judgment for the Defendants.

BACKGROUND

The background regarding HIPAA and the Privacy Rules is set forth in detail in the Department's brief and is summarized here.

In 1996, Congress enacted HIPAA to "improve the efficiency and effectiveness" of health care, in part by "establish[ing] standards and requirements for the electronic transmission of certain health information." Appx. 549 (42 U.S.C. § 1320d note (codifying Pub. L. 104–191, title II, § 261)). Congress instructed HHS to adopt uniform standards "to enable health information to be exchanged electronically." 42 U.S.C. § 1320d–2(a)(1). That direction encompassed instructions to adopt uniform standards regarding the electronic exchange of health information, *id.* § 1320d–2(a), unique identifiers for participants in the health care system, *id.* § 1320d–2(b), standards for transactions and related data, *id.* § 1320d–2(a), and the security of health care information, *id.* § 1320d–2(d). Congress also expressly considered the need to adopt standards protecting the privacy of health information maintained under HIPAA and, in Section 264(a), directed HHS to submit to Congress "detailed recommendations on standards with respect to the privacy of individually identifiable health information." Appx. 561 (42 U.S.C. § 1320d–2 note). As required by HIPAA, the Department transmitted these recommendations to Congress within 12 months, on September 11, 1997. *Id.*; 42 U.S.C. § 1320d–2(a)(1); Appx. 012 (65 Fed. Reg. at 82470 (Dec. 28, 2000)).

Congress provided that if it did not enact legislation establishing these standards within 36 months after HIPAA's enactment, "the Secretary of Health and Human Services shall promulgate final regulations containing such standards." Appx. 561 (42 U.S.C. § 1320d–2 note). Further, Congress directed the Secretary to "review the standards" and "adopt modifications to the standards (including additions . . .), as determined appropriate." 42 U.S.C. § 1320d–3(b)(1). It also included an express preemption provision, mandating that "a provision or requirement under [HIPAA], or a standard or implementation specification adopted under [HIPAA] . . . shall supersede any contrary provision of State law," with limited exceptions, including for "public health." *Id*. § 1320d–7(a)(1), (b). In its preemption provision, Congress made clear that the privacy regulations to be promulgated by HHS would constitute a floor nationwide, preempting and superseding less stringent protections but not contrary provisions of state law that may be "more stringent" than the requirements of HHS's HIPAA rules. Appx. 561–62 (42 U.S.C. § 1320d–2 note).

In 2000, after Congress did not enact legislation within the 36-month period, the Department proposed and ultimately promulgated regulations about medical privacy: the Standards for Privacy of Individually Identifiable Health Information (the 2000 Privacy Rule). 45 C.F.R. §§ 164.102–164.106, 164.500–164.535; Appx. 012 (65 Fed. Reg. at 82470 (Dec. 28, 2000)). The 2000 Privacy Rule established a set of national standards for protecting certain health information. 45 C.F.R. § 164.502; Appx. 006 (65 Fed. Reg. at 82464 (Dec. 28, 2000)). This included "general rules" for the use and disclosure of protected health information ("PHI") and rules establishing individuals' rights regarding their PHI, as well as listing specific circumstances when a covered entity is permitted to use or disclose PHI without an individual's consent. 45 C.F.R. § 164.512. The Department has continuously administered and enforced the Privacy Rule since 2000. Appx. 373 (89 Fed. Reg. at 32977 (Apr. 26, 2024)).

The Department proposed to amend the 2000 Privacy Rule to address more recent developments consistent with the principles and policy set forth by Congress in HIPAA—following an iterative rulemaking process that the statute expressly contemplated and authorized. 42 U.S.C. § 1320d–3(b)(1) ("[T]he Secretary shall review the standards adopted under section 1320d–2 of this title, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate . . . "); *see also* Appx. 377 (89 Fed. Reg. at 32981 (Apr. 26, 2024)) ("Congress contemplated that the Department's rulemaking authorities under HIPAA would not be static. Congress specifically built in a mechanism to adapt such regulations as technology and health care evolve . . . ") (citing 42 U.S.C. § 1320d-3). After consulting with federal and state agencies and the National Committee on Vital and Health Statistics ("NCVHS"), and considering more than 25,900 comments, the Department promulgated the Privacy Rule To Support Reproductive Health Care Privacy (the 2024 Rule). Appx. 372, 374, 387 (89 Fed. Reg. at 32976, 32978, 32991 (Apr. 26, 2024)). The 2024 Rule's purpose is to "amend provisions of the [2000] Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care." *Id.* at 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)). This rule went into effect on June 25, 2024. *Id.* at 372 (89 Fed. Reg. at 32976 (Apr. 26, 2024)).

Texas asserts that "these rules significantly harm the State of Texas's investigative abilities because covered entities frequently cite the 2000 Privacy Rule as a reason they cannot comply with a valid investigative subpoena for documents and have already begun invoking the 2024 Privacy Rule for similar purposes." Compl. ¶ 8; *see also* ¶¶ 85, 88. Texas does not identify any specific instance of such noncompliance at any point since either Privacy Rules' issuance.

PROCEDURAL HISTORY

On September 4, 2024, the State of Texas brought suit against the Department, the Department's Secretary Xavier Becerra, and the Department's Director of the Office for Civil Rights Melanie Fontes Rainer (Defendants) alleging two counts under the Administrative Procedure Act: that, by promulgating the 2000 Privacy Rule and 2024 Rule, Defendants purportedly exceeded their statutory jurisdiction or authority per 5 U.S.C. § 706(2)(A) (Count I), and acted in a manner that was arbitrary and capricious per 5 U.S.C. § 706(2)(C) (Count II). On November 18, 2024, the Court entered the parties' agreed-upon briefing schedule and requested dispositive motions on or before January 17, 2025. *See* Dkt. 15. On January 15, 2025, Texas requested an extension to the briefing schedule for dispositive motions, which the Court granted that same day, ordering dispositive motions due on or before February 7, 2025. *See* Dkts. 17–18. On January 17, 2025, Intervenor–Defendants filed their Motion to Intervene, seeking to protect their interests and to be heard regarding the sweeping relief that the State seeks, including by moving for summary judgment and dismissal as to both counts of the Complaint under Fed. R. Civ. P. 12(b)(1) and 56(a).

ARGUMENT

Summary judgment should be granted when "there is no genuine dispute as to any material fact" and the moving party "is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). It is the movant's burden to demonstrate "the absence of a genuine issue of material fact," and entry of summary judgment is required against any party "who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Jones v. United States*, 936 F.3d 318, 321 (5th Cir. 2019) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994)). A court may grant summary judgment if it determines that plaintiffs lack "standing to pursue their claims." *Paxton v. Dettelbach*, 105 F.4th 708, 711 (5th Cir. 2024).

A motion to dismiss for lack of subject matter jurisdiction should be granted if a plaintiff lacks the standing required for the Court to adjudicate the claims. Fed. R. Civ. P. 12(b)(1); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (holding that standing is jurisdictional; absent standing, the court lacks subject matter jurisdiction to adjudicate the claims and must dismiss). In assessing the allegations on a motion to dismiss, the Court must accept the complaint's well-pled, factual allegations as true, *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981), but not its conclusory allegations or legal conclusions, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "'The party invoking federal jurisdiction bears the burden of establishing' standing" throughout the case, "and, at the summary judgment stage, such a party 'can no longer rest on . . . 'mere allegations,' but must 'set forth' by affidavit or other evidence 'specific facts.'" *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 411–12 (2013) (quoting *Lujan*, 504 U.S. at 561).

A motion to dismiss for lack of jurisdiction should be granted when the claims are time-barred. Plaintiff bears the burden of establishing the timeliness of each claim alleged; untimely claims must be dismissed. *See Austral Oil Co. v. Nat'l Park Serv.*, 982 F. Supp. 1238, 1246 (N.D. Tex. 1997) ("Plaintiffs must show" APA claim timely "within six years prior to filing suit."). "[F]ailure to sue . . . within the limitations period" under the APA "is not merely a waivable defense. It operates to deprive federal courts of jurisdiction." *Am. Stewards of Liberty v. Dep't of Interior*, 960 F.3d 223, 229 (5th Cir. 2020).

I. THE APA CLAIMS FAIL BECAUSE THE DEPARTMENT ACTED WITHIN ITS AUTHORITY AND WITH DUE CONSIDERATION OF THE RELEVANT FACTORS, AND THE RULES ARE NOT ARBITRARY AND CAPRICIOUS.

As Defendants establish in their opening brief, Congress expressly delegated rulemaking authority to the Department under HIPAA, and the Privacy Rules are squarely within the scope of that delegated statutory authority and valid under the APA. *See* 5 U.S.C. § 706(2)(A). Under the APA, an agency's action must be upheld, unless it is "arbitrary, capricious, an abuse of discretion,

or otherwise not in accordance with law" or is in excess of statutory authority. *Id.* § 706(2)(A), (C). In reviewing a claim under the APA, the Court is to presume the agency's action is valid and is to consider only whether that action "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). The Court's review is "'neither sweeping nor intrusive." *Fort Bend Cnty v. U.S. Army Corps of Eng'rs*, 59 F.4th 180, 194 (5th Cir. 2023). The Court may not "substitute [its] judgment for that of the agency." *Overton Park*, 401 U.S. at 416 (quoting *Amin v. Mayorkas*, 24 F.4th 383, 393 (5th Cir. 2022)); *see also Barr v. Sec. & Exch. Comm'n,* 114 F.4th 441, 447 (5th Cir. 2024) ("Agency decisions are 'presumptively valid; the petitioner bears the burden of showing otherwise.'") (quoting *Tex. Tech Physicians Assocs. v. U.S. Dep't of Health & Hum. Servs.*, 917 F.3d 837, 844 (5th Cir. 2019)) (cleaned up). When Congress statutorily grants an agency the authority and discretion to propose and enact rules, the agency's discretion is notably broad. *Little Sisters of the Poor v. Pennsylvania*, 591 U.S. 657, 676–77 (2020) (agency has broad discretion to craft guidelines when granted on the face of the statutory text).

A. The APA Claims Fail as to the 2000 Privacy Rule.

HHS acted within its delegated statutory authority in promulgating the 2000 Privacy Rule, and appropriately exercised its discretion, as the APA requires. The 2000 Privacy Rule took the relevant factors into account and addressed precisely the issues Congress directed the Department to address, namely: "(1) The rights that an individual who is a subject of individually identifiable health information should have. (2) The procedures that should be established for the exercise of such rights. (3) The uses and disclosures of such information that should be authorized or required." Appx. 561 (42 U.S.C. § 1320d–2 note).

First, the Department addressed the rights of an individual who is a subject of individually identifiable health information. *See id.*; 45 C.F.R. §§ 164.524(a)(1), 164.526(a)(1), 164.528(a)(1);

Appx. 005 (65 Fed. Reg. at 82463 (Dec. 28, 2000)). The Privacy Rule granted "individual[s] . . . a right of access to inspect and obtain a copy of protected health information in designated record set," 45 C.F.R. § 164.524(a)(1), a "right to have a covered entity amend protected health information or a record about the individual," *id.* § 164.526(a)(1), and "a right to receive an accounting of disclosures of protected health information," *id.* § 164.528(a)(1). The Department recognized that privacy of personal information—and particularly, of personal medical information—is a vital individual interest and essential to the effective provisions of health care. Appx. 006, 009 (65 Fed. Reg. at 82464, 82467 (Dec. 28, 2000)). It found that medical privacy is necessary for individual patients and clinicians alike, and for the functioning of the health care system as a whole; effective care cannot be provided unless individuals are willing and able to share their most intimate details, and that willingness depends on an expectation of privacy and confidential treatment. *Id.* at 009–010 (65 Fed. Reg. at 82467–68 (Dec. 28, 2000)). It concluded that individuals have an interest in avoiding the disclosure of such personal matters, including "matters vital to the care of their health." *Whalen v. Roe*, 429 U.S. 589, 600 (1977); *see also* Appx. 005 (65 Fed. Reg. at 82464 (Dec. 28, 2000)).

Second, the Department addressed the procedures required to protect those rights. *See* 45 C.F.R. §§ 164.506(b)–(c), 164.508–10; Appx. 561 (42 U.S.C. § 1320d–2 note). The Privacy Rule details the process for patients to access and request amendment to their own protected health information, 45 C.F.R. §§ 164.524; 164.526, and vests them with the right to direct disclosure of their records to another doctor, *id.* § 164.506(b)(1) ("A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations."). The 2000 Privacy Rule also confers a right to file a complaint against a "covered entity [for] not complying" with the rule and to have that complaint investigated. *Id.* § 160.306(a). Critically, the Department recognized that the advancement of technology and shift to electronic record-keeping and communications "have reduced or eliminated many of the financial

and logistical obstacles that previously served to protect the confidentiality of health information and the privacy interests of individuals," Appx. 007 (65 Fed. Reg. at 82465 (Dec. 28, 2000)), and concluded that "protection of privacy must be built into the routine operations of our health care system." *Id*. at 009 (65 Fed. Reg. at 82467 (Dec. 28, 2000)).

Third, and of particular relevance to Texas's purported interest, the Department addressed "[t]he uses and disclosures of such information that should be authorized or required." Appx. 561 (42 U.S.C. § 1320d–2 note); *see* 45 C.F.R. § 164.512. The 2000 Privacy Rule sets out detailed standards regarding the use and disclosure of PHI; *see, e.g.*, 45 C.F.R. §§ 164.502, 164.512, which is defined as "individually identifiable health information" that is "transmitted" or "maintained" in "electronic media" or "any other form or medium," *id.* § 160.103. The 2000 Privacy Rule provides that PHI is protected from use or disclosure without an individual's authorization, ***except in certain circumstances***, also specified in the 2000 Privacy Rule. *Id.* § 164.502(a). Those exceptions include exceptions for law enforcement and other state interests: PHI can be used and disclosed without written patient authorization for purposes including treatment, payment, and health care operations, *id.* § 164.502(a)(1)(ii), and may be disclosed to law enforcement officials pursuant to a court order, subpoena, or administrative request, and in any judicial or administrative proceeding in response to an order of the court or tribunal, *id* § 164.512(e)–(f).

There is no dispute, and no allegation to the contrary, that the Department considered the relevant factors—including the rights that individuals who are the subject of individually identifiable health information should have, the procedures for the exercise of such rights, and the uses or disclosures of such information that should be authorized or required—and engaged in thorough consultation with federal and state agencies, and an extensive public comment process, before promulgating the final 2000 Privacy Rule. *See* Compl. ¶¶ 24–35 (making no allegations regarding the rulemaking process); Appx. 005–007, 009–010, 012 (65 Fed. Reg. at 82463–65, 82467–68,

82470, 82474 (Dec. 28, 2000)) (considering factors Congress detailed, noting delay caused in part by approximately 17,000 comments received, and engaging in required consultations); 45 C.F.R. § 164.502 (detailing general rules for uses and disclosures of PHI); Appx. 561 (42 U.S.C. § 1320d–2 note) (requiring the Secretary's recommendations to address specific considerations).

The undisputed record of rulemaking, consistent with statutory authority, considering and addressing the relevant factors, also establishes that the Department did not engage in action that was "arbitrary, capricious, [or] an abuse of discretion" when promulgating the 2000 Privacy Rule. 5 U.S.C. § 706(2)(A); *see Barr*, 114 F. 4th at 447 ("Agency decisions are presumptively valid; the petitioner bears the burden of showing otherwise.") (cleaned up); *Huawei Techs. USA, Inc. v. Fed. Commc'ns Comm'n*, 2 F.4th 421, 434 (5th Cir. 2021) ("Our role is to determine whether the agency's decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.") (cleaned up); *Associated Builders & Contractors of Texas, Inc. v. Nat'l Lab. Rels. Bd.*, 826 F.3d 215, 224–25 (5th Cir. 2016) ("To affirm an agency's action, we need only find a rational explanation for how the [agency] reached its decision.").

For these reasons, and those set forth by Defendants in their motions to dismiss and/or for summary judgment on January 17, 2025, Texas's claims regarding the 2000 Privacy Rule fail as a matter of law and should be dismissed in their entirety.

B. The APA Claims Fail as to the 2024 Rule.

Summary judgment is also warranted with respect to claims seeking to enjoin and set aside the 2024 Rule. While more recent, the Department's issuance of the 2024 Rule falls just as squarely within its authority and discretion.

That the 2024 Rule was promulgated more recently is not a reason to set it aside, as Texas seems to suggest. HIPAA expressly authorizes the Secretary to "review" and "adopt modifications to the standard . . . as deemed appropriate." 42 U.S.C. § 1320–3(b)(1). Pursuant to this grant of

authority, the Department issued the 2024 Rule consistent with HIPAA's purpose "to improve the efficiency and effectiveness of the health care system, which includes ensuring that individuals have trust in the health care system." Appx. 385 (89 Fed. Reg. at 32989 (Apr. 26, 2024)). More specifically, the 2024 Rule "directly advances the purposes of HIPAA by setting minimum protections for PHI . . . thereby improving the effectiveness of the health care system by ensuring that persons are not deterred from seeking, obtaining, providing, or facilitating reproductive health care." *Id.* at 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)).

Texas maintains that the Department lacks the authority to promulgate new rules limiting how regulated entities share information with state governments and seeks to set those rules aside in favor of allowing broad access by the State to reproductive health care information, in particular. That Texas disagrees with the policy enacted by Congress in HIPAA and followed by the Department in enacting the 2024 Rule is not a sufficient legal basis to strike it down under the APA.

The Department's authority and appropriate exercise of discretion are yet again clear on the record. In enacting HIPAA, Congress made clear that, in the promulgation of privacy regulations, HHS should balance the rights of individuals against certain public interests: HIPAA states that it should not be understood to invalidate or limit "reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d–7(b). In accordance with that provision, the Department issued rules that make clear that covered entities may disclose an individual's PHI, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. *See* 45 C.F.R. § 164.512(b)(1).

The 2024 Rule follows HIPAA's directive. It does not prohibit disclosures of PHI where the request is to lawfully investigate a matter of public health, consistent with 42 U.S.C. § 1320d–7(b), *see* Appx. 388–90, 394 (89 Fed. Reg. at 32992–94, 98 ((Apr. 26, 2024)), and maintains the existing

provisions permitting use and disclosure for public health oversight activities. 45 C.F.R. § 164.512(b), (c). But because the Department defined "public health" to encompass "population-level activities to prevent disease and promote health of populations," Appx. 396 (89 Fed. Reg. at 33000 (Apr. 26, 2024)), as opposed to the kind of investigations of individuals for "the mere act of seeking, obtaining, providing, or facilitating health care," *id.* at 398 (89 Fed. Reg. at 33002 (Apr. 26, 2024)), the permitted disclosure is more narrow than Texas would like. The 2024 Rule also does not prohibit disclosure in connection with the ***unlawful*** provision of reproductive health care, 45 C.F.R. § 164.502(a)(5)(iii)(B), again consistent with Congress's directive–but more narrow than Texas's preferred policy.

The 2024 Rule's definitions are clear, and the Rule is well within the ambit of the Department's discretion and authority, including for all of the reasons Defendants argue.

As with the 2000 Rule, on this undisputed record, Texas cannot show that the Department engaged in action beyond its authority or that was "arbitrary, capricious, [or] an abuse of discretion" when promulgating the 2024 Rule. 5 U.S.C. § 706(2)(A), (C); *see Barr*, 114 F.4th at 447 ("Agency decisions are presumptively valid; the petitioner bears the burden of showing otherwise.") (cleaned up); *Huawei Techs.*, 2 F.4th at 434 ("Our role is to determine whether the agency's decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.") (cleaned up); *Associated Builders & Contractors of Texas, Inc.*, 826 F.3d at 224–25 ("To affirm an agency's action, we need only find a rational explanation for how the [agency] reached its decision."). Texas cannot satisfy its burden with respect to the 2024 Rule, and its claims should be dismissed in their entirety and judgment entered for Defendants as to that Rule too.

C. The Privacy Rules Do Not Improperly Infringe on State Law Enforcement Authority.

Moreover, for all of the reasons stated by the Defendants, the Privacy Rules do not improperly infringe on state law enforcement authority; the exceptions provided by the Privacy Rules regarding law enforcement and judicial administrative proceedings are consistent with the Department's legal authority, reflect its reasoned judgment and consideration of the relevant factors, and are legally valid. *See* Dkt. 20 at 15-27. Texas's claims have no merit on this ground either.

II. THE COMPLAINT FAILS AT THE THRESHOLD BECAUSE THE INJURY ALLEGED IS INSUFFICIENT TO SUPPORT STANDING, AS WELL AS TIME-BARRED.

The Court should not reach the merits of Texas's claims because Texas lacks standing and its claims as to the 2000 Privacy Rule are untimely. As a result, the Court lacks subject matter jurisdiction, for all of the reasons Defendants argue.

To meet the "irreducible constitutional minimum of standing," *Lujan*, 504 U.S. at 560, a plaintiff must demonstrate: (1) "injury in fact," (2) "that is fairly traceable to the challenged conduct of the *defendant*," and (3) "likely to be redressed by a favorable judicial decision," *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (emphasis added). "[S]tanding is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press" and "for each form of relief that they seek." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021). The burden to plead those facts and establish its standing rests on plaintiff. *See Clapper*, 568 U.S. at 411–12. Standing is jurisdictional; absent standing, the Court cannot adjudicate the claims and must dismiss. *See Lujan*, 504 U.S. at 559–61.

Plaintiffs also bear the burden of establishing the timeliness of their claims under the APA. 28 U.S.C. § 2401(a); *Corner Post, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 603 U.S. 799, 800 (2024). The general statute of limitations for civil suits against the government applies to APA challenges when, as here, Congress has not enacted another statute of limitations for a specific type

of challenge. *Corner Post, Inc.*, 603 U.S. at 808. That limit provides that complaints are barred unless "filed within six years after the right of action first accrues." 28 U.S.C. § 2401(a); *Corner Post, Inc.*, 603 U.S. at 800 (quoting *Bay Area Laundry and Dry Cleaning Pension Tr. Fund v. Ferbar Corp. of Ca.*, 522 U.S. 192, 201 (1997)). A claim accrues when it is "complete and present," at which point a litigant can sue. *Corner Post, Inc.*, 603 U.S. at 800.

A. Texas Has Failed to Establish Standing.

The generalized objections that Texas asserts are inadequate to establish its standing to sue on these claims. Texas does not plead any facts identifying any injury to its interests as a result of either the 2000 Privacy Rule or the 2024 Rule. Instead, it relies on generalized and conclusory allegations that "these rules significantly harm the State of Texas's investigative abilities," Compl. ¶ 8, without specifying a single instance in which such harm has occurred. Although Texas complains that "the 2000 Privacy Rule harms" it "because covered entities in receipt of an administrative subpoena will frequently cite the rule as the reason they cannot comply," *id.* ¶ 85, and "[i]n at least one instance a covered entity has cited the 2024 Privacy Rule as a reason it cannot comply" with Texas's subpoena, *id.* ¶ 88, it does so in wholly conclusory fashion and without factual allegations that the recipients in fact refused to provide information or that the purported investigation was affected by these responses. Texas completely ignores that the Privacy Rules expressly allow disclosure of PHI even without patient authorization for clearly defined, legitimate law enforcement purposes, including rules that specifically permit disclosures when reporting "child abuse or neglect," reporting "abuse, neglect, or domestic violence" to the extent "required by law," and responding to legally authorized information demands, such as warrants and subpoenas. 45 C.F.R. §§ 164.512(b), (c), (e), (f); *see also* Appx. 391 (89 Fed. Reg. at 32995 (Apr. 26, 2024)) ("The Privacy Rule always has and continues to permit disclosure of PHI to support public policy goals, including disclosures to support criminal, civil, and administrative law enforcement activities . . . ."). Texas provides no

specific facts, nor has it detailed specific crimes it is investigating, to support a conclusion that these exceptions are inadequate or in any way injurious to the state's interest.

In light of its failure to plead the type of concrete injury-in-fact necessary to establish standing under binding precedent, including *Lujan*, as Defendants demonstrate, Texas has failed to carry its burden on this threshold jurisdictional issue and its claims must be dismissed. 504 U.S. at 560–61, 563–67; *Ctr. for Biological Diversity v. U.S. Env't Prot. Agency*, 937 F.3d 533, 545 (5th Cir. 2019) ("Article III demands more than . . . conclusory assertions.").

B. If Texas's Injury Is Adequate to Establish Standing, Any Claim Related to the 2000 Privacy Rule Is Necessarily Time-Barred.

Because the only injury Texas even attempts to allege is a generalized injury arising from the promulgation of the 2000 Privacy Rule, Compl. ¶ 8, its claims are time-barred. Even if such allegations were sufficiently concrete to confer standing—and they plainly are not—they would arise only from the 2000 Privacy Rule itself and not from any subsequently occurring injury. Even under *Corner Post*, 603 U.S. at 809, the APA's six-year limit expired long ago. For that reason, too, the claims regarding the 2000 Privacy Rule, which Texas has been subject to for over two decades, fail as a matter of law and should be dismissed as untimely.

CONCLUSION

For the foregoing reasons and those set forth by Defendants in support of their motion to dismiss or in the alternative for summary judgment, *see* Dkt. 20, and the administrative record cited therein, the Court should dismiss the Complaint in its entirety pursuant to Fed. R. Civ. P. 12(b)(1) and/or enter judgment for Defendants and dismiss as to the entirety of the Complaint pursuant to Fed. R. Civ. P. 56(a).

Date: January 17, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Jennifer R. Ecklund
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