**IN THE UNITED STATES OF AMERICA**
**EASTERN DISTRICT OF TENNESSEE**
**KNOXVILLE DIVISION**

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| State of Tennessee, *et al.*,<br><br>*Plaintiffs*,<br>v.<br><br>United States Department of Health and Human Services, *et al.*,<br><br>*Defendants*,<br><br>and<br><br>City of Columbus, Ohio; City of Madison, Wisconsin; and Doctors for America,<br><br>*Proposed Intervenor-Defendants.* | No. 3:25-cv-00025-KAC-JEM |

**MEMORANDUM OF LAW OF PROPOSED INTERVENOR-DEFENDANTS IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGEMENT AND PRELIMINARY INJUNCTION**

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## PRELIMINARY STATEMENT

Plaintiffs challenge rules that protect the confidentiality, use, and disclosure of patient health information involving lawful reproductive care. The confidentiality of patient health information that Plaintiffs seek to undermine is a cornerstone of effective health care and is governed by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936. Patients and clinicians alike rely on the protections afforded by HIPAA to use and disclose information regarding patient health care efficiently, effectively, and confidentially. HIPAA and its implementing regulations (the "Privacy Rules") ensure that identifiable patient information—including sensitive information touching on patients' symptoms, questions, fears, diagnoses, prognoses, test results, images, treatment, medical history, medication, wishes, and bills—is used and disclosed appropriately. When patient information does need to be disclosed for certain non-health care purposes, the Privacy Rules ensure that information remains confidential.

Plaintiffs target the final rule promulgated by the Department of Health and Human Services ("HHS" or the "Department") in 2024. *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) (codified at 45 C.F.R. pts. 160, 164) (the "2024 Rule" or the "Rule"). The Department promulgated the 2024 Rule consistent with the statutory authority expressly delegated to it by Congress in HIPAA. Congress directed the Department to "promulgate final regulations" containing "standards with respect to the privacy of individually identifiable health information," including specifically as 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." 42 U.S.C. § 1320d-2 note (codifying Pub. L. 104-191, title II, § 264). Congress further directed the Department to "adopt modifications to the standards (including

additions to the standards), as determined appropriate." *Id.* § 1320d-3(b)(1). In promulgating the 2024 Rule, the Department considered the relevant factors and acted well within its discretion.

Plaintiff States now request an order preliminarily enjoining the 2024 Rule, preventing its enforcement in the 15 states represented in the suit. Additionally, Plaintiffs request that this Court vacate and permanently enjoin the 2024 Rule nationwide, prioritizing their preferences over the clearly articulated will of Congress as represented by the text of the governing HIPAA statute. Plaintiffs cannot justify this extraordinary request.

At this juncture, the Court should only rule on Plaintiffs' request for preliminary relief, as Plaintiffs' motion for summary judgment is premature in the absence of the administrative record.

On the merits, the Court should deny Plaintiffs' motion for preliminary relief and for permanent relief, if the Court reaches that motion. Plaintiffs offer no meaningful argument that the 2024 Rule violates the APA. Though Plaintiffs assert that "nothing in HIPAA provides clear notice that Congress intended to upend" the States' police powers, Pls.' Mem. in Supp. of Summ. J. and Prelim. Relief ("Pls.' Mem."), ECF no. 26 at 19, they gloss over HIPAA's *explicit* preemption provision which states that "a provision or requirement under [HIPAA], or a standard or implementation specification adopted under [HIPAA] . . . shall supersede any contrary provision of State law." 42 U.S.C. § 1320d-7(a). Moreover, Plaintiffs' argument depends on a warped and atextual construction of both the scope of the preemption exceptions detailed in 42 U.S.C. § 1320d-7(b) and the 2024 Rule itself.

The remainder of Plaintiffs' claims are equally invalid. Neither the vagueness, non-delegation, nor major questions doctrines provide any basis to invalidate the Rule. Further, Plaintiffs claim that the 2024 Rule is arbitrary and capricious but fail to identify a single relevant factor that the Department did not consider. Pls.' Mem. at 20–22. To the contrary, HHS engaged in extensive,

reasoned analysis and fully explained the 2024 Rule.

The relief that Plaintiffs seek contravenes equitable principles. Plaintiffs are not likely to succeed on the merits and have utterly failed to assert irreparable harm. Moreover, vacating, enjoining, and setting aside the 2024 Rule—whether nationwide or in the 15 Plaintiff States—would be devastating for patients, providers, cities, and all who participate in the health care system.

## BACKGROUND

### I. THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

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." 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," *id.* § 1320d-2(a)(1), including unique identifiers for participants in the health care system, *id.* § 1320d-2(b), standards for transactions and data relating to health information, *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." *Id.* § 1320d-2 note. As required by the Act, the Department transmitted these recommendations to Congress within 12 months, on September 11, 1997. *Id.* §§ 1320d-2 note, 1320d-2(a)(1); *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82462, 82470 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164).

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." 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." *Id*. § 1320d-3. Congress 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. *Id*. § 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"). 65 Fed. Reg. 82470. The 2000 Privacy Rule established a set of national standards for protecting certain health information. *See* 45 C.F.R. § 164.502; 65 Fed. Reg. 82464. This included "general rules" for the use and disclosure of protected health information ("PHI"), as well as rules establishing individuals' rights regarding their PHI and listing specific circumstances when a covered entity is permitted to use or disclose PHI without an individual's consent. *See* 45 C.F.R. § 164.512; 89 Fed Reg 32982. Congress outlined penalties for wrongful disclosure—but only if it was a knowing violation of these rules. 42 U.S.C. § 1320d-6(a). The Department has continuously administered and updated the Privacy Rule since 2000. 89 Fed. Reg. 32977.

## II. THE 2024 RULE

The 2024 Rule that is the target of Plaintiffs' Complaint was finalized after the Department

proposed to amend the 2000 Privacy Rule to address recent legal developments, consistent with the principles and policy set forth by Congress in HIPAA and following an iterative rulemaking process that the statute expressly contemplated and authorized. *See* 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 . . . "); 89 Fed. Reg. 32981 ("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). The Department consulted with federal agencies and the National Committee on Vital and Health Statistics ("NCVHS"), and considered more than 25,900 comments, before finalizing the 2024 Rule. 89 Fed. Reg. 32976, 32978, 32991. 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 [it] 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 32978. This rule went into effect on June 25, 2024. *Id.* at 32976.

## LEGAL STANDARDS

A preliminary injunction is an "extraordinary and drastic remedy" that "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Fowler v. Benson*, 924 F.3d 247, 256 (6th Cir. 2019) (citations omitted). The movant must demonstrate that they are likely to succeed on the merits, they would suffer irreparable injury absent the injunction, and the balance of equities and the public interest support preliminary relief. *Id*. (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)).

Under FED. R. CIV. P. 56(a), "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Here, "[t]he application of that standard is shaped by the fact that, 'when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal,' not a forum of first impression." *Chamber of Com. of United States v. Sec. & Exch. Comm'n*, 670 F. Supp. 3d 537, 550–51 (M.D. Tenn. 2023) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)) "[A] court's review of an agency action under the APA . . . is limited to the administrative record, which includes materials compiled by the agency at the time its decision was made." *Latin Ams. for Soc. & Econ. Dev. v. Adm'r of Fed. Highway Admin.*, 756 F.3d 447, 464–65 (6th Cir. 2014) (citing *Sierra Club v. Slater*, 120 F.3d 623, 638 (6th Cir. 1997)). Summary judgment is the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record.

## ARGUMENT

### I. SUMMARY JUDGMENT IS PREMATURE

Plaintiffs' summary judgment motion is premature at this time because the full administrative record has not yet been submitted. It should be denied for that reason alone. "The APA *requires* courts to 'review the whole record'" and therefore, courts must "confine their review to the 'administrative record.'" *Sierra Club*, 120 F.3d at 638 (6th Cir. 1997). Plaintiffs implicitly acknowledge their own mistake—correctly stating that "[the] issues here . . . can be resolved *on the administrative record*." Pls.' Mem. at 11 (emphasis added). Without that full record, Plaintiffs' summary judgment motion and request for universal vacatur are untimely.[1] *See Dopico v.*

[1] In any event, vacatur would be improper because the Rule is lawful and any remedy should be

*Goldschmidt*, 687 F.2d 644, 646 (2d Cir. 1982) (concluding a "grant of summary judgment against the federal defendants" was "premature" because administrative record was not complete).[2] The Court should therefore only rule at this time on Plaintiffs' request for preliminary relief, deny or set aside their request for final judgment, and set a schedule for production of the administrative record and for all parties to file cross-motions for summary judgment with the benefit of that record.

## II. MANY PLAINTIFFS HAVE NOT DEMONSTRATED STANDING FOR A PRELIMINARY INJUNCTION

Because the Plaintiffs' request for summary judgment is premature, standing should be analyzed under the law applicable to a request for a preliminary injunction. In the Sixth Circuit, "a party who fails to show a 'substantial likelihood' of standing is not entitled to a preliminary injunction." *Memphis A. Philip Randolph Inst. v. Hargett*, 978 F.3d 378, 386 (6th Cir. 2020) (quoting *Waskul v. Washtenaw Cnty. Comm. Mental Health*, 900 F.3d 250, 256 n.4 (6th Cir. 2018)). The standard applies to *each* Plaintiff-State: "[I]f any [s]tate can't make this showing, [the court]

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tailored to Plaintiffs and account for the Rule's express severability provision. *See Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d 501, 521–27 (W.D. Ky. 2024); 45 C.F.R. § 164.535 ("If any provision . . . is held to be invalid or unenforceable . . . as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law"). To the extent the Court concludes that the Department did not adequately explain its reasoning in promulgating the Rule, those errors could be rectified on remand to the agency. *See Sierra Club v. EPA*, 60 F.4th 1008, 1022 (6th Cir. 2023) ("[R]emand without vacatur is surely appropriate" when "it is not at all clear that the agency's error incurably tainted the agency's decision[-]making process.").

[2] *See also Harkness v. Sec'y of Navy*, 174 F. Supp. 3d 990, 1004 (W.D. Tenn. 2016), *aff'd sub nom. Harkness v. Sec'y of Navy*, 858 F.3d 437 (6th Cir. 2017) ("in an APA claim, summary judgment becomes the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review. . . [t]he court's review is limited to the administrative record") (quoting *Nw. Motorcycle Ass'n v. Dep't of Agric.*, 18 F.3d 1468, 1472 (9th Cir. 1994)); *Oak Ridge Env't Peace All. v. Perry*, 412 F. Supp. 3d 786, 808-09 (E.D. Tenn. 2019) (same).

must deny it preliminary relief." *State of Tennessee v. Dep't of Educ.*, 104 F.4th 577, 588 (6th Cir. 2024). At the preliminary injunction stage, Plaintiffs cannot rest on mere pleadings; they must provide actual evidence of harm. *Waskul*, 900 F.3d, 255 n.3; *Littman v. Dep't of Lab.*, 2024 WL 5402344, at *6 (M.D. Tenn. Nov. 13, 2024).

The states of Arkansas, Alabama, Georgia, Idaho, Indiana, Iowa, Montana, Ohio, South Dakota, and West Virginia fail to adduce such evidence. Plaintiffs' brief offers only bare allegations that the Rule "impedes state investigations" and causes "expend[iture of] significant time and resources." Pls.' Mem. at 11-12. Plaintiffs' declarations are similarly conclusory, with declarants expressing general concerns about how those working in a state office may need to account for "time spent on completing the attestations [and] awaiting administrative approval," Decl. of Tanya Joiner, ECF no. 26-10, ¶ 9, or that or that the Rule "has the *potential* to complicate" state fraud investigations, Decl. of Ashley Klenski, ECF no. 26-9, ¶ 20 ("Klenski Decl.") (emphasis added)—hardly evidence of concrete, irreparable harm. *See also infra* Section V. Plaintiffs have not provided specific facts about imminently impacted investigations, outlined allocation of time or resources impacted by the Rule, or explained how compliance would differ from what is already required under HIPAA—mere allegations may be sufficient to satisfy the generous pleading standard, but they do not entitle Plaintiffs to injunctive relief. *Waskul*, 900 F.3d at 255 n.3.

## III. THE 2024 RULE IS CONSISTENT WITH HIPAA AND NOT IN EXCESS OF AUTHORITY

### A. HIPAA Provides for Broad Preemption of State Laws with Only Narrow and Enumerated Exceptions.

The claims of the remaining states that have standing also fail because the 2024 Rule is consistent with the text of the HIPAA statute. The HIPAA statute contains a clear and express preemption of contrary state law, 42 U.S.C. § 1320d-7(a), paired with a limited set of exceptions, *id*.

§§ 1320d-7(b), (c). Plaintiffs ignore this careful construction entirely and quote individual terms from the statute without any context. They ask the Court to endorse some nebulous and (in their view) inviolable "substantial sovereign power" regardless of the statute's express preemption language, Pls.' Mem. at 19, and in so doing, try to carve out a mile-wide exception that would entirely swallow the default rule of preemption.

Plaintiffs do not challenge HIPAA's general preemption provision itself. Nor could they—all that is required of Congress is a plain statement that makes its intention "clear and manifest" to "pre-empt the historic powers of the States." *Will v. Mich. Dep't. of State Police*, 491 U.S. 58, 65 (1989) (citation omitted). HIPAA clearly does so. 42 U.S.C. § 1320d-7(a) ("[A] provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall supersede any contrary provision of State law . . . ."). Such preemption is necessary to further the core purpose of HIPAA, and the rules promulgated thereunder, to provide uniform, nationwide standards for the secure exchange of private health information. *Id.* §§ 1320d note, 1320d-2(a)(1), (d), 1320d-2 note. This general preemption provision is subject only to limited exceptions:

> Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

*Id.* § 1320d-7(b).

Plaintiffs do not identify any particular exception within this list that the 2024 Rule infringes. Instead, they assert that this specific and limited carveout amounts to a broad and unrestricted pronouncement that no HIPAA rule can limit a State's broad police powers as it relates to public health and welfare. Pls.' Mem. at 17. Plaintiff's approach contravenes the fundamental rule "that when interpreting statutes, the language of the statute is the starting point for interpretation, and it

should also be the ending point if the plain meaning of that language is clear." *Tennessee v. Becerra*, 117 F.4th 348, 366 (6th Cir. 2024) (quoting *Saginaw Chippewa Indian Tribe of Mich. v. Blue Cross Blue Shield of Mich.*, 32 F.4th 548, 557 (6th Cir. 2022)); *see also Tennessee v. Dep't of Health and Hum. Servs.*, 720 F. Supp. 3d 564, 582–84 (E.D. Tenn. 2024), *aff'd sub nom. Tennessee v. Becerra*, 117 F.4th 348 (6th Cir. 2024).

Here, Congress has made a clear statement—there are only limited exceptions to general preemption under HIPAA. This list contains no general terms, references to state police powers, or any other open-ended language. There are only six specific and identified exceptions to the broad preemption explicitly provided for by the statute. 42 U.S.C § 1320d-7(b). For the 2024 Rule to run afoul of the statute, Plaintiffs must demonstrate that at least one these enumerated carveouts is implicated. Plaintiffs fail to make any such showing.

### B. The Plain Meaning of the Term "Public Health" Indicates That It Relates to Population-Level Health Information.

While Plaintiffs have not outright argued that the 2024 Rule prevents them from conducting any "public health surveillance, or public health investigation or intervention," *id.*, they use the term "public health" more than twenty times in their brief—mostly alongside generic references to allegedly inherent state powers in areas such as "public-health enforcement." Pls.' Mem. at 13–14. Thus, to the extent that Plaintiffs can be understood to be relying on any of the specific exceptions to the general preemption of state laws, it appears that Plaintiffs are suggesting that the 2024 rule impermissibly limits a reserved power to conduct "public health surveillance" or "public health investigation." Not so.

"Public health" is a well-established term of art used to describe *population-level* efforts to study and promote health. The dictionary definition of public health is: "the art and science dealing

with the protection and improvement of community health by organized community effort and including preventive medicine and sanitary and social science." "Public Health," MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (11th ed. 2014). Definitions of the term from medical and legal dictionaries as well as the Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry are in accord. 89 Fed. Reg. 33001 (citing "Health, Public Health," BLACK'S LAW DICTIONARY (11th ed. 2019) and "Public Health," STEDMAN'S MEDICAL DICTIONARY 394520). And the 2024 Rule itself defines "public health" as meaning "population-level activities." *Id.* at 33000–01.

The 2024 Rule, which concerns *individuals'* health records and investigation or imposition of liability on *specific individuals* for the mere act of seeking or providing legal health care, therefore has no impact at all on the public health-related exceptions in the HIPAA statute. Public health surveillance, investigation, and intervention may rely on information concerning individuals' health status and treatments—but that information is typically aggregated and anonymized, and used to benefit the overall population, not to prosecute individuals for lawful health care. From its inception, HIPAA was premised on striking a balance, protecting individual privacy without impeding the flow of information used to benefit the broader public—for example, through research or the management and control of infectious disease outbreaks. *See* Brief of Am. Coll. Of Obstetricians and Gynecologists and Soc'y for Maternal-Fetal Med., *Purl v. Dep't of Health & Hum. Servs.*, No. 2:24-cv-228 at 8–10 (N.D. Tex. Mar. 10, 2025), (ECF No. 77-1) (hereinafter "*Purl* ACOG Amicus Brief"). The 2024 Rule is fully consistent with this directive. Population-level public health efforts like public health investigations or interventions are distinguished from activities punishing individuals for the legal health care they seek or provide—with the 2024 Rule intentionally leaving intact state powers over the former. 89 Fed. Reg. 33001; *see also* 45 C.F.R. § 160.103. In short, when an

individual receives or provides lawful health care, and the state seeks that data for no purpose other than to investigate that individual, the state does not act under any "public health" purpose contemplated by Congress.

### C. The 2024 Rule Does Not "Limit" Valid State Public Health Authority Within the Meaning of HIPAA.

Even if the 2024 Rule does involve "public health" powers within the meaning of the exceptions to HIPAA's preemption provision, it still would not violate HIPAA for two related reasons: Plaintiffs misconstrue the meaning of "limit" as used in the applicable statute and Plaintiffs misconstrue the import of the 2024 Rule.

*First*, Plaintiffs adopt a remarkably and insupportably broad definition of the word "limit," as used in the phrase "invalidate or limit" in 42 U.S.C. § 1320d-7. Under Plaintiffs' reading, any HHS requirement—from the use of new reporting software to the presence of a new attestation form—would be an impermissible "limit" on state authority. *See* Compl., ECF no. 1 at ¶¶ 35, 63, 125, 130; Pls.' Mem. at 1, 13, 22. Such a reading is only possible because Plaintiffs read the word "limit" in a vacuum and ignore the actual text and *context* of the word "limit." *Contra Sackett v. EPA*, 598 U.S. 651, 674 (2023) ("The meaning of a word 'may only become evident when placed in context . . . .'") (quoting *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132, (2000)); *Greenbaum v. EPA*, 370 F.3d 527, 535–36 (6th Cir. 2004) (quoting the same); ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 195 (2012).

The word "limit" follows the word "invalidate," and, applying the *noscitur a sociis* canon of construction, must be understood with reference to its partner. Invalidate means that rules promulgated under HIPAA may not *literally* eliminate the "authority, power, or procedures established under any law" outlined in § 1320d-7(b). "Limit," then, is best understood to refer to

*substantial impairment* of the same—in other words, HHS may not effectively eliminate one of the enumerated powers, even if it has not been literally invalidated. To find otherwise would allow "the exception to swallow the rule" of preemption. *Cent. and S. Motor Freight Tariff Ass'n, Inc. v. U.S.*, 843 F.2d 886, 897 (6th Cir. 1988) (interpreting statute to avoid having exception swallow rule); *see also Bloate v. U.S.*, 559 U.S. 196, 210 (2010) (same); *Cuomo v. Clearing House Ass'n, L.L.C.*, 557 U.S. 519, 530 (2009) (same).

*Second* Plaintiffs misconstrue the scope of the 2024 Rule. That rule is narrow in scope and effect such that it does not "limit," any preserved state authority, even assuming such authority is shown to have been implicated. The 2024 Rule sets new standards governing requests for information about *lawful* reproductive health care for the *purposes of investigating or imposing liability* on a person for the *mere act* of seeking or providing the care. 45 C.F.R. § 164.502(a)(5)(iii)(A). It "*does not* seek to prohibit disclosures of PHI where the request is for reasons *other than* investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating [lawful] reproductive health care." 89 Fed. Reg. 32994 (emphases added). As explained above, the 2024 Rule reaffirms protection of individuals' personal records but explicitly does not cover population-level information—states remain free to seek and collect anonymized data to carry out their public health operations. The Rule only prevents disclosure of individual records regarding lawful health care, when the purpose of the request is to investigate or prosecute an individual on the sole basis of having obtained or provided that lawful care.

### D. The 2024 Rule Is Within HIPAA's General Grant of Authority.

HIPAA's grant of authority to HHS to promulgate the 2024 Rule is clearly constitutional. As a threshold matter, Congress expressly granted HHS the authority to promulgate, review, and modify

health privacy regulations. 42 U.S.C. § 1320d-2 note (statutory section titled "Promulgation of Rule"). Amendments to the HIPAA privacy rules, especially in response to changes in the health law landscape, are not "novel[]." Pls.' Mem. at 17-18. The 2024 Rule fits into a history of modifications to the HIPAA privacy rule, adopted in accordance with HIPAA's mandate for "review" and "modification." 42 U.S.C. § 1320d-3.[3]

Plaintiffs gesture at various constitutional arguments, none of which have merit.

*First,* the major questions doctrine is not implicated. Pls.' Mem. at 18-19. The 2024 Rule regulates only the disclosure of health care records pursuant to powers the agency has had for decades. 42 U.S.C. § 1320d-2 note. The major questions doctrine, on the other hand, applies, if at all, only when an agency "'exercise[s] powers of vast economic and political significance,'" *Tennessee*, 117 F.4th at 365 (quoting *Alabama Ass'n of Realtors v. Dep't of Health and Hum. Servs.*, 594 U.S. 758, 764 (2021)). The 2024 Rule does no such thing. It merely reinforces the privacy protections regarding the disclosure of health care records for lawful care, *after* care has been sought—it does not regulate whether that care should be sought in the first instance. *See*, *e.g.*, 45 C.F.R. § 164.502(a)(5)(iii)(B) (prohibiting disclosure when the "reproductive health care is lawful *under the law of the state* in which such health care is provided," or "protected, required, or authorized by Federal law") (emphasis added); *id.* § 160.103 (stating that the reproductive health

[3] As here, modifications to the HIPAA privacy rule have historically been made after changes to the health law landscape. In 2009, the Breach Notification Rule was added to the privacy rules, in response to passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act. 74 Fed. Reg. 42740 (Aug. 24, 2009). In 2013, the Omnibus Rule modified the Privacy Rule to strengthen protection of genetic information, in response to the Genetic Information Non-Discrimination Act. 78 Fed. Reg. 5566 (Jan. 25, 2013). In 2014 the Privacy Rule was modified to in response to the Clinical Laboratory Improvement Amendments (CLIA) regulations. 79 Fed. Reg. 7290 (Feb. 6, 2024). A 2016 Privacy Rule change allowed covered entities to disclose PHI to the National Instant Criminal Background Check System. 81 Fed. Reg. 382 (Jan. 6, 2016).

care definition "shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care"). And rather than grounding its authority in "the vague language of an ancillary provision of the Act," or ". . . effect[ing] a fundamental revision of the statute, changing it from one sort of scheme of . . . regulation into an entirely different kind," *West Virginia v. EPA*, 597 U.S. 697, 724, 728 (2022) (internal quotations omitted), the 2024 Rule's disclosure prohibition is an exercise of the Department's core authority under HIPAA to promulgate rules concerning permissible "uses and disclosures" of PHI, 42 U.S.C. § 1320d-2 note, and to adopt appropriate modifications to those rules, *id.* § 1320d-3(b)(1), as it has done for decades. 89 Fed. Reg. 32982–83; *see also Tennessee*, 117 F.4th at 365 (finding the major questions doctrine not to be implicated when an intelligible principle supported Congress's delegation).

*Second*, as explained in Section III.A above, Plaintiffs' reference to federalism ignores that Congress made its intention to preempt state regulatory and policing authority "clear and manifest," Pls.' Mem. at 19 (citing *Will*, 491 U.S. at 65)—it drafted HIPAA to include an *explicit* preemption provision cabined only by limited and specific exceptions.

*Third*, Plaintiffs' non-delegation argument is contradicted by *S.C. Med. Ass'n v. Thompson*, which found that HIPAA's delegation of authority to HHS expresses a clear intelligible principle to guide the agency's rulemaking such that it is "well within the outer limits" of the non-delegation doctrine. 327 F.3d 346, 351–52 (4th Cir. 2003). As Plaintiffs acknowledge, 42 U.S.C. § 1320d-7(b) *itself* constrains HHS's ability to limit the "reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." Pls.' Mem. at 20. Thus, because the 2024 Rule does not run afoul of 42 U.S.C. § 1320d-7(b), *see* Section III.A, Plaintiffs' nondelegation argument is inapposite.

*Finally,* HIPAA's strict scienter requirement allays concerns regarding arbitrary and

discriminatory enforcement. The Supreme Court has relied on scienter requirements as a way to "alleviate vagueness concerns," as they may "narrow the scope of the . . . prohibition and limit prosecutorial discretion." *Gonzales v. Carhart*, 550 U.S. 124, 149–150 (2007). HIPAA's criminal penalties provision includes a clear scienter requirement such that a violation of the Rule would only result in criminal penalties if the individual engaged in a *knowing* violation of the Rule. 42 U.S.C. § 1320d-6(a).

## IV. THE 2024 RULE IS NOT ARBITRARY AND CAPRICIOUS

HHS engaged in extensive, reasoned analysis before promulgating the 2024 Rule. In asserting that the 2024 Rule is arbitrary and capricious, Plaintiffs fail to identify a single relevant factor that the Department did not consider. *See* Pls.' Mem. at 20-22; *Adi v. United States*, 2011 WL 9613, at *5, *7 (N.D. Ohio Jan. 3, 2011) (rejecting APA claim where agency weighed the evidence differently than plaintiff and reached contrary but reasonable policy conclusions because "a court cannot re-weigh evidence simply because the plaintiff disputes the agency's finding") (internal quotations omitted).

In conducting arbitrary and capricious review 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) (abrogated on other grounds); *see also Volpe Vito, Inc. v. Dep't of Agric.*, 172 F.3d 51, at *1 (6th Cir. 1999) (unpublished table decision) (The court's "review of an administrative decision is narrow" and the court will "set aside an agency's action only if it is not supported by substantial evidence."). "'The court is not empowered to substitute its judgment for that of the agency.'" *Horton v. Dep't of Agric.*, 559 F. App'x 527, 530 (6th Cir. 2014) (quoting *Ne. Ohio Reg'l. Sewer Dist. v. EPA*, 411 F.3d 726, 732 (6th Cir. 2005)).

The Department's explanation for adopting the Rule readily meets this "narrow" and "highly deferential" standard. *See Horton*, 559 F. App'x at 530. After consulting with federal and state agencies and NCVHS and considering more than 25,900 comments representing approximately 51,500 individuals and 350 organizations, the Department found that "th[e] changing legal landscape increases the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system," and that the Rule's minimum protections and amendment to the Privacy Rule would "provide[] peace of mind that is essential to individuals' ability to obtain lawful reproductive health care." 89 Fed. Reg. 32978; *see also* 89 Fed. Reg. 32976, 32991; *FCC v. Fox TV Stations, Inc*., 556 U.S. 502, 515 (2009) (An agency does not act in an arbitrary and capricious manner by improving a regulatory scheme where "the new policy is permissible under the statute, [] there are good reasons for it, and [] the agency *believes* it to be better.") (emphasis in original). The Department also explained how the Rule is consistent with § 1320d-7(b) and clarified that a covered entity may not "disclose PHI as part of a report of suspected child abuse based *solely* on the fact that a parent seeks reproductive health care (*e.g.,* treatment for a sexually transmitted infection) for a child." 89 Fed. Reg. 33004 (emphasis added).

Plaintiffs' contrary arguments, *see* Pls.' Mem. at 20-22, ignore this careful review and are premised on an incorrect understanding of the Rule. The Department reasonably explained the Rule's requirements, including how covered entities determine the legality of reproductive health care when applying the 2024 Rule's disclosure prohibition. *See*, *e.g.*, 89 Fed. Reg. 33009–32. "[W]here a request for PHI is made to the regulated entity that provided the relevant reproductive health care" that entity should review "all available relevant evidence bearing on whether the reproductive health care was lawful under the circumstances in which it was provided." *Id*. at 33015.

Plaintiffs presumably must already assess the legality of any services that they provide to their patients. *Purl* ACOG Amicus Brief at 14. Conversely, the Rule recognizes that when a covered entity "did not provide the reproductive health care at issue, it may not have access to all of the relevant information" to make a legal determination and is "*not* expected to conduct research or perform an analysis of an individual's PHI." 89 Fed. Reg. 33014–15 (emphasis added). The covered entity is also "*not* required to make a determination about the lawfulness of such health care." *Id*. at 33012 (emphasis added). Instead, the entity can "presume[]" that the care was "lawful" unless it has "either actual knowledge, or factual information supplied by the person requesting the use or disclosure, that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id*. at 33014; 45 C.F.R. § 164.502(a)(5)(iii)(C).

The Department also provided a detailed account of how covered entities can comply with the attestation requirement. *See, e.g.*, 89 Fed. Reg. 33029–32. The Department explained that the attestation serves to alleviate "difficult[y] for regulated entities to distinguish between requests for the use and disclosure of PHI based on whether the request is for a permitted or prohibited purpose" by requiring the relevant state or federal agency to provide certain forms of information to the covered entity when they seek information potentially related to reproductive health care, *id.* at 33029–30, described when covered entities are entitled to rely solely on the attestation and when they should consider additional factors, *id.* at 33031–32, and provided a model attestation form and other resources to assist covered entities in applying the Rule, *see, e.g.*, Model Attestation, HHS (attached as Ex. A).

Plaintiffs' assertion that the Department provided "explanatory failures" for the Rule's framework, Pls.' Mem. at 21, is at odds with the facts and ignores the scores of descriptions and examples of how covered entities can comply with the Rule's requirements. *See, e.g.*, 89 Fed. Reg.

33009–32. The fact that the 2024 Rule requires covered entities to determine whether governmental requests for information are valid is "consistent with the current and longstanding practice under the Privacy Rule" where covered entities are responsible for determining the applicability of the Privacy Rule's permitted disclosures. *Id*. at 33013. Further, the Privacy Rule requires covered entities to make assessments involving "applicable law" to determine the authority of a "personal representative," 45 C.F.R. § 164.502(g), providing information about a deceased patient, *id*. § 164.512(g), and disclosing information relevant to a serious health threat, *id*. § 164.512(j). Plaintiffs have put forward no explanation for why covered entities can comply with pre-existing determinations but cannot ascertain the validity of the government's request for PHI. *See* Pls.' Mem. at 21.

Nor does the Rule require covered entities to "ignore what they may know" about state law. Pls.' Mem. at 21. The Department was clear that "if a person obtains reproductive health care that was unlawful" then the Rule's "prohibition does not apply" and the PHI may be disclosed consistent with the Privacy Rule. 89 Fed. Reg. 33012; *see* 45 C.F.R. § 164.502(a)(5)(iii)(B). The Rule's prohibitions would therefore be inapplicable if a covered entity has actual knowledge or a substantial factual basis to conclude that the care provided by someone else violates State law. *See* 89 Fed. Reg. 33012; 45 C.F.R. § 164.502(a)(5)(iii). Neither is it unreasonable, let alone a "clear error of judgment," *Overton Park*, 401 U.S. at 416, to require covered entities to determine whether the reproductive health care they provide is "protected, required, or authorized by Federal law," 45 C.F.R. § 164.502(a)(5)(iii)(B), when they presumably must already determine the legality of the care that they provide under federal law in their usual course of professional practice, or rely on the presumption of lawfulness when the care was provided by another entity, *id.* § 164.502(a)(5)(iii)(C).

The Department also explained at length how the Rule's scope balances "enhancing privacy

protections without unduly interfering with legitimate law enforcement activities." 89 Fed. Reg. 32993–95. Because the Rule only applies to disclosures in connection with *lawful* care, "in most situations involving reproductive health care that is not lawful . . . [the Rule] will not prevent the use or disclosure of PHI to investigate or impose liability on persons" for legal violations. *Id*. at 32994. The Department also provided several examples of law enforcement investigations outside the Rule's ambit, including governmental audits into federal programs and investigations into abusive conduct in connection with reproductive health care, *see id*. at 32994, and explained that the Rule "leav[es] unaffected" alternative investigatory means. *Id.* at 32995.

Finally, Plaintiffs' objections to how the Department defined "reproductive health care" are unfounded. *See* Pls.' Mem. at 21. The Department provided a detail explanation of the definition of reproductive health care, which was intended to "encompass[] the full range of health care related to an individual's reproductive health," in order to, among other reasons, "decrease the perceived burden to regulated entities of complying with the rule by helping them determine whether a request for the use or disclosure of PHI includes PHI that is implicated by [the Rule]." *See* 89 Fed. Reg. 33005–06. That "approach is consistent with the approach the Department took when it adopted the definition of 'health care' in the HIPAA Rules," which was framed broadly to avoid "confusion" and "the risk that important activities would be left out." 89 Fed. Reg. 33005.

In light of this record, Plaintiffs cannot show that the Department engaged in action that was "arbitrary, capricious, [or] an abuse of discretion" when promulgating the 2024 Rule. 5 U.S.C. § 706(2)(A); *see Kroger Co. v. Reg'l Airport Auth. of Louisville and Jefferson Cnty.*, 286 F.3d 382, 389 (6th Cir. 2002) ("The arbitrary or capricious standard is the least demanding review of an administrative action," requiring the challenging party to "show that the action had no rational basis or that it involved a clear and prejudicial violation of applicable statutes or

regulations.") (internal quotations omitted).

## V. AT A MINIMUM, PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION SHOULD BE DENIED

A preliminary injunction is an "extraordinary and drastic remedy" that "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Fowler v. Benson*, 924 F.3d 247, 256 (6th Cir. 2019) (citations omitted). The party moving for a preliminary injunction bears the burden of proof, *see Overstreet v. Lexington-Fayette Urban Cnty. Gov't*, 305 F.3d 566, 573 (6th Cir. 2002), and that burden must be met "by a clear showing." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (internal quotation marks and emphasis omitted).

In determining whether to issue a preliminary injunction, courts consider "(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury absent the injunction; (3) whether the injunction would cause substantial harm to others; and (4) whether the public interest would be served by the issuance of an injunction." *Daunt v. Benson*, 956 F.3d 396, 406 (6th Cir. 2020). Where the government is the defendant, the last two factors merge. *See id.* at 422. Courts consider these same factors in evaluating the granting of a stay pursuant to 5 U.S.C. § 705. *Barton v. Dep't of Lab.*, 2024 WL 4886048, at *6 (E.D. Ky. Nov. 25, 2024); *see also State of Ohio ex rel. Celebrezze v. Nuclear Regul. Comm'n*, 812 F.2d 288, 290 (6th Cir. 1987).

Plaintiffs cannot show any of the preliminary-injunction factors.

**Likelihood of Success on the Merits.** For the reasons stated above in Sections III and IV, they cannot show that they are likely to prevail on the merits of their claims. That alone is reason to deny preliminary relief. *See Tiger Lily, LLC v. Dep't of Hous. & Urban Dev.*, 992 F.3d 518, 524 (6th Cir. 2021). Nor have Plaintiffs shown that they face irreparable harm while this case is litigated,

and the equities tilt decisively against preliminary relief.

**Irreparable Harm.** Plaintiffs have "the burden of establishing a clear case of irreparable injury," *Garlock, Inc. v. United Seal, Inc.*, 404 F.2d 256, 257 (6th Cir. 1968) (per curiam), which is higher than what is required to establish standing. *See Ohio v. Yellen*, 539 F. Supp. 3d 802, 820 (S.D. Ohio 2021). Plaintiffs have failed to "establish[] a clear case of irreparable injury." *Garlock*, 404 F.2d at 257; *see also Yellen*, 539 F. Supp. 3d at 820 (irreparable harm standard is higher than ordinary injury to establish standing). To satisfy the heightened standard, Plaintiffs must show that their asserted injuries are "real," "substantial," and "immediate," not speculative or conjectural. *City of L.A. v. Lyons*, 461 U.S. 95, 111 (1983); *see also Memphis A. Philip Randolph Inst.*, 978 F.3d at 391 (6th Cir. 2020).

Plaintiffs' stated concerns regarding injury to their sovereignty are unfounded, and certainly not "immediate." As explained above, nothing in the 2024 Rule infringes on the States' valid public health efforts or any other exception to HIPAA's general preemption provision. *Supra* Section III. The Rule also respects a state's legitimate policy judgments by continuing to allow disclosure of information, consistent with the Privacy Rule's longstanding exceptions, in cases of *unlawful* reproductive health care. As described above, Plaintiffs have not even argued, much less shown, that the Rule conflicts with any state's duly enacted laws or their ability to report on "disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention," 42 U.S.C. § 1320d-7(b). *See* Pls.' Mem. at 12-22. Nor have they identified even a single pending enforcement action against them, a far cry from any "certain and immediate" harm that would warrant a preliminary injunction. *See Memphis A. Philip Randolph Inst.*, 978 F3d at 391.

Plaintiffs' perfunctory and vague assertions regarding "compliance costs" are equally unavailing. *See* Pls.' Mem. at 24. Because compliance costs "commonly result from new

government regulation," courts look to the "peculiarity and size" of those costs in evaluating whether they suffice to constitute irreparable harm. *Kentucky v. Biden*, 57 F.4th 545, 556 (6th Cir. 2023). Plaintiffs, however, have made no effort to quantify their costs, and their allegations that the Rule "may require" substantial resources to comply with are far too speculative. *See*, Decl. of Kelley Groover, ECF no. 26-1, ¶ 15 ("Groover Decl."); *see also* Klenski Decl. ¶ 16 (averring "time and resources" had to be spent to comply with Rule); Decl. of Jordan Stover, ECF no. 26-14,¶ 12 (Rule's attestation requirement "has imposed compliance costs"); Decl. of Katherine Ziegler, ECF No. 26-2, ¶ 17 (same).

**Equities and Public Interest.** The equities and public interest tilt decisively against relief. Preliminarily enjoining the Rule as to Plaintiffs would frustrate HIPAA's purpose by risking disclosure of patients' sensitive and protected reproductive health information across fifteen states. As the Department found, "[i]nformation about reproductive health care is particularly sensitive and requires heightened privacy protection." 89 Fed. Reg. 32990; *see also id.* at 32986–87 (citing the American Medical Association's Principles of Medical Ethics and recommendations of NCVHS). Enjoining the Rule would lead to the exposure of patient reproductive health information, particularly in light of the shifting legal landscape, *see id*. at 32987, and exact irreparable harm to untold patients in Plaintiffs' jurisdictions. *See Lee v. City of Columbus, Ohio*, 2008 WL 2557255, at *11 (S.D. Ohio June 24, 2008) (stating that irreparable harm arises from "impermissible disclosure of confidential medical information"). Records can always be released in the future—but once disclosed, that information cannot reasonably be clawed back. *See id.*

The possibility of disclosure will also jeopardize access to necessary medical care by generating fear among patients about how their private medical information may be used. As the Department has long recognized, "individuals may be deterred from seeking needed health care if

they do not trust that their sensitive information will be kept private." 89 Fed. Reg. 32984; *see* 88 Fed. Reg. 23508 (Apr. 17, 2023) (citing scientific studies, NCVHS letters, news articles, and legal briefs to illustrate the damaging effects of medical mistrust); 65 Fed. Reg. 82468 (citing studies demonstrating the widespread fear of disclosure of medical information). Other patients may seek care but withhold information from their providers, depriving providers of "necessary information . . . for an appropriate treatment plan, which may result in negative health outcomes at both the individual and population level." 89 Fed. Reg. 32991. And even when a provider receives accurate information, if they do not trust that the records will be kept private, the "provider may leave gaps or include inaccuracies when preparing medical records, creating a risk that ongoing or future health care would be compromised." *Id.* at 32985.

Plaintiffs' stated concern for the interests of investigations into fraud, abuse, and substandard care is unfounded. *See* Pls.' Mem. at 25. As explained above, nothing in the 2024 Rule interferes with legitimate investigations into *unlawful* reproductive health care, or requests not directed at imposing liability for the mere act of receiving lawful care. 89 Fed. Reg. 33012; *see supra* Section III.C, IV. Though Plaintiffs complain that they have been denied access to patient records pursuant to investigatory requests, their examples make clear that these denials were simply because Plaintiffs *failed to provide the requisite attestation*. *See* Pls.' Mem. at 5, 9; Groover Decl. ¶¶ 5-8. Moreover, Plaintiffs fail to provide sufficient, non-conclusory justifications for declining to provide such attestation. *See* Pls.' Mem. at 9, Groover Decl. ¶ 8. There is also "inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to direct that agency to develop and enforce." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008). If the merits are unclear, the importance of protecting the private medical information of patients should carry the day over Plaintiffs' unfounded concerns about compliance with the 2024 Rule.

## CONCLUSION

For these reasons, the Court should deny Plaintiffs' and Defendants' motion for summary judgement and for preliminary injunction and grant Intervenor-Defendant's motion for summary judgement.

Date: March 13, 2025

Respectfully submitted,
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**CERTIFICATE OF SERVICE**

I hereby certify that on March 13, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

*/s/ Shannon R. Selden*
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