IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

AMERICAN HOSPITAL ASSOCIATION, et al.,	§	
Plaintiffs,	§	
v.	§	No. 4:23-cv-1110-P
BECERRA, et al.,	§	
Defendants.	§	

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Jonathan D. Guynn (TX 24120232)
JONES DAY
2727 N. Harwood St., Ste. 500
Dallas, Texas 75201
(214) 220-3939
(214) 969-5100 (fax)
jguynn@jonesday.com

Hashim M. Mooppan* (DC 981758)
Rebekah B. Kcehowski* (PA 90219)
Jack L. Millman* (NY 5517180)
Audrey Beck* (DC 1739917)
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939
(202) 626-1700 (fax)
hmmooppan@jonesday.com
rbkcehowski@jonesday.com
jmillman@jonesday.com
abeck@jonesday.com
* *Pro hac vice*

Counsel for Plaintiffs

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

INTRODUCTION AND SUMMARY

The U.S. Department of Health and Human Services (HHS) has issued a new rule that is flawed as a matter of law, deficient as a matter of administrative process, and harmful as a matter of policy. The rule prohibits the use of certain technologies that make healthcare providers' public webpages more effective in sharing vital information with their communities. In doing so, it exceeds the government's statutory and constitutional authority, violates the substantive and procedural requirements for agency rulemaking, and injures the very people it purports to protect. A gross overreach by the federal bureaucracy, imposed without any input from healthcare providers or the general public, this new rule is being actively enforced by HHS against hospitals and health systems across the country, even while the federal government's own healthcare providers continue to use these purportedly prohibited technologies on their own webpages.

The rule is contrary to law because it restricts the use of information that is not protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Count 1), and it also is final agency action that violates the Administrative Procedure Act (APA) because it provided an arbitrary-and-capricious rationale (Count 2) and failed to go through the notice-and-comment process (Count 3). On each of these purely legal claims, Plaintiffs are entitled to summary judgment because there are no genuine disputes of material fact. This Court should declare the rule unlawful, set it aside, and enjoin its enforcement against Texas Health Resources and United Regional Health Care System (the Hospitals) and the other members of the American Hospital Association and the Texas Hospital Association (the Associations).

As HHS itself has recognized, "[a] major goal" of HIPAA and its implementing regulations is to "strike[] a balance." HHS, *Summary of the HIPAA Privacy Rule* (2022), https://perma.cc/MCG3-QFHX. While "assur[ing] that individuals' health information is properly protected," they "allow[] the flow of health information needed to provide and promote high

quality health care and to protect the public's health and well being." *Id.* Especially given that the U.S. Surgeon General has urged healthcare providers to combat "[h]ealth misinformation" by "shar[ing] accurate health information with the public," V. Murthy, *Confronting Health Misinformation* 10 (2021), https://perma.cc/YD2V-4QJE, it is "fundamental" that patients "be able to quickly and easily access needed information," HHS, *Understanding Some of HIPAA's Permitted Uses and Disclosures* (2016), https://perma.cc/N7FC-DTW8.

Healthcare providers have honored the balance HIPAA strikes. While safeguarding the privacy of data like patient records and billing statements, they have shared non-private health-related information with the communities they serve, including through publicly accessible webpages that do not require or request visitors to enter login information for user authentication (an Unauthenticated Public Webpage). And to strengthen the effectiveness of such webpages in informing the public, many providers have used third-party technologies that rely on the IP address of a page visitor's computer to function. For example, map and location tools can expedite travel to hospitals when time may be of the essence, and analytics tools can improve the usefulness of the pages for visitors and the allocation of resources by health systems.

Until recently, this widespread and beneficial practice was not affected by HIPAA. Consistent with the HIPAA balance, providers could provide technology vendors with the IP addresses of visitors to Unauthenticated Public Webpages, because such information is not "individually identifiable health information" (IIHI) protected from disclosure. As explained further below, it is not "information" that (1) "relates to" the health condition, healthcare, or healthcare payments "of an individual"; and (2) "identifies the individual" or at least provides "a reasonable basis to believe that the information can be used to identify the individual." 42 U.S.C. § 1320d(6)(B); *accord* 45 C.F.R. § 160.103.

In late 2022, however, HHS's Office for Civil Rights (OCR) issued a sub-regulatory "Bulletin" purporting to extend HIPAA's disclosure restrictions to this type of information. HHS, *Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates* (2022) (Bulletin); Appx. 1-14. While the Bulletin addresses various issues, Plaintiffs here challenge only the Bulletin's new rule that when an online technology connects (1) an individual's IP address with (2) a visit to an Unauthenticated Public Webpage that addresses specific health conditions or healthcare providers, that combination of information (the Proscribed Combination) is IIHI subject to HIPAA's disclosure restrictions. *See id.* at 5. That rule is unlawful for three separate reasons.

First, and most fundamentally, the rule exceeds HHS's authority. The computer IP address of a person who visited an Unauthenticated Public Webpage that addresses specific health conditions or healthcare providers falls far outside the IIHI definition. It is not even remotely "information" that provides a reasonable basis to identify "the individual" (if any) whose own health, healthcare, or payment for health care actually "relates to" the visit. 42 U.S.C. § 1320d(6)(B); *accord* 45 C.F.R. § 160.103. Even assuming (without conceding) that such information may provide a reasonable basis for identifying the person who *visited* the webpage—say, that John Smith visited a page for booking dialysis appointments, or Mary Jones visited a page about the onset of Alzheimer's disease—that establishes nothing. There are many *generic reasons* why they may have visited such pages, entirely unrelated to the health, healthcare, or payment for healthcare of *any* particular individual (*e.g.*, they could be public-health researchers or hospital employees). In addition, even if their visits were related to *some* individual's healthcare needs, they could have been acting for family members, friends, or countless other *third parties*. And their IP addresses provide no reasonable basis to determine otherwise. Without contesting any of this, HHS baldly asserted that the Proscribed Combination is "indicative" of the visitor's own

health status or treatment, *see* Appx. 4, but any such inference drawn from internet metadata falls far short of what the IIHI definition requires, as courts have recognized. Moreover, a narrower construction of the definition is compelled by the canon of constitutional avoidance, given the serious First Amendment concerns posed by restricting hospitals' right to provide metadata from their public webpages to their technology vendors in order to improve those communicative tools.

Second, even if the rule were arguably permissible under the IIHI definition, HHS's rationale was arbitrary and capricious, violating the APA's substantive requirements. HHS's conclusory assertion that the Proscribed Combination constitutes IIHI based on an "indicative" connection is not supported by any reasoning of any kind. Nor did HHS give any consideration to the myriad motivations that individuals may have for visiting an Unauthenticated Public Webpage besides their own health, or to the competing policy concerns in light of the beneficial ways in which providers actually use webpage metadata. In fact, HHS did not even acknowledge, much less justify, the novelty of its position—a sea change that drastically upsets reliance interests in this sphere and starkly conflicts with the federal government's own use of third-party technologies on agency webpages that are themselves covered by HIPAA.

Third, at the very least, the rule is procedurally defective under the APA because it did not go through notice-and-comment rulemaking, a process that would have allowed covered entities to raise their concerns and required HHS to respond. No exception to that process applies here, because the rule speaks with the force of law by significantly altering covered entities' obligations and conduct under the regulatory status quo. Indeed, soon after issuing its new rule, HHS began systematically enforcing it, publicly warning covered entities to comply and privately launching compliance investigations backed by the threat of civil penalties.

Accordingly, Plaintiffs are entitled to summary judgment and relief from this unlawful rule.

BACKGROUND

A. Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, § 264(c)(1), 110 Stat. 1936, 2033 (1996), HHS promulgated the Privacy Rule, a longstanding set of regulations that establish standards for the privacy of certain health-related information. *See* 45 C.F.R. § 160.101 *et seq.*, § 164.102 *et seq.*, § 164.500 *et seq*. Under the Privacy Rule, covered entities "may not use or disclose protected health information [PHI]," except as permitted by the regulations. *Id.* § 164.502(a); *see id.* § 160.103 (defining a covered entity to include "a health care provider who transmits any health information in electronic form in connection with a transaction" subject to the Privacy Rule).[1]

Critically, the disclosure prohibition does not apply to *all* health-related information. Consistent with the balance struck by HIPAA and the Privacy Rule, PHI is a carefully defined and narrowly circumscribed term. *See Wilson v. UnitedHealthcare Ins. Co.*, 27 F.4th 228, 245-46 (4th Cir. 2022). In particular, PHI is limited to certain types of "individually identifiable health information [IIHI]," which in turn is defined as health information that:

> (1) Is created or received by a health care provider [or other covered entity]; and
> (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
>
> (i) That identifies the individual; or
>
> (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

45 C.F.R. § 160.103; *accord* 42 U.S.C. § 1320d(6). In short, IIHI is limited to information that is related to a *specific person's health* and reasonably capable of being used to identify *that person*—

[1] The Privacy Rule permits a covered entity to disclose PHI to a "business associate" only if that third party is willing to enter into an agreement that, among other things, requires the associate to accept the covered entity's legal obligations if it is performing the entity's duties, to implement appropriate safeguards, and to make certain information available to individuals and the government. *See* 45 C.F.R. §§ 164.502(e), 164.504(e).

such as, for example, unredacted patient records or billing statements. *See Wilson*, 27 F.4th at 246-47 (distinguishing between "generic documents" related to a health plan and "medical records" containing "contents from which [the patient] could be reasonably identified").

B. In December 2022, HHS issued the Bulletin, which purports to explain how HIPAA's Privacy Rule applies to covered entities when using certain online technologies. Although the Bulletin addresses various topics that are not at issue here (such as password-protected patient portals), Plaintiffs are challenging only the new rule in the Bulletin treating as IIHI the Proscribed Combination—*i.e.*, where an online technology connects (1) an individual's IP address with (2) a visit to an Unauthenticated Public Webpage that addresses specific health conditions or healthcare providers. *See* Appx. 5.[2]

In contrast to other portions of the Bulletin that use hedging language to qualify the positions taken, the Bulletin definitively adopted the rule that the Proscribed Combination constitutes IIHI. In particular, when discussing "unauthenticated webpages," the Bulletin unequivocally said the following: "For example, tracking technologies could collect an individual's email address and/or IP address when the individual visits a regulated entity's webpage to search for available appointments with a health care provider. *In this example*, the regulated entity *is disclosing PHI* to the tracking technology vendor, and *thus the HIPAA Rules apply*." *Id.* (emphasis added). And that example simply illustrated the Bulletin's broader conclusion in the preceding sentence that "[t]racking technologies on a regulated entity's

[2] Although the Bulletin treats webpages that require visitors to enter login information for access as user-authenticated pages, it treats the login pages themselves as unauthenticated because they merely request the login information. *See* Appx. 4-5. Because Plaintiffs are not challenging the Bulletin's application to patient portals or the login pages for such portals, they have defined Unauthenticated Public Webpage narrowly here for ease of exposition—to repeat, Plaintiffs challenge the Bulletin's application *only* to publicly accessible webpages that *neither* require *nor* request visitors to enter login information for user authentication.

unauthenticated webpage that addresses *specific symptoms or health conditions* … or that permits individuals *to search for doctors or schedule appointments* without entering credentials may have access to PHI in certain circumstances." *Id.* (emphasis added).

In other words, the "certain circumstances" that HHS deems sufficient for an Unauthenticated Public Webpage's technology to create PHI is that the page addresses specific health conditions or healthcare providers *and* technology on the page collects the IP addresses (or email addresses) of visitors to the page. *See id.* After all, the only difference between the broader qualified sentence and the specific unqualified example is the collection of the IP or email address. *See id.* In HHS's view, that Proscribed Combination is IIHI "even if the individual does not have an existing relationship with the regulated entity," because the information purportedly "*connects* the individual to the regulated entity (*i.e.*, it is *indicative* that the individual has received or will receive health care … from the covered entity), and thus relates to the individual's past, present, or future health or health care or payment for care." *Id.* at 4. (emphasis added). Despite recognizing that the "insights" derived from technologies collecting such metadata "could be used in beneficial ways to help improve care or the patient experience," HHS never explained why such metadata threatens patient privacy in the absence of any reason to think, or basis to conclude, that the individual's own health was the reason for visiting the page. *See id.* at 3.[3]

Having issued the Bulletin without consulting with the regulated community, *see id.* at 25-26, OCR then sent an identical warning letter about the Bulletin to 130 hospital systems and telehealth providers. Belying the Bulletin's nominal disclaimer that it "do[es] not have the force and effect of law" and is "not meant to bind the public in any way," *id.* at 9, OCR's warning letter

[3] HHS did acknowledge, though, that its rule does not extend to Unauthenticated Public Webpages that merely provide "general information about the regulated entity." Appx. 5. And it similarly suggested there may be "limited situations" where "an IP address … by itself may not" identify the visitor, such where the visitor "uses a computer at a public library." *Id.* at 12 n.21.

"strongly encourag[ed]" recipients "to review" and "take actions" in light of the Bulletin, admonishing that the agency is "closely watching developments in this area," Letter 1-3 (July 20, 2023); Appx. 15-17. Soon thereafter, the government publicly released the recipients' names.

In a press release announcing the warning letters, OCR Director Rainer emphasized that HHS "will use all of its resources to address" its "concern[]" that covered entities' use of online technologies results in "impermissible disclosures of health information." HHS, *HHS Office for Civil Rights and the Federal Trade Commission Warn Hospital Systems and Telehealth Providers About Privacy and Security Risks from Online Tracking Technologies* (July 20, 2023); Appx. 18-22. The press release further confirmed that HHS has been conducting "active investigations nationwide to ensure compliance" with the Bulletin. *Id.* Among other tools, HHS has the power to subject covered entities to onerous compliance reviews and to impose civil penalties for asserted violations. *See* 45 C.F.R. §§ 160.310, 160.312, 160.314.

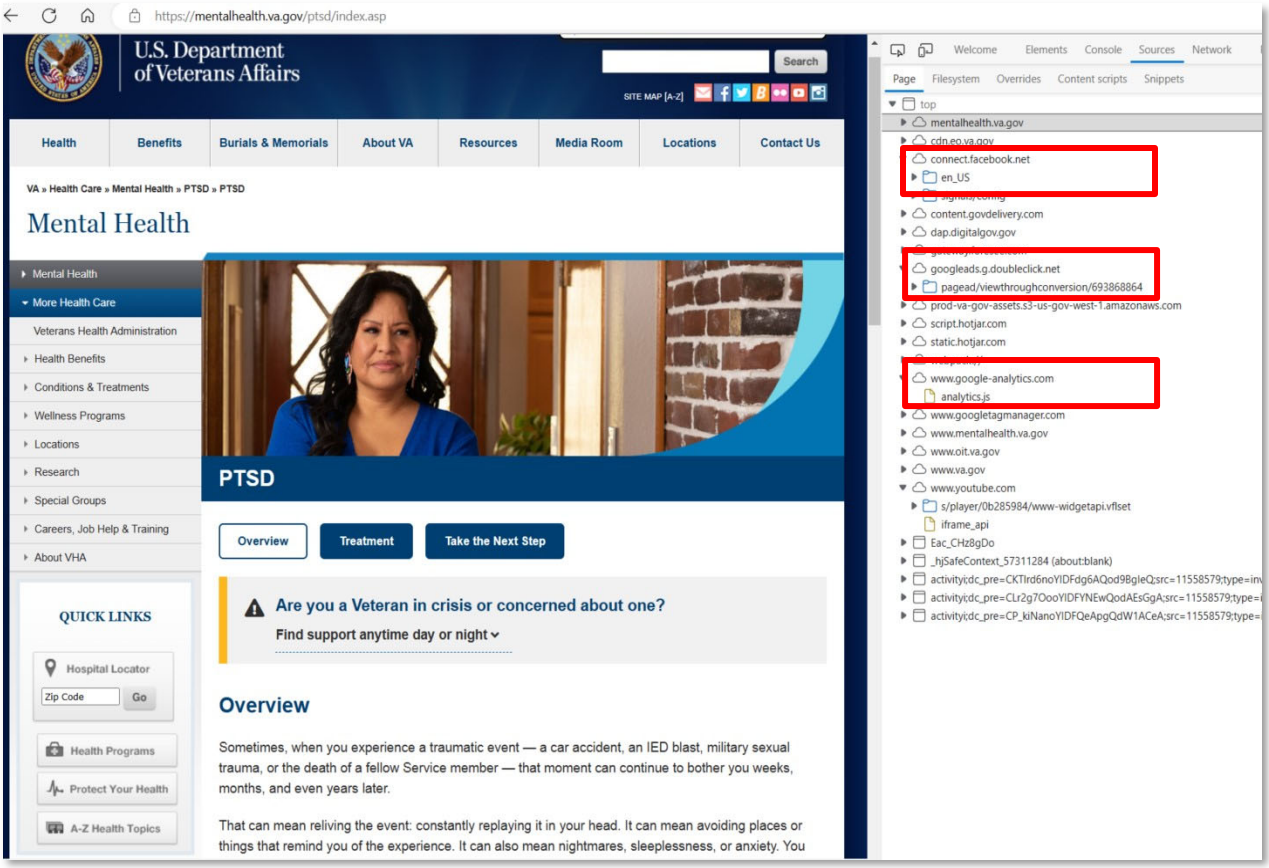
A month later, acting OCR Deputy Director Susan Rhodes reiterated that HHS is "continuing to investigate … to really make sure that healthcare providers" understand the Bulletin's rule for online technologies. Asked when enforcement action may be taken, she stated this is "a very important area for [HHS]," emphasizing that there are "open investigations … across the country right now" and that HHS "do[es] use [its] investigations to … highlight messages to the industry." Healthcare Info Security, *Why HHS Regulators Are Heavily Scrutinizing Web Tracker Use*, Video (Aug. 17, 2023), https://perma.cc/E9SF-MB6S (1:56, 3:22, 3:33, 3:43).

C. The Bulletin's new rule that the Proscribed Combination constitutes IIHI under HIPAA threatens to fundamentally disrupt how healthcare providers operate their Unauthenticated Public Webpages. Appx. 26. Many providers have long strengthened the utility and functionality

of their webpages by employing online technologies that disclose the IP addresses of page visitors to third-party technology vendors. *Id.* at 24-25.

For example, analytics tools convert web users' interactions with hospital webpages into critical data. *Id.* They can show the level and concentrations of community concern on particular medical questions—say, how many IP addresses in certain areas looked for information about RSV vaccines or diabetes treatment—allowing hospitals to more effectively allocate their medical and other resources. *Id.* They can also help improve the navigability of the webpages, identifying areas where users had difficulty or making the experience more seamless for individuals with disabilities. *Id.* In addition, map and location tools that rely in part on IP addresses provide better information about where healthcare services are available, including through embedded applications that provide bus schedules or driving directions to and from a community member's location. *Id.* at 25. Likewise, third-party video tools that allow hospitals to educate the community about health conditions and treatments typically rely on visitors' IP addresses to function, as do third-party translation tools that facilitate access to their webpages by non-English speakers. *Id.*

Indeed, "[g]overnment programs that pay for health care, such as Medicare, Medicaid, and the military and veterans health care programs" are themselves "covered entities" under HIPAA, HHS, *Covered Entities and Business Associates* (2017), https://perma.cc/VY4K-M55S, *and yet they continue to use* such third-party technologies on their own webpages. As one of many possible examples, web browser inspection and source tools show that, among other technologies, third-party analytics and advertising tools are present on Veterans Health Administration webpages addressing specific health conditions or healthcare providers, including but not limited to a page describing the symptoms of post-traumatic stress disorder and pointing veterans to treatment sources:



See Compl., ECF 1, at 4-5; *see also, e.g.*, *id.* at 5-7 (depicting additional examples from HHS's Medicare.gov website and the Defense Department's Military Health System webpages). Thus, the federal government's own HIPAA-covered entities continue to create the Proscribed Combination and disclose that information to their third-party technology vendors, notwithstanding HHS's Bulletin.[4]

D. The Hospitals and the Associations' other members are covered entities subject to the Bulletin because they are healthcare providers who transmit health information in electronic form in connection with transactions covered by the Privacy Rule. *See* 45 C.F.R. § 160.103; Appx.

[4] This Court may take judicial notice of information contained within government webpages. *See Cicalese v. Univ. of Texas Med. Branch*, 456 F. Supp. 3d 859, 871-72 (S.D. Tex. 2020) (posted license); *L'Garde, Inc. v. Raytheon Space & Airborne Sys.*, 805 F. Supp. 2d 932, 937-38 (C.D. Cal. 2011) (search results).

24, 35, 40, 47. One of the Hospitals, and other members of the Associations, received HHS's warning letter about the Bulletin and were exposed as recipients. Appx. 29, 37-38. In fact, some members of the Associations are currently undergoing HHS investigations regarding the online technologies used on their Unauthenticated Public Webpages. *Id.* at 28-29.

As a result of HHS's systematic threats of enforcement, the Bulletin imposes a significant obstacle to using these valuable tools, and the Hospitals and the Associations' other members have been forced to incur substantial compliance costs. This includes both the financial costs in ensuring that their Unauthenticated Public Webpages that address specific health conditions or healthcare providers do not use third-party technologies that can disclose IP addresses, and the more consequential operational harm that they are refraining in various ways from the use of such information to improve the efficacy of their webpages. *Id.* at 27-28, 30, 36-38, 41-44. But for HHS's threatened enforcement of the Bulletin, the Hospitals and other members of the Associations would employ such technologies in those ways. *Id.*

Plaintiffs filed this action in November 2023, claiming that the Bulletin's new rule exceeds HHS's authority and violates the APA. Compl., ECF 1, at 19-21. They seek an order declaring that the Proscribed Combination is not IIHI, setting aside the Bulletin's contrary rule, and enjoining HHS from enforcing that rule against the Hospitals and the Associations' other members. *Id.* at 21. This Court granted the parties' joint request to dispense with a responsive pleading and proceed to cross-motions for summary judgment. Order, ECF 22, at 1.

JURISDICTION

Starting with constitutional jurisdiction, the Hospitals and Associations have Article III standing to bring this action. That doctrine requires plaintiffs to prove an "injury in fact," a sufficient "causal connection" between the injury and defendants' challenged conduct, and a likelihood that the injury "will be redressed" by the relief requested. *SBA List v. Driehaus*, 573

U.S. 149, 157-58 (2014); *see Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977) (an association has standing to sue on behalf of members who "otherwise have standing to sue in their own right" where, as here, "the interests it seeks to protect are germane to the organization's purpose" and the claim for relief does not "require[] the participation of individual members").

In the context of a pre-enforcement challenge to allegedly unlawful government regulation of private conduct, the standing elements are satisfied where there is a "credible threat of enforcement" by the government that would be eliminated if the court deems the regulation unlawful. *SBA List*, 573 U.S. at 159. Regulated entities are "not require[d] … to expose [themselves] to liability before bringing suit to challenge the basis for the threat," especially where the "course of conduct" that the government is threatening is "arguably affected with a constitutional interest." *Id.* Instead, the threatened enforcement itself "creates an Article III injury," by chilling the challenged conduct and requiring regulated parties to incur other costs of compliance. *See id.* at 158. For example, in *Braidwood Management, Inc. v. EEOC*, 70 F.4th 914 (5th Cir. 2023), the Fifth Circuit held that certain employers had standing to bring a pre-enforcement challenge to "EEOC guidance" that raised "statutory and constitutional issues" and "forc[ed]" them to either "restrict their religious practices" or "risk potential penalties." *Id.* at 926. The court emphasized that the employers had "a legitimate fear" of enforcement and that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Id.* at 926-27.[5]

[5] Likewise, prudential ripeness concerns "generally" do not prevent an affected party from "secur[ing] review before enforcement" of "agency regulations," "so long as the issues are fit for judicial review without further factual development and denial of immediate review would inflict a hardship on the challenger—typically in the form of its being forced either to expend non-recoverable resources in complying with a potentially invalid regulation or to risk subjection to costly enforcement processes." *Seegars v. Gonzales*, 396 F.3d 1248, 1253 (D.C. Cir. 2005) (citing *Abbott Labs v. Gardner*, 387 U.S. 136, 149 (1967)); *accord Braidwood*, 70 F.4th at 930-32.

The Hospitals and Associations here plainly have standing for the same reasons. In the Bulletin, HHS definitively decreed that the Proscribed Combination is IIHI subject to HIPAA's disclosure and use restrictions, *see supra* at 6-7, and it has commenced a robust effort to enforce the Bulletin, including by sending warning letters to one of the Hospitals and initiating investigations of other members of the Associations, *see supra* at 7-8. As a result, the Hospitals and the Associations' other members are incurring financial costs to comply with the Bulletin's new rule and are being deterred from using online technologies on their Unauthenticated Public Webpages that address specific health conditions or healthcare providers, *see supra* at 8-11. The operational harm from that chilling effect is especially injurious because they have a First Amendment interest in providing information about the metadata from their public webpages to third-party technology vendors in order to improve the utility and functionality of those webpages in communicating with the public about important healthcare matters. *See infra* at Part I.C.

Turning to statutory jurisdiction, this Court has subject-matter jurisdiction because Plaintiffs raise claims under two federal laws (HIPAA and the APA) and also seek relief against the United States. 28 U.S.C. §§ 1331, 1346(a)(2). Congress has waived the federal government's sovereign immunity against those claims, in a statute providing that "[a]n action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States." 5 U.S.C. § 702. Plaintiffs' action falls squarely within the plain terms of that sentence in Section 702, which would be sufficient to establish the waiver of immunity in most courts. *See Walmart Inc. v. U.S. Dep't of Justice*, 21 F.4th 300, 307-08 (5th Cir. 2021). And while

the Fifth Circuit has (erroneously) construed the Section 702 waiver more narrowly, *see id.*, that difference is immaterial here because Plaintiffs' suit also satisfies the narrower standard.

The Fifth Circuit has held that Section 702 waives immunity only if a plaintiff can satisfy the additional requirements in the judicial-review sentence preceding the immunity waiver: the plaintiff (1) "must identify some 'agency action' affecting him in a specific way"; and (2) "must show that he … is adversely affected or aggrieved by that action within the meaning of a relevant statute." *Alabama-Coushatta Tribe of Tex. v. U.S.*, 757 F.3d 484, 489 (5th Cir. 2014). The second requirement is straightforward: to satisfy the "adversely affected or aggrieved" standard, "the plaintiff must establish that the injury he complains of falls within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for his complaint." *Apter v. HHS*, 80 F.4th 579, 589-90 (5th Cir. 2023). The first requirement is more nuanced, as the type of "agency action" necessary depends on the nature of the claim: where the plaintiff asserts "a statutory or non-statutory cause of action that arises completely apart from the general provisions of the APA," "there only needs to be 'agency action' as set forth by 5 U.S.C. § 551(13)"; but where the plaintiff asserts a claim "pursuant only to the general provisions of the APA" itself, the higher standard for "final agency action" under 5 U.S.C. § 704 must be met. *Alabama-Coushatta Tribe*, 757 F.3d at 489.

Here, as for the "adversely affected or aggrieved" requirement—which applies the same to all three of Plaintiffs' claims—the Hospitals and the Associations' other members easily satisfy the "not especially demanding" standard of showing that they are "arguably within the zone of interests to be protected" by HIPAA. *See Apter*, 80 F.4th at 592. After all, HHS itself concedes that HIPAA "strikes a balance" by "protecting the privacy of people who seek care and healing" while "allowing the flow of health information needed to provide and promote high quality health

care." *Summary of the HIPAA Privacy Rule*, *supra*. Plaintiffs are aggrieved because the Bulletin upset that balance by improperly prohibiting them from transmitting beneficial information that should not be subject to disclosure restrictions in light of the limited scope of the IIHI definition.

As for the "agency action" requirement, the Bulletin's conclusion that the Proscribed Combination is IIHI plainly qualifies as a "rule," 5 U.S.C. § 551(13), which is defined to "mean[] the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy …," *id.* § 551(4); *see Apter*, 80 F.4th at 590 ("[T]he APA defines the term 'rule' broadly enough to include virtually every statement an agency may make."). That is sufficient for Plaintiffs' first claim that the rule exceeds HHS's statutory and constitutional authority, *see infra* at Part I, because that claim does not depend on the APA's general review provisions. Rather, the Declaratory Judgment Act provides express authority to issue declaratory relief to resolve the parties' federal-law controversy, *see Braidwood*, 70 F.4th at 932-33, and federal courts' equity jurisdiction implicitly authorizes "injunctive relief" against "violations of federal law by federal officials," *see Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327 (2015) (citing *American Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 110 (1902)); *see also Apter*, 80 F.4th at 587, 590 (similarly holding that plaintiffs had a "non-statutory" cause of action to challenge statements the FDA allegedly had "no authority" to make). Moreover, because the rule easily satisfies the "final agency action" standard under 5 U.S.C § 704, *see infra* at Part II.A, Plaintiffs can invoke the APA's general review provisions. *See Alabama-Coushatta Tribe*, 757 F.3d at 489. So they may raise their second claim that the rule is arbitrary and capricious, *see infra* at Part II.B, raise their third claim that the rule failed to go through the notice-and-comment process, *see infra* at Part II.C, and seek relief, for all three claims, that "set[s] aside" the rule as "not in accordance with law," 5 U.S.C. § 706(2)(A).

ARGUMENT

This Court should grant Plaintiffs summary judgment. In this "solely … legal challenge," Order, ECF 22, at 1 (Dec. 11, 2023), "there is no genuine dispute as to any material fact" and Plaintiffs are entitled to prevail on their claims for relief "as a matter of law," *Firearms Policy Coalition, Inc. v. McCraw*, 623 F. Supp. 3d 740, 745 (N.D. Tex. 2022).

I. HHS EXCEEDED ITS AUTHORITY BY PROMULGATING THE BULLETIN

"[A]n agency literally has no power to act … unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). So the threshold problem with the Bulletin is also the most fundamental: The Bulletin's new rule exceeds HHS's authority under HIPAA. The webpage metadata information created in the Proscribed Combination—the IP address of the computer that a person uses to visit a covered entity's Unauthenticated Public Webpage that addresses specific health conditions or healthcare treatments—falls far outside the statutory definition of IIHI that is subject to the Privacy Rule's restrictions on disclosure and use. HHS's conclusory assertion to the contrary is irreconcilable with the express limits imposed by the reticulated IIHI definition. Moreover, that definition must be narrowly construed to avoid the serious First Amendment concerns that would be raised in this context by restricting healthcare providers' provision of metadata to third-party technology vendors in order to improve the operation of webpages used to communicate with the public at large.

A. The Proscribed Combination Falls Outside The Plain Text Of The Definition Of Individually Identifiable Health Information

Consistent with the core balance struck by HIPAA and the Privacy Rule, the restriction on disclosure and use of "protected" health information, 45 C.F.R. § 164.502(a), applies only to "individually identifiable health information," *id.* § 160.103; *accord* 42 U.S.C. § 1320d(6). The statute and regulation use an identical definition of IIHI, which has two core elements that are

relevant for present purposes: IIHI is health information that *both* (1) "relates to" the "past, present, or future physical or mental health or condition," receipt of "health care," or "payment for" healthcare, "of an individual"; *and* (2) "identifies the individual" or provides "a reasonable basis to believe that the information can be used to identify the individual." 42 U.S.C. § 1320d(6); *see supra* at 5 (block-quoting the full definition). Accordingly, even where information relates to *some* individual's health, healthcare, or payment for healthcare, a covered entity may disclose the information so long as it cannot reasonably be used to identify that *particular* individual. *See* 45 C.F.R. § 164.514(a) (providing that PHI subjected to "[d]e-identification" "is not [IIHI]"). And *a fortiori*, a covered entity may disclose *general* health-related information that does not relate to *any* individual at all. *See Wilson*, 27 F.4th at 246 ("generic documents governing [health insurer's] assessment of any beneficiary's claims").

The conflict between the IIHI definition's plain text and the Bulletin's new rule is clear and indisputable. The Bulletin concluded that a "regulated entity is disclosing PHI to [a] tracking technology vendor, and thus the HIPAA rules apply," so long as (1) the technology "collect[s] an individual's email address and/or IP address when the individual visits" an Unauthenticated Public Webpage; and (2) the page allows the visitor "to search for available appointments with a health care provider." Appx. 5; *accord id.* (same rule applies to "unauthenticated webpage[s] that address[] specific symptoms or health conditions"). The combination of those two pieces of information, however, can never provide a reasonable basis to identify "the individual" whose own health, healthcare, or payment for healthcare actually "relates to" the visit (if such an individual even exists at all).

Recall John Smith and Mary Jones, who visit a hospital's Unauthenticated Public Webpages for booking dialysis appointments or discussing the onset of Alzheimer's disease (and

whom we will assume, without conceding, could be reasonably identified based on the IP address of the computer they used to visit). They may have been visiting the pages for any of various *generic reasons* that are *unrelated to any particular individual's* health, healthcare, or payment for healthcare. To tick off several obvious examples, they could be public-health researchers studying these issues; hospital employees confirming the pages' accuracy; employees of another hospital scoping out the competition's offerings; webpage designers searching for inspiration; lawyers testing whether the pages are nondiscriminatory; hackers probing for vulnerabilities; local busybodies who are simply curious about these pages; or clumsy-fingered web surfers who just clicked on the wrong hyperlink. In addition, even if they were in fact looking into dialysis appointments or Alzheimer's disease for an actual person, it could have been for any one of *numerous third parties*: a family member, a close friend, a fellow parishioner, an acquaintance without a computer, etc. Of course, it is *possible* that Mr. Smith or Mrs. Jones navigated to the page in connection with their own healthcare needs, but their IP addresses cannot provide any reasonable basis for the hospital or its third-party technology vendor to so determine. As such, the information comprising the Proscribed Combination does not satisfy the IIHI definition.

B. HHS's Conclusory Rationale Is Irreconcilable With The Statutory Definition

HHS did not dispute any of the preceding points. Indeed, it did not even acknowledge them, much less refute them. Instead, HHS rested its new rule on a single assertion. The Bulletin claimed that, "even if [an] individual does not have an existing relationship with the regulated entity," the Proscribed Combination is "information [that] connects the individual to the regulated entity (*i.e.*, it is *indicative* that the individual has received or will receive health care services or benefits from the covered entity), and thus relates to the individual's past, present, or future health or health care or payment for care." Appx. 4 (emphasis added). This conclusory rationale would eviscerate the express limits on the IIHI definition in several respects.

First, HHS essentially rewrote the IIHI definition to eliminate a core requirement. Again, the definition's two key elements are the "relates to" prong and the "identifies" prong:

> *[R]elates to* the past, present, or future physical or mental health or condition [or healthcare or payment for healthcare] *of an individual* …, *and*—
>
> (i) *identifies* the individual; *or*
>
> (ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

42 U.S.C. § 1320d(6) (emphasis added). The "relates to" prong plainly requires that the health information at issue *actually* relate to an individual person's health, but HHS treated that language as including information that *might* relate to an individual's health—*i.e.*, that is "indicative" of a relationship—*but might instead* have nothing whatsoever to do with any particular individual's health, let alone the one identified as having visited the webpage.

That "indicative" gloss on the "relates to" prong of the IIHI definition is an untenable interpretation. If Congress had wanted that rule, it would have said something like: the information must either (i) actually "relate to" an individual's health or (ii) *at least possibly be "indicative"* of something about an individual's health. Not only did Congress *refrain* from using a formulation like that in the "relates to" prong, but it *did* use a formulation like that in the "identifies" prong: information that relates to an individual's health *either* (i) must actually "identif[y] the individual" *or* (ii) at least provide "a *reasonable basis to believe* that the information can be used to identify the individual." *Id.* (emphasis added). "[W]here Congress includes particular language" in one statutory sub-section "but omits it in another" sub-section of the same provision, "it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion." *In re Burnett*, 635 F.3d 169, 172 (5th Cir. 2011). So the fact that Congress did not even include language like "may reasonably relate to an individual's health" makes crystal clear that HHS rewrote the definition. And the rewrite is especially egregious

because HHS's "indicative" gloss on the "relates to" prong is an *even laxer* standard than the "reasonable basis" language Congress included *only* in the "identifies" prong.

Second, even if the "relates to" prong could be construed to tolerate some uncertainty about whether the information actually concerns an identifiable individual's health, HHS's "indicative" gloss pushes well past the breaking point. Although "'relates to'" is a broad standard, some connections are "too tenuous, remote, or peripheral" to satisfy it. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 100 n.21 (1983). That is the case in this context because a person may visit an Unauthenticated Public Webpage that addresses specific health conditions or healthcare providers for countless reasons that are *entirely unrelated* to any particular individual's health, and there are countless additional reasons why the person may be visiting on behalf of *some third party* who cannot reasonably be identified. To treat the IIHI definition as satisfied here would be "to read Congress's words of limitation as mere sham" by extending "'relate to' … to the furthest stretch of its indeterminacy." *NY State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995); *accord Jones v. Halliburton Co.*, 583 F.3d 228, 238-39 (5th Cir. 2009).

Third, HHS disregarded the HIPAA balance. Despite recognizing that the "insights" from online technologies "could be used in beneficial ways to help improve care or the patient experience," the Bulletin fixated on the possibility that metadata about webpage visitors "could also be misused to promote misinformation, identity theft, stalking, and harassment." Appx. 3. HHS thus lost sight of the important principle that "no law pursues its purposes at all costs" and that "the textual limitations upon a law's scope are no less a part of its 'purpose' than its substantive authorizations." *United States v. Lauderdale Cnty.*, 914 F.3d 960, 968 (5th Cir. 2019). Given that HIPAA "strikes a balance" by "protecting the privacy of people who seek care and healing" while "allowing the flow of health information needed to provide and promote high quality health care,"

Summary of the HIPAA Privacy Rule, *supra*, HHS gravely erred by expanding the IIHI definition to reach metadata about visitors to publicly accessible webpages. Such data does not come close to meeting the reticulated definition of individually identifiable health information, and it serves a vital role in how healthcare providers communicate with the communities they serve.

Given all this, it is unsurprising that courts have rejected the Bulletin's new rule (or the interpretation underlying it) when invoked by private litigants. As one district court bluntly held, "[t]he interpretation of IIHI offered by HHS in its guidance goes well beyond the meaning of what the statute can bear." *Kurowski v. Rush Sys. for Health*, No. 22 C 5380, 2023 WL 4707184, at *4 (N.D. Ill. July 24, 2023). "Th[is] type of metadata … transmitted via third-party source code does not in the least bit fit into th[e] category" of information covered by the definition. *Id.*; *see Hartley v. Univ. of Chi. Med. Ctr.*, No. 22 C 5891, 2023 WL 7386060, at *2 (N.D. Ill. Nov. 8, 2023) (holding that disclosure of "IP addresses" and "URLs" is insufficient to "plausibly" allege HIPAA violation); *Smith v. Facebook, Inc.*, 745 F. App'x 8, 9 (9th Cir. 2018) (holding that "the connection between a person's browsing history" on "publicly accessible websites" and "his or her own state of health is too tenuous" to implicate HIPAA). Indeed, the federal government's own HIPAA-covered entities are evidently of the same view, as they continue to use third-party technologies on their own public webpages that address specific health conditions or healthcare providers, thus creating the Proscribed Combination in flagrant disregard of HHS's Bulletin. *See supra* at 9-10.

C. The Canon Of Constitutional Avoidance Forecloses HHS's Rule

The final nail in the Bulletin's coffin is that "the constitutional-avoidance canon" requires this Court to "shun" an interpretation" of HIPAA that "raises serious constitutional doubts." *Turtle Island Foods, S.P.C. v. Strain*, 65 F.4th 211, 219 (5th Cir. 2023). HHS's new interpretation of the IIHI definition creates, at the very least, serious constitutional concerns that the Bulletin abridges healthcare providers' own First Amendment rights.

Outside the traditional zone of confidentiality entailed by a provider-patient relationship, disseminating information about the use of publicly accessible webpages on health-related topics is core protected speech, and content-based restrictions on such speech must satisfy strict scrutiny. This serious constitutional problem with HHS's interpretation of the IIHI definition follows inexorably from *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011). There, the Supreme Court invalidated a state law restricting pharmacies from selling prescriber-identifying information for purposes of pharmaceutical marketing. *Id.* at 557. It held that a private entity's dissemination of lawfully possessed information is protected speech, not mere commercial conduct. *Id.* at 566-71. It further held that the law at issue was a content-based speech restriction, because it applied only if the information was used for certain types of speech. *Id.* at 562-66. And the law failed strict scrutiny because it was not narrowly tailored to protect privacy, as it permitted disclosure of the prescriber-identifying information for reasons other than marketing. *Id.* at 571-73.

Here, the Bulletin is, if anything, more vulnerable to First Amendment challenge than the law invalidated in *Sorrell*. To begin, the Bulletin is more clearly content-based. As discussed, HHS's new rule is that, even if a visitor to an Unauthenticated Public Webpage lacks any relationship with the healthcare provider, the provider may not disclose the visitor's IP address to online technology vendors *if, but only if*, the page contains "specific" health-related content (as opposed to "general information" about the provider). *See* Appx. 5. Accordingly, this rule directly "targets speech based on its communicative content," as it "applies to particular speech because of the topic discussed." *City of Austin v. Reagan Nat'l Advert. of Austin, LLC*, 596 U.S. 61, 69 (2022). In addition, the Bulletin is more likely to fail strict scrutiny. Compared to prescriber-identifying information sold by pharmacies, metadata about the IP addresses of visitors to a public webpage implicates no real privacy interest, because such information cannot reasonably identify the person

whose own health actually relates to the visit (if there even is such a person). *See supra* at 17-18. And conversely, restricting healthcare providers from providing such information to their technology vendors—and prohibiting them from doing so insofar as many vendors refuse to sign an onerous business associate agreement, Appx. 26, 33—is a much greater burden on speech, because providers use the data to improve the utility and functionality of their webpages in communicating important health-related information with the public at large. *See supra* at 8-11.

Whether or not HHS could ultimately defend the constitutionality of its broad interpretation of the IIHI definition, the Bulletin at minimum "raises serious constitutional doubts." *Turtle Island Foods*, 65 F.4th at 219. So this Court is "required []to accept [the] narrowing construction" advanced by Plaintiffs here. *Id.* at 220. It is the *better* interpretation of the definition, and thus more than "plausible" enough to invoke the constitutional-avoidance canon. *Jennings v. Rodriguez*, 583 U.S. 281, 296 (2018). This confirms that HHS lacked authority to adopt the Bulletin's rule that the Proscribed Combination constitutes IIHI under HIPAA.

II. HHS VIOLATED THE APA IN PROMULGATING THE BULLETIN

Even if HHS arguably had the statutory authority under HIPAA, it violated the APA's requirements when issuing the Bulletin's new rule that the Proscribed Combination constitutes IIHI. That rule is final agency action subject to challenge under the APA because it establishes HHS's definitive and novel determination of how HIPAA applies in this context, with immediate binding impacts on regulated entities and the agency itself. The rule, however, is both substantively and procedurally defective. The rule's reasoning is arbitrary and capricious because HHS failed to offer any meaningful explanation for its conclusion or to perform any serious assessment of competing policy concerns. In addition, the rule failed to undergo the notice-and-comment process that is necessary for a policy such as this, which speaks with the force of law by

significantly altering regulated parties' obligations and conduct under the status quo. Each of these defects is an independent basis to set the rule aside under the APA.

A. The Bulletin's Rule That The Proscribed Combination Constitutes IIHI Is Final Agency Action Subject To APA Review

The Bulletin is subject to the APA's general provisions for judicial review because it is "final agency action." *See Alabama-Coushetta*, 757 F.3d at 489. As discussed, the Bulletin's conclusion that the Proscribed Combination constitutes IIHI plainly qualifies as a "rule," and thus as "agency action," under the APA. *See supra* at 15. And that rule is "final" for APA purposes because it is action (1) that "mark[s] the 'consummation' of the agency's decisionmaking process" and (2) "by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Texas v. Becerra*, No. 23-10246, --- F.4th ----, 2024 WL 20069, at *5 (5th Cir. Jan. 2, 2024) (*Becerra II*) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)). In applying these requirements, the Fifth Circuit has emphasized that "the Supreme Court takes a 'pragmatic approach,' viewing the APA finality requirement as 'flexible.'" *Id.* (cleaned up).

As to the first finality element, "[i]n the Fifth Circuit and elsewhere, 'guidance letters can mark the "consummation" of an agency's decision-making process.'" *Texas v. Becerra*, 623 F. Supp. 3d 696, 720 (N.D. Tex. 2022) (*Becerra I*) (quoting *Nat'l Pork Producers Council v. EPA*, 635 F.3d 738, 755 (5th Cir. 2011)), *aff'd*, No. 23-10246 (5th Cir. Jan. 2, 2024). What matters is that the guidance "is not merely tentative or interlocutory in nature," but rather adopts "a definitive position." *Id.* (cleaned up). In fact, agency guidance can be sufficiently definitive even where the position announced "can be administered flexibly according to the factual situation[] or withdrawn at any time." *NFIB v. Dougherty*, No. 3:16-CV-2568, 2017 WL 1194666, at *7 (N.D. Tex. Feb. 3, 2017). Conversely, threats to "take enforcement action" are compelling evidence the agency's position is definitive. *Texas v. Brooks-LaSure*, No. 6:23-cv-161, 2023 WL 4304749, at *8 (E.D.

Tex. June 30, 2023). Notably, when OCR issued another guidance document that similarly purported to "remind[] [retail pharmacies] of their obligations under federal [law]," a court held that this Pharmacy Guidance had "consummated HHS's decision-making process" because it "remained published and unchanged, hanging over Plaintiffs' heads like the sword of Damocles." *Texas v. HHS*, No. 23-CV-22, 2023 WL 4629168, at *2, *9 (W.D. Tex. July 12, 2023) (*HHS*).

Here, HHS's rule that the Proscribed Combination constitutes IIHI is clearly definitive. As an unequivocal "example" of the rule, the Bulletin proclaimed that a "regulated entity is disclosing PHI to [a] tracking technology vendor, and thus the HIPAA rules apply," so long as the technology "collect[s] an individual's email address and/or IP address when the individual visits a regulated entity's [unauthenticated] webpage to search for available appointments with a health care provider." Appx. 5; *accord id.* (same rule applies to "unauthenticated webpage[s] that address[] specific symptoms or health conditions"). In fact, that unqualified example stands in stark contrast to more hedged language used elsewhere in the Bulletin when discussing other propositions. *See, e.g.*, *id.* at 4 ("Tracking technologies on a regulated entity's user-authenticated webpages *generally* have access to PHI." (emphasis added)). Moreover, far from being a tentative decision subject to further agency review, HHS already has commenced a systematic enforcement effort, sending out warning letters to 130 covered entities and initiating investigations of the use of online technologies on Unauthenticated Public Webpages. *See supra* at 7-8.

As to the second finality element, "[c]ourts have consistently held that an agency's guidance documents binding it and its staff to a legal position produce legal consequences or determine rights and obligations." *Becerra II*, 2024 WL 20069, at *6 (cleaned up); *accord Pharm. Res. & Mfrs. of Am. v. HHS*, 138 F. Supp. 3d 31, 41 (D.D.C. 2015) ("[T]he D.C. Circuit and [the D.C. District] Court" have repeatedly held that a "guidance document" has a sufficiently "binding

effect" when it "set[s] forth [the agency's] view of the law and threaten[s] enforcement if the regulated entity d[oes] not comply."). When a guidance document goes beyond "merely restat[ing]" statutory requirements, by setting out an agency's "legal position—for the first time—regarding how [the statute] operates" in a particular context, *Becerra II*, 2024 WL 20069, at *8, it has an "immediate impact on" regulated parties, *Brooks-LaSure*, 2023 WL 4304749, at *8. They "are reasonably led to believe that failure to conform will bring adverse consequences." *Texas v. EEOC*, 933 F.3d 433, 442 (5th Cir. 2019). While that is especially so when the agency "previews imminent enforcement actions," *Brooks-LaSure*, 2023 WL 4304749, at *8, it holds true even if the agency has not yet brought any such actions carrying the new rule into effect, *see EEOC*, 933 F.3d at 444-45 (discussing *Frozen Food Express v. United States*, 351 U.S. 40, 44-45 (1956)). Regardless, the guidance document *itself* is "intended to carry the chilling threat of legal consequences" and convey "'marching orders' to a regulated entity." *HHS*, 2023 WL 4629168, at *10 (deeming OCR's Pharmacy Guidance to be final agency action); *accord Mock v. Garland*, 75 F.4th 563, 581 & n.45 (5th Cir. 2023).

Nor can a guidance document escape review by including "boilerplate language denying its legal effect." *HHS*, 2023 WL 4629168, at *10. As courts are "mindful but suspicious of the agency's own characterization," a "disclaimer" that the guidance is "mere[ly] a 'reminder' of existing [legal] obligations" should be disregarded *if*, in fact, it "chang[es] the statutory calculus," *Becerra I*, 623 F. Supp. 3d at 721, 732, by announcing a "new policy" that is "not mention[ed]" elsewhere, *Becerra II*, 2024 WL 20069, at *7-8. The use of "mandatory language" concerning such "'obligations,'" paired with "threaten[ed] fines" or other "enforcement," has a "binding effect," for the agency has decreed that it "expects regulated entities to alter their primary conduct to conform to [its] position." *Id.* at *6. Such language also "effectively withdraws the agency's

discretion to adopt a different view of the law," *id.* (cleaned up), because "[a]gencies, of course, are bound to follow their own interpretations of statutes," *Becerra I*, 623 F. Supp. 3d at 722.

Here, HHS's rule that the Proscribed Combination constitutes IIHI clearly has immediate binding impacts. That rule is a novel policy expanding covered entities' obligations under HIPAA. The Bulletin cites no legal authority or historical practice to support the proposition that the IIHI definition reaches the mere IP address of a visitor to an Unauthenticated Public Webpage addressing specific health-related topics. Plaintiffs are not aware of any such authority, and this bolt-from-the-blue Bulletin has disrupted healthcare providers' longstanding practice of using third-party tools that rely on such webpage metadata to function. *See supra* at 8-11. That chilling effect was the foreseeable consequence of the Bulletin's mandatory language that the Proscribed Combination "is disclosing PHI," that "the HIPAA Rules apply," and that "[a] regulated entity's failure to comply with the HIPAA Rules may result in a civil money penalty." Appx. 1, 5. And that chilling effect is exacerbated, once again, by HHS's aggressive enforcement efforts. Likewise, HHS's staff itself is clearly bound by the Bulletin's new rule. If a provider were engaged in the conduct described in the unequivocal "example" provided, agency enforcers would be required to treat that as a HIPAA violation unless and until HHS rescinded this aspect of the Bulletin.

In sum, the Bulletin's new rule easily satisfies the flexible and pragmatic standard for final agency action. Accordingly, the rule is subject to substantive and procedural challenge under the APA's general provisions for judicial review.

B. The Rule's Reasoning Is Arbitrary And Capricious

Even where a final rule otherwise falls within the sphere of the agency's statutory authority, the APA directs a court to set the rule aside if it is "arbitrary" or "capricious." 5 U.S.C. § 706(2)(A); *see Mock*, 75 F.4th at 579 n.38 (reaffirming that arbitrary-and-capricious review is available even for final "interpretive" rules that are exempt from the notice-and-comment process).

The APA's bedrock mandate is that "agency action be reasonable and reasonably explained." *Data Mktg. P'ship v. DOL*, 45 F.4th 846, 855 (5th Cir. 2002) (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)). This standard is not satisfied where the action is "premised on reasoning that fails to account for 'relevant factors' or evinces 'a clear error of judgment.'" *Id.* at 855-56; *see DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (invalidating an agency memorandum for these reasons). Reviewing courts "may consider only the reasoning articulated by the agency itself" at the time, which means they "cannot consider *post hoc* rationalizations." *Data Marketing*, 45 F.4th at 856 (citing, among other cases, *Regents*, 140 S. Ct. at 1909).

Here, the Bulletin's rule that the Proscribed Combination constitutes IIHI is arbitrary and capricious on several overlapping grounds. Each one is sufficient to invalidate the rule.

First, the most "obvious reason" is that the Bulletin "gives no explanation whatsoever" on the key interpretive issue presented. *Clarke v. CFTC*, 74 F.4th 627, 641 (5th Cir. 2023) (holding lack of explanation to be "the epitome of arbitrary and capricious"). HHS nakedly asserted that metadata "connect[ing]" a visitor's IP address to an Unauthenticated Public Webpage with specific health-related content is "indicative" that the individual has received or will receive healthcare from the webpage's provider "and thus relates to the individual's" own health. *See* Appx. 4. The agency did not offer a legal rationale for why any such "indication" is sufficient to satisfy the circumscribed IIHI definition, and it also did not offer a factual basis for deeming such an "indication" to exist notwithstanding the myriad alternative reasons why a visitor may view such a webpage wholly apart from the visitor's own health. *See supra* at Part I.A-I.B. Decreeing "a result," without providing any "*reasoning* for that result," fails to satisfy the most basic duty of reasoned decisionmaking imposed by the APA. *Clarke*, 74 F.4th at 641.

Second, and relatedly, HHS failed even to "display awareness that it *is* changing position." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). HHS claimed merely to be "highlight[ing] the obligations" that covered entities have always had under the "existing requirements" of HIPAA and the Privacy Rule. *See* Appx. 1, 9. But as discussed, the Bulletin's position that the IIHI definition reaches metadata about the IP addresses of visitors to publicly accessible webpages with specific health-related content has no precedent in either legal authority or historical practice. Accordingly, covered entities have "engendered serious reliance interests that must be taken into account" because "[i]t would be arbitrary and capricious to ignore such matters," "[y]et that is what the [Bulletin] did." *Regents*, 140 S. Ct. at 1913.

Third, the Bulletin likewise suffers from an "unexplained inconsistency." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). When federal agencies *themselves operate* webpages as HIPAA-covered entities—including HHS's own Medicare.gov webpage—they too use third-party technologies that create the Proscribed Combination on Unauthenticated Public Webpages about specific health conditions or healthcare providers. *See supra* at 9-10. That the government's own websites do not comply with the Bulletin's new rule starkly illustrates that HHS has acted in an arbitrary-and-capricious manner.

Fourth, and more generally, HHS failed to "adequately substantiate[]" the benefits of its new rule and demonstrate that they "bear a rational relationship" to the costs imposed. *Chamber of Commerce of U.S. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023). On the one hand, HHS worried that online technologies "could … be misused to promote misinformation, identity theft, stalking, and harassment." Appx. 3. But it provided no coherent rationale for how any of those problems could even hypothetically follow from a third-party technology vendor's mere use of metadata to connect a visitor's IP address with a publicly accessible webpage addressing specific health-related

topics—much less the scope of any real-world problem. On the other hand, HHS conceded that the "insights" from online technologies "could be used in beneficial ways to help improve care or the patient experience." *Id.* Yet it did not try to justify sacrificing these many benefits—perhaps because it never bothered consulting with healthcare providers (or, evidently, other federal agencies) to learn just how important these tools are to strengthening their public communications. *See supra* at 8-11. Especially given the serious First Amendment interests at stake, the Bulletin's failure to "weigh" these "competing policy concerns" is indefensible. *Regents*, 140 S. Ct. at 1915.

Simply put, the Bulletin's new rule is the posterchild for arbitrary-and-capricious rulemaking. Lacking any reasoning whatsoever and disregarding every important factor, the Bulletin could not survive even "toothless" review, let alone the "serious bite" that the APA demands. *Data Mktg.*, 45 F.4th at 856.

C. The Rule Was Required To Go Through The Notice-And-Comment Process

At minimum, before HHS could adopt the rule that the Proscribed Combination constitutes IIHI, the agency was required to publish a "notice of proposed rule making," give members of the public "an opportunity to participate" through written comments, and then provide a basis for the rule that gave "consideration" to the comments presented. 5 U.S.C. § 553(b)-(c). "In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment." *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979). Although the APA contains certain "exemptions" to the notice-and-comment requirement for rulemaking, the Fifth Circuit has admonished that they "must be narrowly construed." *Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995). And in evaluating whether an agency rule qualifies for an exemption, "courts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*." *Azar v. Allina Health*

Services, 139 S. Ct. 1804, 1812 (2019). Here, the only exemptions that are even arguably relevant are the ones for "interpretative rules" and "statements of policy," 5 U.S.C. § 553(b)(3)(A), and neither of those exemptions applies under settled precedent.[6]

1. An interpretative rule (often called an "interpretive rule") "clarifies, rather than creates, law" by "advis[ing] the public of the agency's construction of the statutes and rules which it administers." *Flight Training Int'l, Inc. v. FAA*, 58 F.4th 234, 240-41 (5th Cir. 2023). Courts "contrast" an interpretive rule with a "legislative rule," which has the "force and effect of law" because it "'modifies or adds to a legal norm.'" *Id.* (quoting *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997)). Accordingly, there is significant overlap between whether a rule satisfies the "legal consequences" prong of the final-agency-action standard (*see supra* at Part II.A) and whether it has the type of "force and effect of law" that renders inapplicable the interpretive-rule exception to the notice-and-comment requirement. *See, e.g.*, *EEOC*, 933 F.3d at 451 (holding that the "conclusion" that a guidance document was a legislative "rule subject to the APA's notice-and-comment requirement" "follow[ed] naturally from [an earlier] holding that the Guidance [was] a final agency action"); *Mock*, 75 F.4th at 581 & n.45 (invoking the rule's effect on regulated parties to hold both that it was not an interpretive rule and that it was final agency action).

Recently, a Fifth Circuit panel, recognizing that the court "ha[d] not laid out a clear test" for distinguishing between interpretive rules and legislative rules, adopted a "methodology" that considers "five factors": whether the agency (1) used language showing that it "intended to speak with the force of law"; (2) "published its rule in the Code of Federal Regulations"; (3) "explicitly invoked its general legislative authority"; (4) "claimed *Chevron* deference"; and (5) adopted a rule

[6] The remaining exemptions are facially inapposite: the Bulletin does not involve military or foreign-affairs functions, agency management or procedure, or public property or benefits, and HHS made no good-cause finding that notice and comment was impractical, unnecessary, or contrary to the public interest. *See* 5 U.S.C. § 553(a)(1)-(2), (b)(3)(A)-(B).

that "will produce … significant effects on private interests." *Mock*, 75 F.4th at 579-80. Although those factors cut in different directions there, *see id.* at 580-83, the panel deemed the fifth factor "the primary means" for identifying rules "of the type Congress thought appropriate for public participation," *id.* at 581. And that factor "strongly favor[ed]" treating the rule at issue as "legislative, not interpretive": the agency's novel position would have had the "significant implication[]" that "millions of Americans" had been breaking the law for decades without agency objection; the agency's claim that the conduct was "always unlawful" was "flatly unpersuasive given the history of [agency] regulation and action"; and yet the agency's rule was "command[ing]" regulated parties to cease the conduct. *Id.* at 581-82. So "[t]he factors as a whole indicate[d]" that the novel rule required notice-and-comment rulemaking. *Id.* at 582-83.

The same conclusion follows here. The *Mock* factors apply in nearly identical fashion to the Bulletin's new rule that the Proscribed Combination constitutes IIHI.

On the first factor, as in *Mock*, the Bulletin "speak[s] with the force of law" because it uses "prospective, binding language" to "directly govern the conduct of members of the public, affecting individual rights and obligations." 75 F.4th at 581. The Bulletin definitively and unequivocally proclaims that HIPAA's disclosure and use restrictions apply to the Proscribed Combination, and HHS has launched an enforcement offensive to force covered entities to comply with that legal rule. *See supra* at Part II.A (discussion of same points for final agency action). Moreover, that legal rule is not "tightly … drawn linguistically from the actual language of the statute." *Texas Med. Ass'n v. HHS*, No. 6:23-cv-59, 2023 WL 4977746, at *6 (E.D. Tex. Aug. 3, 2023) (quoting *Syncor*, 127 F.3d at 94), as it goes far beyond "reiterat[ing]" the "well-established" meaning of the IIHI definition, *Brooks-LaSure*, 2023 WL 4304749, at *8. Rather than "deriv[ing] a proposition" that "flow[s] fairly from the substance of the existing [statute]," *Cath. Health*

Initiatives v. Sebelius, 617 F.3d 490, 494-95 (D.C. Cir. 2010), the Bulletin "chang[es] the statutory calculus" entirely, *Becerra I*, 623 F. Supp. 3d at 732; it adopts a "new policy," *Becerra II*, 2024 WL 20069, at *8, that imposes an atextual gloss on the IIHI definition to reach webpage metadata that may or may not be "indicative" of the visitor's own health, *see supra* at Part I.B.

The next three factors also cut in different directions here. As in *Mock*, HHS "explicitly invoked its general legislative authority." 75 F.4th at 581. The Bulletin emphasized that "OCR administers and enforces the HIPAA Rules." *See* Appx. 1, 10 n.3 (citing 45 C.F.R. part 160, which includes HHS's authority to issue legislative rules under HIPAA, 45 C.F.R. § 160.104). Conversely, as in *Mock*, HHS "did not invoke *Chevron* deference." 75 F.4th at 580. And in the sole difference from *Mock*, the Bulletin was not "published in the Code of Federal Regulations," *id.*, though the distinction is trivial given that HHS instead published a press release, sent warning letters to 130 covered entities, and is actively investigating compliance with the Bulletin.

With respect to the fifth but primary factor, as in *Mock*, the Bulletin's "significant effects on private interests" "strongly favors" treating it as "legislative, not interpretive." 75 F.4th at 581. At the risk of redundancy, the Bulletin is having an "immediate impact" on covered entities because it proclaims "for the first time" that the Proscribed Combination constitutes IIHI subject to HIPAA's restrictions. *Brooks-LaSure*, 2023 WL 4304749, at *8. The agency's belated claim that it was "always unlawful" for covered entities to create and disclose the Proscribed Combination "is flatly unpersuasive given the history of [HHS] regulation and action," *Mock*, 75 F.4th at 582, and utterly belied by the *continued conduct* of the federal agencies operating HIPAA-covered webpages. And yet the Bulletin is having its intended effect of "carry[ing] the chilling threat of legal consequences" and conveying "'marching orders'" to covered entities, *HHS*, 2023 WL 4629168, at *10, by "command[ing]" compliance with the new rule, *Mock*, 75 F.4th at 582.

In sum, this case is a reprise of *Mock*. "The factors as a whole indicate that the [Bulletin] is a legislative rule" rather than an interpretive rule. *Id.* at 582-83.

2. Finally, for largely the same reasons, the Bulletin also is not a mere statement of policy. A policy statement is "issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Lincoln v. Vigil*, 508 U.S. 182, 197 (1993). Courts "evaluate two criteria to distinguish policy statements from substantive rules: whether the rule (1) 'impose[s] any rights and obligations' and (2) 'genuinely leaves the agency and its decision-makers free to exercise discretion.'" *Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015) (quoting *Professionals & Patients for Customized Care*, 56 F.3d at 595). Here, the first criteria is not satisfied for all the reasons just discussed. *See R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 193-94 (5th Cir. 2023) (holding agency actions not to be "statements of policy" given that they "affected the rights" of numerous persons). And the second criteria likewise is not satisfied, because HHS obviously cannot disregard the Bulletin's definitive and authoritative pronouncement that disclosure of the Proscribed Combination violates HIPAA, as confirmed by the agency's ongoing investigations to enforce that new rule. *See id.* (emphasizing that agency "intend[ed] to bind *itself* to a particular legal position"); *Texas v. EEOC*, 633 F. Supp. 3d 824, 841 (N.D. Tex. 2022) ("How could HHS staff act contrary to this statement?").

Accordingly, because the Bulletin's rule that the Proscribed Combination constitutes IIHI is neither a policy statement nor an interpretive rule, it was required to go through the notice-and-comment process. Although the rule's substantive defects should foreclose HHS from adopting it at all, at the very least HHS was required to seek and consider the views of the regulated community before it altered the regulatory status quo so drastically.

CONCLUSION

This Court should grant summary judgment to Plaintiffs. It should declare that the Proscribed Combination is not IIHI, set aside the Bulletin's contrary rule, and enjoin HHS from enforcing that rule against the Hospitals and the Associations' other members.

January 5, 2024

Respectfully submitted,

Jonathan D. Guynn (TX 24120232)
JONES DAY
2727 N. Harwood St., Ste. 500
Dallas, Texas 75201
(214) 220-3939
(214) 969-5100 (fax)
jguynn@jonesday.com

/s/ Hashim M. Mooppan
Hashim M. Mooppan* (DC 981758)
Rebekah B. Kcehowski* (PA 90219)
Jack L. Millman* (NY 5517180)
Audrey Beck* (DC 1739917)
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939
(202) 626-1700 (fax)
hmmooppan@jonesday.com
rbkcehowski@jonesday.com
jmillman@jonesday.com
abeck@jonesday.com
* *Pro hac vice*

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of January, 2024, a true and correct copy of this document was served electronically by the Court's CM/ECF system on all counsel of record.

/s/ Hashim M. Mooppan
Hashim M. Mooppan
Counsel for Plaintiffs