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

AMERICAN HOSPITAL ASSOCIATION; TEXAS HOSPITAL ASSOCIATION; TEXAS HEALTH RESOURCES; UNITED REGIONAL HEALTH CARE SYSTEM,

Plaintiffs,

v.

MELANIE FONTES RAINER, IN HER OFFICIAL CAPACITY AS DIRECTOR OF OFFICE FOR CIVIL RIGHTS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES OF AMERICA,

Defendants.

NO.

COMPLAINT

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INTRODUCTION AND SUMMARY

1. The American Hospital Association and the Texas Hospital Association (Associations), along with Texas Health Resources and United Regional Health Care System (Hospitals), bring this action because the federal government is threatening to enforce against hospitals and health systems 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, promulgated by the U.S. Department of Health and Human Services (HHS), prohibits the use of certain technologies that make healthcare providers' public webpages more effective in sharing vital information with the community. Yet even as HHS is actively enforcing this new rule against hospitals across the country, the federal government's own healthcare providers continue to use these purportedly prohibited technologies on their websites. A gross overreach by the federal bureaucracy, imposed without any input from the public or the healthcare providers most impacted by it, the HHS rule exceeds the government's statutory and constitutional authority, fails to satisfy the requirements for agency rulemaking, and harms the very people it purports to protect. The Court should bar the rule's enforcement.

2. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations "strike[] a balance." *Summary of the HIPAA Privacy Rule*, U.S. Dep't of Health & Hum. Servs, https://perma.cc/MCG3-QFHX. The law "protect[s] the privacy of people who seek care and healing," while "permit[ting] important uses of information." *Id.*; *see id.* ("A major goal of the Privacy Rule is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being.").

3. Hospitals and health systems have long honored the balance HIPAA strikes. They take seriously their obligation to safeguard the privacy of patient records and billing statements. At the same time, they have embraced the federal government's support for sharing non-private health-related information on their publicly accessible webpages that neither require nor request patients to enter login information for user authentication (an Unauthenticated Public Webpage).

4. Now more than ever, the federal government has called on hospitals and health systems to combat "[h]ealth misinformation"—something the U.S. Surgeon General recently described as a "serious threat to public health." V. Murthy, *Confronting Health Misinformation* (2021), https://perma.cc/YD2V-4QJE. While always working to protect private patient information, hospitals and health systems are keenly aware of their obligation to fulfill the other side of the HIPAA balance by "shar[ing] accurate health information with the public." *Id.*; *see generally Understanding Some of HIPAA's Permitted Uses and Disclosures*, U.S. Dep't of Health & Hum. Servs, https://perma.cc/N7FC-DTW8 ("Information is essential fuel for the engine of health care. Physicians, medical professionals, hospitals and other clinical institutions generate, use and share it to provide good care to individuals, to evaluate the quality of care they are providing, and to assure they receive proper payment from health plans.… The capability for relevant players in the health care system – including the patient – to be able to quickly and easily access needed information to make decisions, and to provide the right care at the right time, is fundamental to achieving the goals of health reform.").

5. As part of these information-sharing efforts, many hospitals and health systems use third-party technologies to enhance their websites, including in the following ways:

- **Analytics tools** convert web users' interactions with hospital webpages into critical data, such as the level and concentrations of community concern on particular

medical questions, or the areas of a hospital website on which people have trouble navigating. Website data analytics can tell a hospital how many IP addresses in the past month looked for information about, say, RSV vaccines or diabetes treatment in a particular area, which in turn allows hospitals to more effectively allocate their medical and other resources. These tools also help hospitals ensure that their public-facing webpages are user-friendly, helping community members to more easily navigate to healthcare information so that they can better manage their healthcare. For instance, hospitals can improve the functionality of their websites' design so that they deliver a maximally seamless experience for individuals with disabilities, facilitating compliance with the Americans With Disabilities Act.

- **Video technologies** allow hospitals to offer a wide range of information to the public, including videos that educate the community about particular health conditions and that allow visitors to virtually tour the facilities where particular procedures are performed.
- **Translation technologies** help non-English speakers access vital healthcare information on hospitals' webpages.
- **Map and location technologies** provide better information about where healthcare services are available, including embedded applications that provide bus schedules or driving directions to and from a community member's location.

6. Third-party technologies like these, which typically rely on a visitor's IP address to function, enable hospitals and health systems to hone their websites' functionality and the helpfulness of their information. Just as crucially, these technologies allow hospitals and health

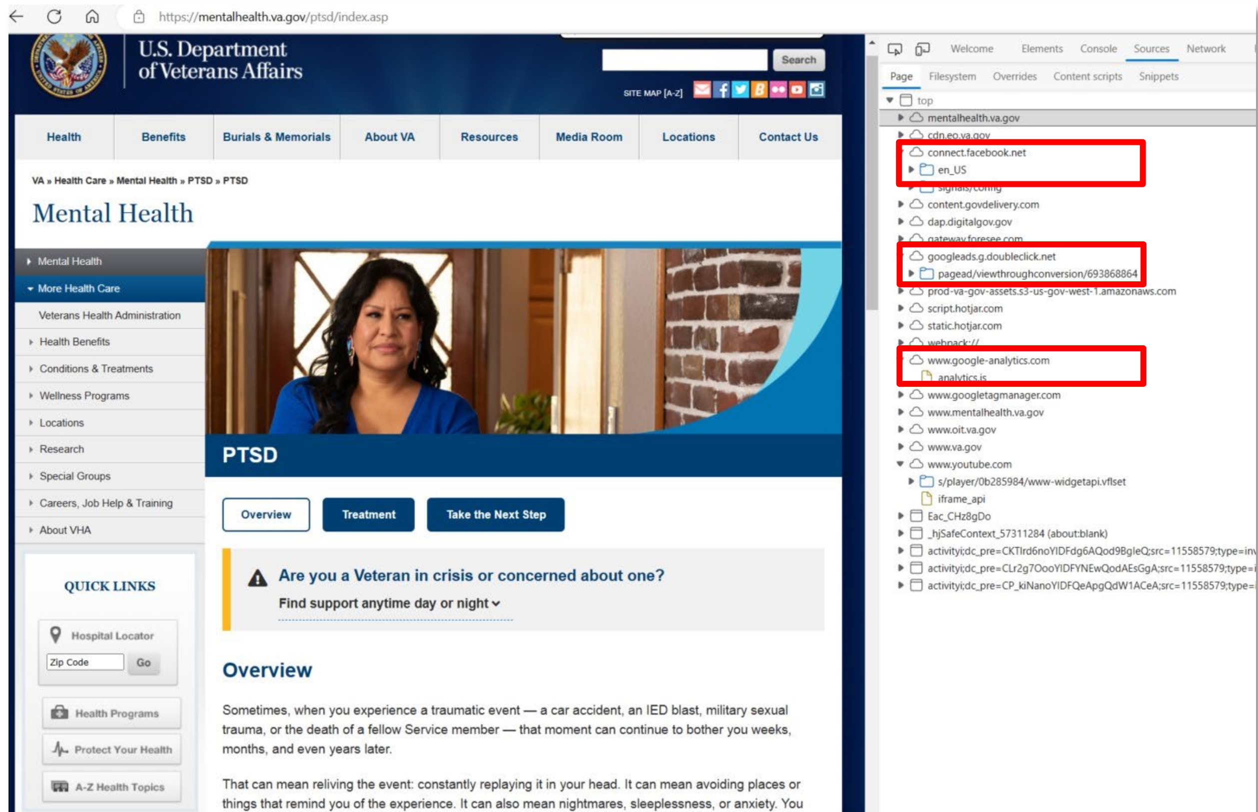
systems to adjust and publicize information and services in response to public need and thereby improve public health, all without compromising the HIPAA balance.

7. In December 2022, however, the Office for Civil Rights (OCR) in HHS precipitously upended the balance that HIPAA and its regulations strike between privacy and information-sharing. Without consulting healthcare providers, third-party technology vendors, or the public at large, the agency issued a sub-regulatory guidance document that has had profound effects on hospitals, health systems, and the communities they serve. *See Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates* (Bulletin), https://perma.cc/58V6-NTMG.

8. In that bolt-from-the-blue "Bulletin," OCR took the position 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 subject to restrictions on use and disclosure under HIPAA. For example, if a public-health researcher used her personal computer to search a hospital's webpage for the availability of dialysis appointments, the technology's combination of (1) the researcher's IP address and (2) the visit to a page addressing dialysis appointments would, according to the Bulletin, be subject to HIPAA's requirements. So too if the technology combined (1) the IP address of an individual who used his personal computer on behalf of an elderly neighbor (2) to read a hospital's webpage with information about the onset of Alzheimer's disease.

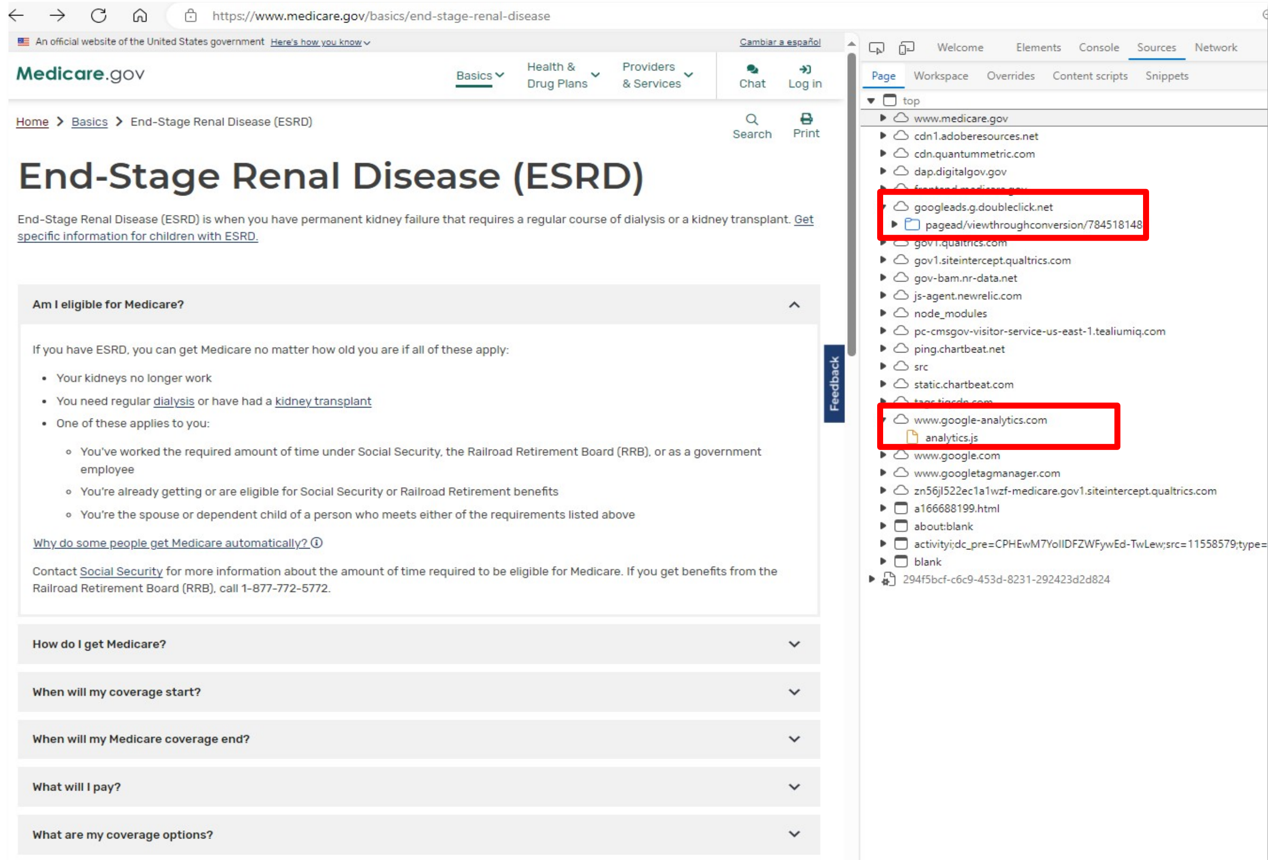
9. Remarkably, it appears that OCR issued the Bulletin without even consulting the federal government's own website operators, because agencies that are covered entities under HIPAA themselves use the same third-party technologies on their webpages and create the Proscribed Combination. As one of many 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 and healthcare providers, including but not limited to a page describing the symptoms of post-traumatic stress disorder and pointing veterans to treatment resources:



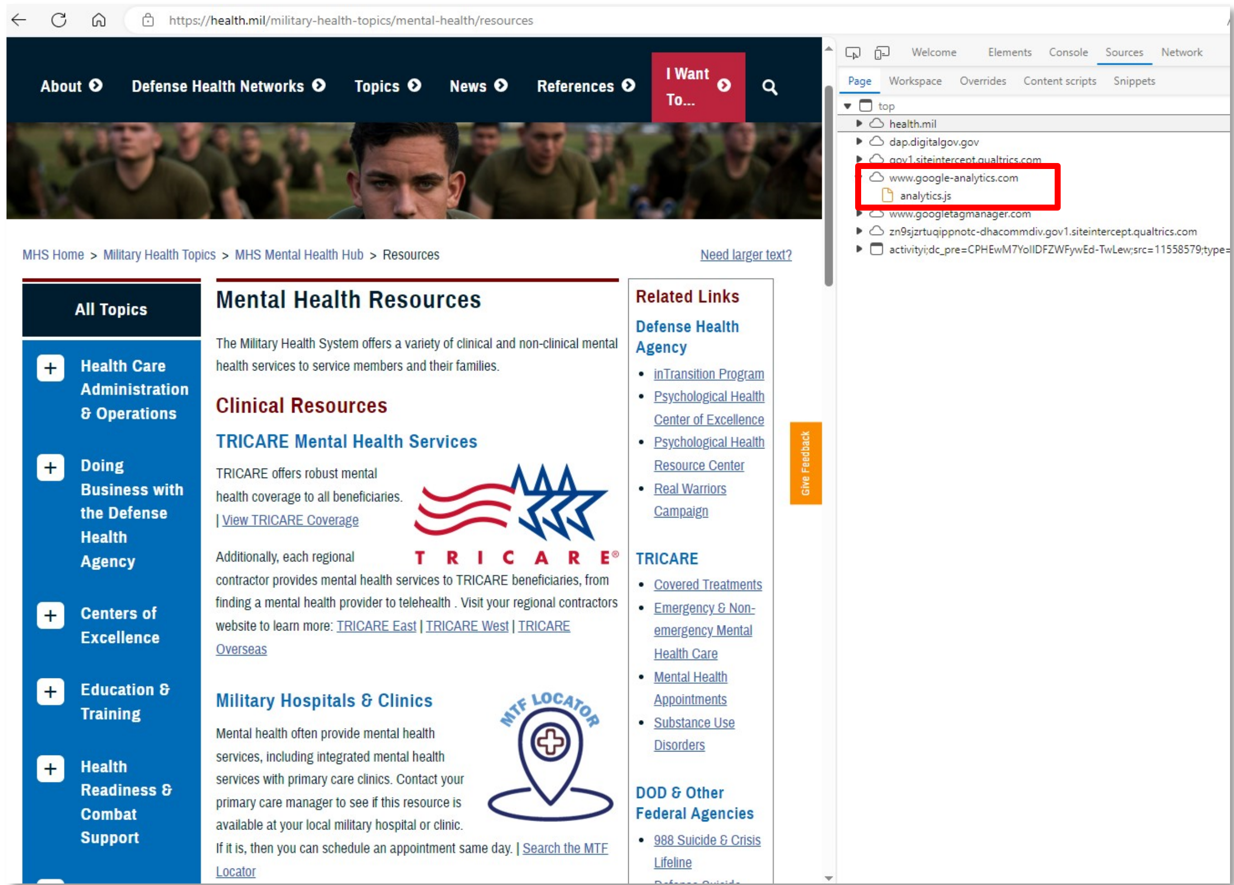
See, e.g., *Mental Health*, U.S. Dep't of Veterans Affairs, mentalhealth.va.gov/ptsd/index.asp (last visited Oct. 31, 2023) (red boxes added for emphasis).

10. Web browser inspection and source tools likewise show that, among other technologies, third-party analytics tools are present on HHS's Medicare.gov webpages that address specific health conditions and healthcare providers, including but not limited to a page addressing End-Stage Renal Disease and explaining coverage eligibility requirements:



See, e.g., *End-Stage Renal Disease (ESRD)*, medicare.gov/basics/end-stage-renal-disease (last visited Oct. 31, 2023) (red boxes added for emphasis).

11. In a third example, web browser inspection and source tools show that, among other technologies, third-party analytics tools are present on the Department of Defense's Military Health System webpages discussing specific health conditions and healthcare providers, including but not limited to a page addressing the mental-health resources available to service members:



See, e.g., *Mental Health Resources*, Military Health System & Defense Health Agency, health.mil/military-health-topics/mental-health/resources (last visited Oct. 31, 2023) (red box added for emphasis).

12. That the government's own websites do not comply with the Bulletin's new rule starkly confirms the rule's invalidity. The Bulletin's rule that the Proscribed Combination constitutes IIHI exceeds HHS's authority under HIPAA and the First Amendment, and it also was promulgated in a substantively and procedurally unlawful manner under the Administrative Procedure Act (APA).

13. Under the longstanding Privacy Rule that implements HIPAA, covered providers like the Hospitals and the Associations' other members "may not use or disclose" certain protected health information except as the regulations permit. 45 C.F.R. § 164.502(a). Critically, HIPAA

does not restrict all health-related information from disclosure. Instead, protected information must be "individually identifiable health information," or IIHI. *See* 45 C.F.R. § 160.103. The statute defines IIHI as "information" that (1) "relates to … an individual['s]" "past, present, or future physical or mental health or condition," receipt of "health care," or "payment for … health care"; and (2) either "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)(B); *accord* 45 C.F.R. § 160.103 (identically defining IIHI). Under this express statutory definition, a healthcare provider may disclose information that does not relate to any particular individual's health, care, or payment, as well as information related to a particular individual that cannot reasonably be used to identify that individual.

14. According to the Bulletin, however, healthcare providers subject to HIPAA would be disclosing IIHI if there are technologies "on a regulated entity's unauthenticated webpage that addresses specific symptoms or health conditions … or that permits individuals to search for doctors or schedule appointments without entering credentials," and they "could collect an individual email address and/or IP address when the individual visits [the] regulated entity's webpage." Bulletin, *supra.* The Bulletin asserts that the Proscribed Combination is IIHI "even if the individual does not have an existing relationship" with the provider whose Unauthenticated Public Webpage he or she accesses, because it 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.* (emphasis added).

15. In concluding that the Proscribed Combination constitutes IIHI, the Bulletin exceeds OCR's authority under the definition of IIHI in 42 U.S.C. § 1320d and 45 C.F.R.

§ 160.103. To fall within that definition, there must be at least a reasonable basis to believe that the Proscribed Combination could identify *"the individual" whose health, healthcare, or payment for healthcare actually "relates to"* the webpage visit. But there is no basis to believe that, and the Bulletin provides none.

16. Even assuming (without conceding) that the IP address that visited a webpage could be reasonably associated with a particular individual, that individual did not necessarily visit the page in connection with his or her own health, healthcare, or payment for healthcare. Indeed, he or she may not have visited the webpage in connection with *any* particular individual's health or care. For example, the visit may have occurred due to academic or journalistic research on a health condition or area provider capacity, general curiosity about something in the news, or just an accidental click on a web link. And even if the visitor actually did navigate to the webpage in connection with a particular person's health, it may well have been *someone else's*—that of a relative, friend, or acquaintance. While of course *some* visitors navigate to a webpage in connection with their own health, the information constituting the Proscribed Combination provides no reasonable basis to determine *which* visitors fall within that category. The Proscribed Combination thus is not IIHI.

17. At least one district court has already concluded that "[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" the definition. *Id.*; *see Smith v. Facebook, Inc.*, 745 F. App'x 8, 9 (9th Cir. 2018) (similarly concluding 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).

18. Moreover, construing the IIHI definition to encompass the Proscribed Combination, as the Bulletin claims, would violate the First Amendment. Outside the privacy of 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 that speech are subject to strict scrutiny. Yet under the Bulletin's new rule, healthcare providers are prohibited from disclosing information about usage of a public webpage depending on whether the page contains specific health-related content, even if the individual does not have an existing relationship with the provider. That content-based restriction would not survive strict scrutiny, among other reasons, because it is not narrowly tailored to protect patient privacy. Because the Bulletin's rule at the very least raises serious First Amendment concerns, the IIHI definition must be construed to avoid those concerns.

19. Even if the IIHI definition arguably could be read to reach the Proscribed Combination despite the foregoing infirmities, the Bulletin still must be set aside under the APA. To begin, it is substantively defective because its reasoning is arbitrary and capricious. The Bulletin baldly asserts that the IIHI definition is satisfied because there is an "indicative" "connection" between a particular individual who visits a hospital's Unauthenticated Public Webpage and the specific health condition or healthcare provider discussed on that webpage. But the Bulletin contains no reasoning supporting that assertion—not a shred of legal analysis or factual substantiation—let alone any consideration of the myriad reasons to visit such a page other than an individual's own health and the competing policy concerns that are thus implicated by this new rule. Further, the Bulletin's unreasoned and unsupported position on this issue marks a stark departure from prior understandings of the IIHI definition, yet OCR did not even acknowledge, much less justify, the novelty of its position—a sea change that drastically upsets the field's

reliance interests and starkly conflicts with the federal government's own use of third-party technologies on the webpages of federal agencies that are covered entities under HIPAA.

20. At a minimum, the Bulletin is procedurally defective because OCR did not undertake notice-and-comment rulemaking. Strikingly, OCR issued this rule without ever consulting hospitals and health systems about their use of online technologies or the impact that its new rule would have on patients or communities. Although the Bulletin purports to be styled as a mere interpretive guidance document, it is a legislative rule because it manifestly speaks with the force of law to condemn a new category of conduct, purporting to create a novel, binding norm that transforms healthcare providers' obligations under HIPAA and significantly affects their interests.

21. The Bulletin's ramifications are widespread and significant. In July 2023, OCR began systematically and publicly threatening the regulated community with enforcement of the Bulletin. The agency wrote to approximately 130 hospital systems and telehealth providers—including Plaintiff Texas Health Resources and many of the Associations' other members—"strongly encourag[ing]" them "to review" and "take actions" in light of "OCR's December 2022 bulletin." Letter 1-3 (July 20, 2023), https://perma.cc/H2HJ-367X; *see 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* (Press Release) (July 20, 2023), https://perma.cc/KAP3-XSXY. OCR warned that it is "closely watching developments in this area." Letter 3.

22. In a press release regarding these warning letters, OCR Director Rainer acknowledged the "beneficial purposes" of the online technologies at issue but nevertheless stated that the agency is "concerned" that hospitals' use of these technologies results in "impermissible

disclosures of health information"—an issue, Director Rainer vowed, that OCR "will use all of its resources to address." Press Release, *supra.* Under 42 U.S.C. § 1320d-5, those resources include the power to impose civil penalties for violations of HIPAA rules. Since issuing the Bulletin in December, the press release noted, "OCR has confirmed its active investigations nationwide to ensure compliance with HIPAA." Press Release, *supra*.

23. Several months later, on or around September 1, 2023, OCR publicly released the names of all hospitals and health systems that received its July 2023 warning letter. OCR has not explained how it selected letter recipients or why it chose to later put a public bullseye on those recipients by releasing their names.

24. Through its vigorous campaign to wield the Bulletin to change the regulated community's conduct, OCR has thus confirmed the Bulletin's import: it is a new mandate that healthcare providers must follow on pain of serious civil penalties.

25. Hospitals across the country have been forced to remove technologies from their webpages, often at significant cost. They also have been subject to widespread and unfounded putative class-action litigation invoking the Bulletin. There are many such lawsuits against providers across the country, imposing substantial litigation costs through meritless claims.

26. As applied to Unauthenticated Public Webpages, the Bulletin is unlawful. The Court should set aside the Bulletin insofar as it provides that the Proscribed Combination is IIHI, declare that the Proscribed Combination is not IIHI under the statutory and regulatory definition, and enjoin OCR from enforcing its contrary position against the Hospitals and the Associations' other members.

THE PARTIES

27. The American Hospital Association (AHA) is a trade association representing hospitals, healthcare systems, networks, and other providers of care. Its principal place of business is in Chicago, Illinois. AHA represents its members, including Texas Health Resources and United Regional Health Care System, in this action: AHA has members, including but not limited to those who received OCR's July 2023 enforcement letter, who are aggrieved by the Bulletin's rule against the Proscribed Combination; protecting those members' interests is germane to AHA's organizational purpose; and the individual members' participation is not required to adjudicate the claims for relief.

28. Plaintiff Texas Hospital Association (THA) is a trade association representing Texas hospitals and healthcare systems. Its principal place of business is in Austin, Texas. THA represents its members, including Texas Health Resources and United Regional Health Care System, Inc., in this action: THA has members, including but not limited to those who received OCR's July 2023 enforcement letter, who are aggrieved by the Bulletin's rule against the Proscribed Combination; protecting those members' interests is germane to THA's organizational purpose; and the individual members' participation is not required to adjudicate the claims for relief.

29. Plaintiff Texas Health Resources is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is a Texas nonprofit corporation with its principal place of business in Arlington, Texas.

30. Plaintiff United Regional Health Care System is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is a Texas nonprofit corporation with its principal place of business in Wichita Falls, Texas.

31. Defendant Melanie Fontes Rainer is the Director of the Office for Civil Rights, an office within the U.S. Department of Health and Human Services. She is sued in her official capacity.

32. Defendant Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services. He is sued in his official capacity.

33. The United States of America is named in accordance with 5 U.S.C. § 702. This is an action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer thereof acted or failed to act in an official capacity.

JURISDICTION, CAUSE OF ACTION, AND VENUE

34. As this action arises under federal law and seeks relief against the United States, this Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1346(a)(2).

35. The United States has waived its sovereign immunity from this suit in 5 U.S.C. § 702. For purposes of § 702's waiver of immunity, the challenged rule in the Bulletin is "agency action" because it sets forth a "statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4), (13). Likewise, the Hospitals and the Associations' other members are "adversely affected or aggrieved" because their "claims are 'arguably within the zone of interests to be protected or regulated by the statute,'" *Texas v. United States*, 50 F.4th 498, 520-21 (5th Cir. 2022). In particular, their claims seek to enforce the limitations to the IIHI definition that implement the balance struck by HIPAA in permitting the use and disclosure of non-covered information. Because the Hospitals and the Associations' other members easily satisfy the "agency action" and "adversely affected or aggrieved" requirements, the § 702 sovereign-immunity waiver applies. *See Alabama-Coushatta Tribe of Texas v. United States*, 757 F.3d 484, 489 (5th Cir. 2014).

36. For their claim that the Bulletin exceeds OCR's statutory and regulatory authority, Plaintiffs have a cause of action to sue for injunctive relief under the equity jurisdiction of federal courts, *see Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326-27 (2015) (citing *Am. Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 110 (1902)), and for declaratory relief, *see* 28 U.S.C. § 2201, 2202.

37. For both that claim and their claims that the Bulletin is substantive and procedurally defective under the APA, Plaintiffs likewise have a cause of action for injunctive and declaratory relief under the APA itself. 5 U.S.C. §§ 702-04, 706. The challenged rule in the Bulletin constitutes final agency action under 5 U.S.C. § 704 because it definitively determines regulated entities' obligations, creating binding prescriptions that carry legal consequences for those entities. *See Bennett v. Spear*, 520 U.S. 154, 178 (1997); *Mock v. Garland*, No. 23-10319, 2023 WL 4882763, at *14 & n.45 (5th Cir. Aug. 1, 2023).

38. Venue is proper in this district under 28 U.S.C. § 1391(e)(1)(B)-(C) and 5 U.S.C. § 703. Defendants are the United States and officers of an agency of the United States, acting in their official capacity; Plaintiff Texas Health Resources maintains its principal place of business in this district and division, and a substantial part of the events or omissions giving rise to its claim are occurring here.

BACKGROUND

39. The Hospitals and the Associations' other members are "health care provider[s] who transmit[] any health information in electronic form in connection with" qualifying transactions. 45 C.F.R. § 160.103. Accordingly, they are HIPAA-regulated entities and "may not use or disclose protected health information" except as the regulations permit. 45 C.F.R. § 164.502(a); *see id.* §§ 164.502(e), 164.504(e) (permitting disclosure of such information to a

"business associate" if it enters into agreement that, among other things, extends covered entity's legal obligations to the associate if it is performing the entity's duties, and requires the associate to implement appropriate safeguards, make certain information available to individuals and the government, and ensure that its subcontractors comply with same terms).

40. In December 2022, OCR issued the Bulletin, which purports to explain how the rules implementing HIPAA apply to regulated entities' use of certain online technologies. *See* Bulletin. Plaintiffs challenge *only* the Bulletin's rule treating as IIHI the Proscribed Combination— *i.e.*, where an online technology connects (1) an individual's IP address with (2) a visit to a publicly accessible webpage that does not require or request login information for user authentication (an Unauthenticated Public Webpage) and that addresses specific health conditions or healthcare providers. *See id.* They do *not* challenge the Bulletin's application to patient portals or other password-protected areas of a hospital's website.

41. The Bulletin definitively adopted the rule governing the Proscribed Combination, even as it cabined some other statements with phrases like "generally" and "in some cases." In particular, when discussing "unauthenticated webpages," the Bulletin unequivocally decreed that, in "th[e] example" of technologies that "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," "the regulated entity is disclosing PHI to the tracking technology vendor, and thus the HIPAA Rules apply." Bulletin, *supra.* And that specific example illustrated the Bulletin's general conclusion that "technologies on a regulated entity's 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 [IIHI]" if they connect a visit to the webpage with a particular individual's IP address or email address. *Id.* The

Bulletin asserts that this Proscribed Combination is IIHI "even if the individual does not have an existing relationship" with the provider whose Unauthenticated Public Webpage he or she accesses, because it 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.* (emphasis added); *see id.* (n.21) (acknowledging that an IP address alone may not identify the individual visiting the webpage).

42. In July 2023, OCR sent letters to approximately 130 hospital systems and telehealth providers, "strongly encourag[ing]" them "to review" and "take actions" in light of the Bulletin, and warning them that the agency is "closely watching developments in this area." Letter, *supra*, at 1-3.

43. In a press release about the warning letters, Director Rainer stated that OCR "will use all of its resources to address" the issue of "impermissible disclosures of health information" through regulated entities' online technologies. Press Release, *supra*. The release also noted that, "[s]ince" issuing the Bulletin, "OCR has confirmed its active investigations nationwide to ensure compliance with HIPAA." *Id.*

44. Indeed, in August 2023, acting OCR deputy director Susan Rhodes, citing the Bulletin, confirmed that OCR is "continuing to investigate related matters to really make sure that healthcare providers" understand their HIPAA obligations with respect to online technologies. Asked when an enforcement action may occur, Rhodes stated that this is "a very important area for [OCR]," and emphasized that there are "open investigations involving web trackers … across the country right now" and that OCR "do[es] use [its] investigations to … highlight messages to

the industry." *Why HHS Regulators Are Heavily Scrutinizing Web Tracker Use*, Video, Healthcare Info Security (Aug. 17, 2023), https://perma.cc/E9SF-MB6S (1:56, 3:24, 3:33, 3:43).

45. AHA and THA members, including Texas Health Resources, received OCR's July 2023 warning letter about the Bulletin and were later exposed as recipients of that letter when OCR chose to amplify its enforcement threat by posting the full set of letters on its website.

46. Although OCR described itself in the Bulletin as providing an overview of existing requirements, and included a general disclaimer of any intent to bind the public, *see* Bulletin, this extension of the IIHI definition to reach the Proscribed Combination is novel and effects a consequential change in healthcare providers' obligations under the Privacy Rule.

47. The Hospitals and other members of the Associations wish to use online technologies on Unauthenticated Public Webpages to collect and disclose the Proscribed Combination to third-party technology vendors, but are refraining from doing so in various ways based on HHS's threat to enforce the Bulletin. The Hospitals and other members of the Associations wish to employ analytics tools to improve website functionality by identifying and addressing areas in which community members struggle to find information, and also wish to use various other technologies described herein. The Bulletin stands in the way of using these valuable tools, in part because many third-party technology vendors refuse to enter into a business associate agreement. Moreover, the Hospitals and other members of the Associations have had to incur significant costs to comply with the Bulletin's new rule.

CLAIMS FOR RELIEF

COUNT ONE
(Rule Exceeds Authority And Is Contrary To Law)

48. The Associations and the Hospitals repeat and reallege each allegation in paragraphs 1-47 above as if fully set forth here.

49. In the Bulletin, OCR announced that the Proscribed Combination constitutes IIHI. That rule expands the definition of IIHI set forth in 42 U.S.C. § 1320d and 45 C.F.R. § 160.103 to reach information that does not satisfy the statutory and regulatory definition. The rule thus exceeds OCR's authority under that definition.

50. The statutory and regulatory definition limits IIHI to "information" that (1) "relates to … an individual['s]" "past, present, or future physical or mental health or condition," receipt of "health care," or "payment for … health care"; and (2) either "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)(B); 45 C.F.R. § 160.103.

51. The Proscribed Combination does not satisfy this definition because there is no reasonable basis to believe that this information could identify "the individual" whose own health, healthcare, or payment for healthcare actually "relates to" the visit to the Unauthenticated Public Webpage. Even assuming (without conceding) that the information provides a reasonable basis for identifying the individual who visited the webpage, that person's visit may not have related to the health, healthcare, or payment for healthcare of any particular individual, or it may have related to some unidentified individual other than the visitor himself or herself. The information in the Proscribed Combination provides no reasonable basis for a regulated entity to determine otherwise.

52. Construing the IIHI definition to reach the Proscribed Combination would violate the First Amendment. This Bulletin's new rule purports to restrict protected speech on information

concerning visitors to a publicly available webpage, and it would do so based on whether that webpage contains specific health-related content. It thus would be subject to strict scrutiny, which it could not survive because, among other things, it is not remotely tailored to protecting patient privacy. And given that the Bulletin's rule at the very least raises serious First Amendment concerns, the IIHI definition must be construed to avoid those concerns.

COUNT TWO
(Arbitrary-And-Capricious Rulemaking)

53. The Associations and Hospitals repeat and reallege each allegation in paragraphs 1-47 above as if fully set forth here.

54. The Bulletin's rule that the Proscribed Combination constitutes IIHI is arbitrary and capricious under 5 U.S.C. § 706(2)(A).

55. In the Bulletin, OCR provided no reasoning for its assertion that the IIHI definition is satisfied by the "indicative" "connection" that purportedly exists between an individual who visits a hospital's Unauthenticated Public Webpage and the specific health-related information on that webpage. *See* Bulletin. That is a novel rule with significant consequences for the regulated community's obligations, none of which OCR even acknowledged, much less weighed and justified. And it is irreconcilable with the use of third-party technologies on the webpages of federal agencies that are themselves covered entities under HIPAA.

COUNT THREE
(Failure To Undertake Notice-And-Comment Rulemaking)

56. The Associations and Hospitals repeat and reallege each allegation in paragraphs 1-47 above as if fully set forth here.

57. The Bulletin's rule that the Proscribed Combination constitutes IIHI is a legislative rule for which OCR was required to, but did not, undertake notice-and-comment rulemaking under the APA. 5 U.S.C. § 553.

58. In declaring that the Proscribed Combination constitutes IIHI, the Bulletin speaks with the force of law to condemn a new category of conduct, creating a novel, binding norm that dramatically shifts healthcare providers' obligations under HIPAA and significantly affects their interests.

PRAYER FOR RELIEF

The Associations and Hospitals request:

(1) That the Bulletin be set aside insofar as it provides that the Proscribed Combination is IIHI;

(2) Declaratory judgment that the Proscribed Combination does not constitute IIHI under the statutory and regulatory definition;

(3) Permanent injunctive relief enjoining OCR from enforcing against the Hospitals and the Associations' other members the rule in the Bulletin that the Proscribed Combination is IIHI;

(4) Such other and further relief as this Court may deem just and proper, including, but not limited to, reasonable fees and costs.

November 2, 2023

Respectfully submitted,

/s/ Hashim M. Mooppan

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* *Pro hac vice application forthcoming*

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