UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

STATE OF WASHINGTON,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, in his official capacity as the Secretary of the United States Department of Health and Human Services;

Defendants.

NO. 2:20-cv-01105

BRIEF OF AMICI NATIONAL HEALTH LAW PROGRAM ET AL., IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION AND STATEMENT OF INTEREST

A decade ago, the Affordable Care Act mandated an end to long accepted, legally allowed discriminatory practices in health care. Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148 (2010) , as amended in the Health Care and Education Reconciliation Act, Pub. L. No. 111-152 (2010). The ACA included provisions to end insurance carriers denying coverage for people with disabilities or chronic health conditions, annual and lifetime benefit limits, and drastically more expensive premiums for women and older adults. In addition, Section 1557 contains a robust section prohibiting discrimination in health care based on race, sex, age, and disability. 42 U.S.C. § 18116. Additionally, Section 1554 prohibits HHS from issuing regulations that, among other things, create unreasonable barriers to obtaining appropriate medical care, impede timely access to care, interfere with communications between the patient and provider, and limit health care under the patient's needs. *Id*. § 18114. Where previously discrimination in health care was often the normal course of business—causing loss of insurance, coverage denials, delayed access to care, and associated negative health outcomes—the ACA said "no more."

Proposed Amici the National Health Law Program, Justice in Aging, Public Citizen Foundation, California Pan-Ethnic Health Network, Center for Public Representation, Communication First, Disability Rights Education and Defense Fund, Disability Rights Washington, Legal Voice, National Council on Interpreting in Health

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Care, and SAGE are health and disability advocacy organizations dedicated to eliminating disparities in health care.[1] Proposed amici have a strong interest in ensuring that the regulations adhere to the statute and that people receive the full protection of Section 1557. *See* 5 U.S.C. § 702. While Washington's Preliminary Injunction motion is based on the changes to the definition of discrimination on the basis of sex, its complaint recognizes that the changes are far more expansive and will harm a range of individuals, including those represented by amici as described below.

The initial rulemaking process for Section 1557 spanned three years and resulted in 25,000 comments reflecting the importance of eliminating longstanding discrimination in health care. This process culminated in the U.S. Department of Health and Human Services ("HHS") issuing a final rule in 2016. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (formerly codified at 45 C.F.R. pt. 92), https://perma.cc/47EC-4NZL ("2016 Final Rule"). Then, just four years later, the Trump Administration issued a revised rule. Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020), https://perma.cc/P2TJ-AN54 ("2020 Revised Rule"). As Washington has shown, the 2020 Revised Rule threw away important protections against sex discrimination that will harm Lesbian, Gay, Bisexual, Transgender, Queer

[1] None of the proposed Amici is a subsidiary of any other corporation and no publicly held corporation owns 10% or more of any proposed Amici's stock.

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Plus ("LGBTQ+") individuals and women. *See* Memo. in Support of Mtn. for Preliminary Inj., ECF No. 4, at 8. As amici discuss below, it also added a host of exemptions contrary to the ACA. It eliminated important notice and effective communication protections for people with limited English proficiency (LEP) and disabilities. And it erased whole categories of entities from coverage by Section 1557.

The 2020 Revised Rule was one of multiple attempts to undermine the ACA and its non-discrimination protections. Previously, the Administration issued a memo to discourage staff from systemic investigations of discrimination. *See* Candice Jackson, OCR Acting Assistant Sec'y Civil Rights, *OCR Instructions to Field Re: Scope of Complaints* (Jun. 8, 2017), https://perma.cc/45L6-8Q5T. It also filed briefs in litigation that challenged the non-discrimination protections.[2]

Caught in the midst of all of these attempted rollbacks are the people whom Congress intended to protect under the ACA. Prior to the ACA, Congress heard testimony about the impact of discrimination on women, people with disabilities, LGBTQ+ individuals, people with limited English proficiency ("LEP"), older adults, and other protected classes. In passing the ACA, Senator Tom Harkin said:

> [U]ntil now, it has been perfectly legal to discriminate against our fellow Americans because of illness-because of illness-and to exclude tens of

[2] *Defendants' Memorandum in Response to Plaintiffs' Mtn. for Summary Judgment, Franciscan Alliance v. Price*, No. 7:16-cv-00108 (N.D. Tex., Apr. 5, 2019), https://perma.cc/48ZU-GAHU (informing court that HHS no longer interpreted "sex" to include gender identity); *c.f. Federal Defendants' Memorandum in Response to Plaintiffs' Application for Preliminary Injunction*, *Texas v. U.S.*, No. 4:18-cv-00167-O (N.D. Tex., Jun. 7, 2018), https://perma.cc/FU5G-HASZ (arguing ACA's pre-existing condition protection is unconstitutional).

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> millions of our citizens from decent health care simply because they could not afford insurance or afford health care-blatant discrimination.

156 Cong. Rec. S1983 (daily ed. Mar. 24, 2010). To ensure that such discrimination remains illegal, proposed amici support Washington's motion.

I. Allowing Exemptions Will Cause Significant Harm to Women, LGBTQ+ People, People with Disabilities, and Older Adults.

The 2020 Revised Rule illegally incorporates harmful exemptions from other laws, including Title IX of the Education Amendments Act of 1972 ("Title IX") and the Americans with Disabilities Act ("ADA"). 20 U.S.C. § 1681 et seq.; 42 U.S.C. § 12101 et seq. These exemptions are contrary to the language of Section 1557, which creates a baseline protection of rights, remedies, and procedures that other non-discrimination provisions may add to, but not take away from. The language of Section 1557(b) protects individual rights. *See* 42 U.S.C. § 18116(b) ("Nothing in this title … shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards" available under the cited non-discrimination statutes or supersede more protective State law). The 2016 Rule appropriately reflected this language. *See* 81 Fed. Reg. at 31,466 (codified at 45 C.F.R. § 92.3(b)). By contrast, the 2020 Revised Rule uses language that cabins Section 1557 and incorporates exemptions from nine statutes never referenced in Section 1557. *See* Exhibit 1 (providing a side-by-side comparison of the language).

Including these exemptions is not only contrary to the statute, but also ignores the ample evidence in the record that the exemptions would cause significant harm, especially to women, LGBTQ+ people, people with disabilities, and older adults. The

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question of including exemptions to Section 1557 was thoroughly commented on and reviewed in the 2016 rulemaking process. Nothing significant has changed in the interim, and HHS has not provided a reasoned justification for its changes.

HHS first solicited comment on whether it should incorporate any religious exemptions to compliance with the sex discrimination component of Section 1557 in 2013, in a "Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities." 78 Fed. Reg. 46,558 (Aug. 1, 2013), https://perma.cc/NJ8P-2VKJ ("RFI") (referencing Title IX).[3] RFI Commenters gave examples of how allowing exemptions from Section 1557's protections would result in real-world discrimination and harm. *See, e.g.*, Lambda Legal, Comment ID HHS-OCR-2013-0007-0161, at 2; Nat'l Latina Inst. Repro. Health, Comment ID HHS-OCR-2013-0007-0101, at 6; Whitman-Walker Health, Comment ID HHS-OCR-2013-0007-0063, at 11. HHS later noted:

> Nearly all commenters who provided a response to this inquiry indicated that Section 1557 includes only one exception—that the statute applies except as otherwise provided in Title I of the ACA. To this end, commenters noted that nothing in the language or legislative history of Section 1557 allows for any other limitations or exceptions regarding its application, highlighting that exceptions to general rules like Section 1557's antidiscrimination provision must be read strictly and narrowly.

[3] All comments received by HHS in response to the 2013 RFI can be found at https://perma.cc/T7J9-YALK. In this brief, individual comments have been identified by their comment ID number the first time they are cited and then by the organization's name thereafter.

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Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,173 (proposed Sept. 8, 2015), https://perma.cc/LTK9-5YET.[4]

HHS solicited comment on the question again in 2015 in its first Notice of Proposed Rulemaking on Section 1557, asking "whether the regulation should include any specific exemptions . . . with respect to requirements of the proposed rule related to sex discrimination" and whether "existing protections . . . provide sufficient safeguards for religious concerns in the context of the proposed rule." *Id.* at 54,173. HHS stated that its goal was to "ensure that the rule has the proper scope and appropriately protects sincerely held religious beliefs to the extent that those beliefs conflict with provisions of the regulation," while noting that "protections already exist with respect to religious beliefs, . . . [and] this proposed rule would not displace the protections afforded by provider conscience laws, the Religious Freedom Restoration Act, provisions in the ACA related to abortion services, or regulations issued under the ACA related to preventive health services." *Id.* (citations omitted). Those existing statutes that allow individuals and entities to refuse to provide certain services based on moral and religious objections are more than sufficient to accommodate any religious objections.

In response to HHS's inquiry, "[m]ost of the organizations that commented on this issue, including professional medical associations and civil rights organizations, and

[4] All comments received by HHS in response to the 2015 NPRM can be found at https://perma.cc/X267-26UZ. In this brief, individual comments have been identified by their comment ID number the first time they are cited and then by the organization's name thereafter.

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the overwhelming majority of individual commenters—many of whom identified themselves as religious—opposed any religious exemption on the basis that it would potentially allow for discrimination on the bases prohibited by Section 1557 or for the denial of health services. . . ." 81 Fed. Reg. at 31,379. In addition, as HHS noted, "mergers of religiously-affiliated hospitals with other hospitals have deepened concerns that would be raised by providing a religious exemption, as the mergers may leave individuals in many communities with fewer health care options. . . ." *Id.* Many commenters also discussed the harm that a religious exemption would have on LGBTQ+ individuals. *See* Nat'l Women's Law Ctr., Comment ID HHS-OCR-2015-0006-0837, at 8-9 (citing ACLU & Merger Watch, *Miscarriage of Medicine: The Growth of Catholic Hospitals and the Threat to Reproductive Health Care* (2013), https://perma.cc/SV62-NDCQ); Nat'l Ctr. Lesbian Rights, Comment ID HHS-OCR-2015-0006-1829, at 10-13 (citing numerous studies on the negative impact of the growth in religiously affiliated hospitals on access to care for women seeking reproductive health services and rape survivors). This impact was reiterated by hundreds of individual commenters, including over one hundred individuals from Washington State. *See, e.g.*, Leslie Gray of Olympia, WA, Comment ID HHS-OCR-2015-0006-2159, at 524-25 (describing experience of a transgender woman whose urological medical condition was not treated due to her transgender identity, which caused blood clots to form in her heart, resulting in permanent cardiac damage).

Thus, in promulgating the 2016 Final Rule, HHS stated that while "some commenters urged us also to incorporate Title IX's blanket religious exemption into this

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final rule, we believe that applying the protections in [existing] laws . . . offers the best and most appropriate approach for resolving any conflicts between religious beliefs and Section 1557 requirements." 81 Fed. Reg. at 31,380. With respect to Title IX's exemptions, HHS emphasized that these exemptions are limited to educational institutions and noted key differences between the educational and health care contexts, concluding, "[t]hus, it is appropriate to adopt a more nuanced approach in the health care context, rather than the blanket religious exemption applied for educational institutions under Title IX." *Id.* HHS recognized that in health care, people often have little choice as to where an ambulance takes them or may have few choices of providers in rural areas heavily populated with religious providers. *See id.*

Nevertheless, the 2020 Revised Rule adds Title IX's blanket exemption for religiously affiliated entities along with a range of other religious exemptions. *See* Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846, 27,892 (proposed June 14, 2019), https://perma.cc/FY4Z-ZUBA (to be codified at § 92.6).[5] This 180 degree turn is all the more significant given the growing percentage of the health care market that is occupied by religiously affiliated hospitals and health systems. *See* ACLU of Illinois, Comment ID HHS-OCR-2019-0007-138982, at 7-8 (citing Louis Uttley & Christine Khaikin, *Growth of Catholic Hospitals and Health Systems: 2016*

[5] All comments received by HHS in response to the 2019 NPRM can be found at https://perma.cc/4VCN-Y2DK. In this brief, individual comments have been identified by their comment ID number the first time they are cited and then by the organization's name thereafter.

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Update of the Miscarriage of Medicine Report, MergerWatch, (2016), https://perma.cc/A9TW-Y6P5); Amelia Thomson-DeVeaux and Anna Maria Barry-Jester, *Insurers Can Send Patients to Religious Hospitals that Restrict Reproductive Care*, FiveThirtyEight (Aug. 1, 2018), https://perma.cc/3V2Z-CYGV); *see also* ACLU Founds. of Cal., Comment ID HHS-OCR-2019-0007-149859, at 8-10 (the growing size and scope of Catholic hospitals will increase the likelihood of harm to women and LBGTQ+ individuals). This issue is particularly acute in Washington as it has the second highest proportion of short-term acute-care beds in hospitals under Catholic restrictions at 40.9%. Legal Voice, Comment ID HHS-OCR-2019-0007-151507, at 8.

The inclusion of sweeping religious exemptions to Section 1557's protections will result in serious harm. As commenters noted these exemptions will disproportionately harm women, especially Black, Indigenous, and women of color, who are often denied reproductive health care due to the proliferation of entities that discriminate by refusing to provide such care based on religious beliefs. *See* Ass'n Am. Med. Colls., Comment ID HHS-OCR-2019-0007-115960, at 3-4 (religious exemptions will exacerbate race-based discrimination in family planning care); Nat'l Hisp. Leadership Agenda, Comment ID HHS-OCR-2019-0007-149018, at 11 (citing study finding that 4 in 10 Latina/o voters under age 45 (41 percent) have gone without the birth control method they wanted in the past two years because of access issues); *see also* Legal Voice at 8; In Our Own Voice: Nat'l Black Women's Reproductive Justice, Comment ID HHS-OCR-2019-0007-140963, at 7; Nat'l Women's Law Ctr., Comment ID HHS-OCR-2019-0007-149018, at 5-11.

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The 2020 Revised Rule's religious exemptions also disproportionately harm LGBTQ+ people. According to a study published in 2018, 8% of LGBQ people were refused health care because of their sexual orientation, and 29% of transgender people were denied care because of their gender identity. *See* NHeLP, Comment ID HHS-OCR-2019-0007-127004, at 51 (citing Shabab Ahmed Mirza & Caitlin Rooney, Ctr. Am. Progress, *Discrimination Prevents LGBTQ People From Accessing Health Care* (2018), https://perma.cc/ZG7E-7WK8); Justice in Aging, Comment ID HHS-OCR-2019-0007-149354, at 7 ("Many [LGBTQ+] older adults report having to go back 'in the closet' because of stigma and fear when transitioning to a long-term care facility. . . .").

HHS also acted contrary to the ACA and Section 1557 by incorporating the exemptions set forth in the ADA. The ADA includes religious exemptions, private club exclusions, and exclusions related to drug use that are not found in Section 1557. NHeLP at 24. The ADA also includes a safe harbor provision that exempts insurers, hospitals, managed care entities, benefit administrators, and other organizations "underwriting risks, classifying risks, or administering such risks" from the disability discrimination protections in Titles I through III of the ADA. 42 U.S.C. § 12201(c). Under the safe harbor provision of the ADA, insurers and others have been allowed to discriminate against people with disabilities. *See, e.g.*, Samuel R. Bagenstos, *The Future of Disability Law*, 114 Yale L.J. 1, 41 nn.168-70 (2004) (collecting cases that did not analyze whether content of benefits was discriminatory when they upheld exclusions on the basis of treatment or diagnosis). Although disability discrimination claims under Section 504 of the

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Rehabilitation Act are allowed, courts have narrowly construed certain types of claims. *Id.* The ACA contains many examples of corrections to exemptions and definitions that courts had upheld in disability discrimination challenges under the ADA and Section 504, including prohibitions against discriminatory benefit design. *See, e.g.,* 42 U.S.C. § 300gg-6; 42 U.S.C. § 18022; Consortium for Citizens with Disabilities ("CCD"), Comment ID HHS-OCR-2019-0007-146162, at 2-7; *see generally* Sara Rosenbaum et al., *Crossing the Rubicon: The Impact of the Affordable Care Act on the Content of Insurance Coverage for Persons with Disabilities,* 25 Notre Dame J. L. Ethics & Pub. Pol'y 235 (2014).

The 2020 Revised Rule purports to recreate some of the very gaps that Section 1557 was intended to fill. Under the 2020 Revised Rule individuals with disabilities who are facing discriminatory benefit designs outside of the qualified health plan context may have limited, if any, options for challenging such harmful discrimination. *See* Coalition to Preserve Rehabilitation, Comment ID HHS-OCR-0007-146075, at 2 (noting that Section 1557 "acted as a capstone to the ADA expanding disability protections in the provision of health insurance.").

The ACA reformed disability discrimination in health care. Many of the discriminatory practices that had been allowed are now prohibited. Section 1557 was included as the mechanism to enforce this seismic shift. The 2020 Revised Rule turns this mechanism on its head by incorporating all of the exemptions, exclusions, definitions, and defenses of statutes not even mentioned in Section 1557. HHS lacks the authority to promulgate regulations interpreting Section 1557 that "create[] any unreasonable

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barriers to the ability of individuals to obtain appropriate medical care." 42 U.S.C. § 18114. Yet HHS's action will do just that. For these reasons, the 2020 Revised Rule's addition of exemptions and exclusions untethered to the text of Section 1557 is contrary to law and is arbitrary and capricious.

II. Removal of the Notice, Tagline, and Effective Communication Requirements Will Harm Individuals with Limited English Proficiency ("LEP"), Older Adults, and People with Disabilities.

Before the ACA, individuals who needed communication assistance experienced barriers to regularly receiving quality health care, leaving important information uncommunicated or ineffectively communicated between providers and patients. The result: preventive visits did not happen, treatment regimens were not followed, and appointments were missed. 81 Fed. Reg. at 31,459. Congress passed the ACA to "help uninsured and underserved populations gain access to care[.]" 81 Fed. Reg. at 31,443. The 2016 Final Rule recognized the ACA and Section 1557's purposes to "expand access to care and eliminate barriers to access," including by preventing disability discrimination. *Id.* at 31,377.

In the 2020 Revised Rule, HHS has removed provisions that are essential to ensure that individuals with limited English proficiency ("LEP"), older adults, and people with disabilities can regularly access quality health care. In particular, the Rule eliminates notice requirements that are critical for people to understand their rights. *See* 85 Fed. Reg. at 37,204. The 2020 Revised Rule also removes requirements for taglines—short statements commonly added to documents to inform individuals in their language of

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their right to language assistance and how to seek such assistance—a critical language access provision designed to ensure that LEP individuals can access needed care. *Id.* at 37,175. In addition, the Rule harms people with disabilities by limiting access to necessary effective communication. *Id*. at 37,213-37,215; *see also* CCD at 20-21.

A. Harm of Repealing the Notice and Tagline Requirements

The 2016 Final Rule contained a number of provisions to ensure that patients understand their rights and are able to communicate effectively with health care staff. In particular, the 2016 Final Rule required covered entities to provide notice of nondiscrimination policies, including notice of the availability and how to access auxiliary aids and services necessary for certain patients with disabilities and language assistance services for LEP patients. 81 Fed. Reg. at 31,469. The 2016 Final Rule required covered entities to post this notice in physical locations, in significant communications, and on its website. *Id*. The 2020 Revised Rule has entirely eliminated the notice requirements. *See* 85 Fed. Reg. at 37,204.

In crafting the 2016 Final Rule, HHS noted that "the use of incompetent or ad hoc interpreters, such as family members, friends, and children, is not uncommon and can have negative implications." 80 Fed. Reg. at 54,184. Accordingly, the 2016 Final Rule required covered entities to include taglines on all significant documents in the top 15 languages spoken by individuals with LEP in their state. 45 C.F.R. § 92.8(d)(1); *see* 81 Fed. Reg. at 31,469. Despite commenters raising concerns about the benefits of the 2016 Final

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Rule and the harms of eliminating these provisions, the 2020 Revised Rule entirely eliminated the tagline requirements. *See* 85 Fed. Reg. at 37,204.

Eliminating these critical language access provisions will result in some of these individuals failing to understand or assert their rights. *See* NHeLP at 29 ("All too often, individuals with limited English proficiency do not understand their rights, and will not know their new rights under Section 1557[.]"); *see also* Asian Health Services, Comment ID HHS-OCR-2019-0007-146378; California Pan-Ethnic Health Network, Comment ID HHS-OCR-2019-0007-152828. It will also result in some people failing to receive adequate care, delaying care, or not seeking care at all, because they are unaware of their right to receive accommodations and language services, undermining the purpose and intent of Section 1557. *See* Leadership Conference, Comment ID HHS-OCR-2019-0007-138231, at 7 ("Protections for language access are also required in order to combat discrimination based upon national origin."); NHeLP at 29 (individuals often "believe they have to bring their own interpreter or use a child, other patient, or unqualified individual to interpret."); Disability Law Ctr., Comment ID HHS-OCR-2019-0007-127904, at 2 ("Without the notice, members of the public will have limited means of knowing that auxiliary aids and services are available, how to request them, what to do if they face discrimination, and their right to file a complaint."); Justice in Aging at 2 (describing particular needs of LEP older adults, including the four million plus LEP Medicare beneficiaries); Medicare Rights Ctr., Comment ID HHS-OCR-2019-0007-145479, at 6-7 (describing importance of language access protections for older adults,

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including LEP older adults, people with disabilities, and older adults who are deaf, hard of hearing, blind, or have low vision, to access health care, understand medical instructions, and engage with providers).

As a result of the repeal of the notice and tagline requirements, it will be more difficult for LEP patients to navigate complex documents with specialized terminology. *See* Commonwealth of Mass., Comment ID HHS-OCR-2019-0007-136510, at 4. In addition, there will be an increase in LEP patients and patients with disabilities who are unable to communicate with health care workers, resulting in incorrect diagnoses or inappropriate care. *See* Leadership Conference at 7-8 (citing The Joint Comm'n, *Overcoming the Challenges of Providing Care to LEP Patients* (May 2015), https://perma.cc/BE6A-5QYP); Wash. State Coalition for Language Access, Comment ID HHS-OCR-2019-0007-127779, at 2 ("[I]nadequate language services[] have been well-documented as contributing to U.S. health and healthcare disparities, including: reduced access to regular care; lesser quality of care; higher rates of uninsurance; increased risk of medical errors; difficulty in following post-care instructions; more frequent hospitalizations and higher rates of readmissions; unnecessary tests and procedures; and higher rates of mortality.") (citing WASCLA Tools for Health, *What Does Language Access Have to Do With Health?* (2014)); Justice in Aging at 4 (consistent access to professional interpreters in hospital setting was associated with decreased readmission rates for LEP individuals 50+ years old receiving palliative care services); Disability Law Center at 1 ("Persons with sensory impairments also experience challenges understanding or

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complying with care instructions because interpreters are more often than not unavailable or materials are not offered in alternative formats.").

The cost of these language and communication barriers can be deadly. A 2010 report found that patients lost their lives and suffered irreparable harm from medical errors, worse clinical outcomes, and lower quality of care due to language barriers. NHeLP at 28 (citing Kelvin Quan & Jessica Lynch, *The High Costs of Language Barriers in Medical Malpractice*, Univ. of Cal. Berkeley and Nat'l Health Law Program (2011), https://perma.cc/59PM-4NHU). Others may be improperly billed if their LEP status prevents them from successfully navigating the healthcare system. *See* Justice in Aging at 3 ("Especially for older adults with limited income and high health care needs, the consequences of an erroneous bill or forgoing care can be catastrophic.").

As the 2016 Final Rule recognized, studies have shown that "when reliable assistance services are utilized, patients experience treatment-related benefits, such as enhanced understanding of physician instruction, shared decision-making, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance." 81 Fed. Reg. at 31,459 (citing *Institute of Medicine, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* 17 (Brian D. Smedley et al. eds., 2002) (citation omitted), https://perma.cc/RQK2-U9RA).

Despite HHS's suggestion that the notice and tagline requirements were duplicative, these requirements are not met by other non-discrimination provisions. For example, HHS cites the Medicare Advantage (Part C) and Prescription Drug Plans (Part

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D) as requiring taglines in Medicare Communications and Marketing Guidelines (MCMG), but the Centers for Medicare & Medicaid Services eliminated this requirement effective this year. *See* CMS, *MCMG* (2018), https://perma.cc/2T3G-DTAR. Requirements for notices and taglines in other contexts are also not duplicative. For example, HHS cites requirements in Medicaid and Medicaid managed care, but these differ from the specific requirements of the 2016 rule. *See* Justice in Aging at 5.

The elimination of the notice and tagline requirements undermines the purpose of Section 1557. Failing to provide taglines does not provide adequate notice of language assistance services and thus will not ensure entities comply with the statutory nondiscrimination requirements of Section 1557. As such, the 2020 Revised Rule is not in accordance with the underlying law and is in excess of HHS's statutory authority.

B. The 2020 Revised Rule Discriminates by Limiting Access to Effective Communication for People with Disabilities.

The lack of effective communication has "significant adverse effects on . . . access to, participation in, compliance with, and decision-making in health care." American Speech-Language-Hearing Association, Comment ID HHS-OCR-2019-0007-127462, at 3; *see also* ANCOR, Comment ID HHS-OCR-2019-0007-104180, at 2 ("It is essential that this access [to effective communication devices] is protected to ensure that [individuals with disabilities] can be active in decision making for their health and to reach the best outcomes."). To address this problem, the 2016 Final Rule provided clear definitions regarding auxiliary aids and services, interpreters, and other disability related definitions, eliminated by the 2020 Final Rule. *Compare* 81 Fed. Reg. at 31,466-67 (former

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45 C.F.R. § 92.4, § 92.202) *with* 85 Fed. Reg. at 37,213-16 (new § 92.102). The 2016 Final Rule required that all auxiliary aids and services be provided timely and free of charge as is required by other disability non-discrimination laws. Yet the 2020 Final Rule only requires that a subset of auxiliary aids and services—interpreters--be provided free of charge and in a timely manner. 45 C.F.R. § 92.102(b)(2).

Significantly, interpreters provide effective communication for a very narrow subset of people with disabilities. Auxiliary aids and devices include a broad range of services such as closed captioning, qualified readers, Braille materials, telephone handset amplifiers, and other similar devices. They also include using people with training, skill, or experience to communicate. Further, individuals with similar disabilities may need different devices or assistance. For example, a person who is hard of hearing may not always know American Sign Language or be able to use closed captioning but may be able to use an amplifying device compatible with their hearing aid.

The 2020 Final Rule's distinction between type of auxiliary aids and devices that will be provided free and timely discriminates against people who need other auxiliary aids and devices, in direct contravention of Section 1557's statutory prohibition on disability-based discrimination. *See also* 28 C.F.R. § 36.301; 34 C.F.R. § 104.4 (entity receiving Federal financial assistance is prohibited from providing an aid, benefit, or service that is not as effective as that provided to others and cannot perpetuate discrimination through criteria or methods of administration).

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III. HHS Relies on an Inappropriate Calculation of the Cost of Providing Notice and Taglines and Underestimates the Benefits.

HHS improperly relied on an incomplete cost-benefit analysis to repeal the notice and tagline requirements. HHS admits that "[r]epealing the notice and tagline requirements may impose costs, such as decreasing access to, and utilization of, healthcare for non-English speakers by reducing their awareness of available translation services[,]" 85 Fed. Reg. at 37,232, but stated that it was unaware of "a way to quantify those potential effects." *Id*. at 37,234. HHS ignored numerous comments quantifying the harm of this change and indicates that HHS failed to adequately consider the record.

HHS failed to address multiple comments on the 2019 Proposed Rule which demonstrated that the costs of providing notice under the 2016 Final Rule are not prohibitive. *See* Ass'n of Am. Med. Colls. (HHS's cost estimates related to notice were inflated and notice, at most, adds incremental burden given hospital operating procedures); ACCESS, Comment ID HHS-OCR-2019-0007-144346, at 4 (the majority of the costs estimated by HHS are associated with provision of EOBs). As many commenters pointed out, HHS provided a sample notice and translated it into 64 languages, alleviating entities from the cost of developing their own. HHS also made clear that it expected most covered entities to avoid costs by using its sample notices and exhausting current publications before printing new notices. 81 Fed. Reg. 31,453. Commenters also noted that any burdens of wall space and use of resources to post the notice were greatly outweighed by the benefits of conspicuous notice so that people are

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aware of and able to access the services that the notice promises. *See* Asian Americans Advancing Justice – Los Angeles, Comment ID HHS-OCR-2019-0007-155779, at 8-9.

HHS did not acknowledge these comments or provide any assessment or explanation why other options to reduce the purported burden of the notice requirement would not work or why eliminating the notice provision was the only option considered. Moreover, in estimating costs, HHS heavily relied on studies and reports it received from insurers and pharmacy benefit managers that were not provided to the public. *See, e.g.*, 84 Fed. Reg. at 27,258-59. Because HHS failed to adequately weigh the costs and burdens associated with repealing the notice requirement as described in the administrative record, eliminating this provision was arbitrary and capricious.

Similarly, HHS failed to provide an adequate explanation or consideration of the comments regarding the costs and burdens of the tagline requirements. At the outset, HHS failed to provide sufficient information about the basis of its cost-benefit analysis in the 2019 Proposed Rule. The information provided did not reveal information about HHS's source or methodology of the data it used in its repeal of the taglines. Without this information, commenters could not adequately comment on HHS's decision-making. *See* Leadership Conference at 8; NHeLP at 4; *see also, e.g.*, *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008) (requiring agency to make "critical factual material" upon which it relies available for public comment); *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 393 (D.C. Cir. 1973) ("It is not consonant with the purpose of a

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rule-making proceeding to promulgate rules on the basis of inadequate data, or on data that, to a critical degree, is known only to the agency.").

In promulgating the 2020 Revised Rule, HHS failed to adequately consider and address the comments explaining the value of these provisions. *See, e.g.,* Nat'l Latina Inst. Repro. Health at 1-3; California Pan-Ethnic Health Network at 1-2; Colorado Ctr. Law & Pol'y, Comment ID HHS-OCR-2019-0007-147722, at 7; NHeLP at 37; Wash. State Coalition for Language Access at 2; Justice in Aging at 4. HHS also failed to consider alternatives suggested by the commenters that could balance the potential costs with the need for individuals to be informed of their rights. *See, e.g.,* NHeLP at 68-69 (suggesting clarifying the definition of "significant document" or examining whether taglines could be included in fewer documents if the same document is sent multiple times a year); Aimed Alliance, Comment ID HHS-OCR-2019-0007-125987, at 4 (suggesting requiring more notice to be provided online rather than by mail); Viva Health, Comment ID HHS-OCR-2019-0007-127421, at 1 (suggesting annual mailings).

Instead, HHS relied solely on data provided by insurers and pharmacy benefits managers, which were not provided to the public for review before the rule was finalized. *See* 84 Fed. Reg. at 27,858-59, 27,880-82. That data did not contain any information about the reaction of individuals with LEP to the taglines or the impact on this population. HHS acknowledged comments indicating that a hospital observed a 10% increase in the volume of interpreter service encounters and another saw a 28% reduction on its per-member per-month claims cost with Spanish-speaking patients. 85

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Fed. Reg. at 37,233. It then also acknowledged one plan's minimally supported comments about the inclusion of taglines not yielding an increase in interpreter requests after 2016. Without providing any analysis of this data or additional reasoning, HHS determined that the inclusion of taglines did not improve language access. *Id.*

Further, HHS's cost-benefit analysis conflicts with the agency's prior findings. In the 2016 Final Rule, HHS acknowledged substantial benefits of notices and taglines to patients and providers. 81 Fed. Reg. at 31,459 (citing Institute of Medicine Report). The Preamble to the 2016 Final Rule additionally stated that "the burdens of taglines on covered entities are outweighed by the benefits . . . for individuals with limited English proficiency by making them aware, in their own languages, of the availability of language assistance services." 81 Fed. Reg. at 31,401. But in 2019 HHS determined that the impact of reduced awareness would be "negligible." 84 Fed. Reg. at 27,882 (citing a two-year old assertion from a single insurer about the lack of appreciable rise in translation services after the 2016 rule). HHS further reasoned that the vast majority of recipients of taglines do not benefit from them. 85 Fed. Reg. at 37,211. This rationale ignores the purpose of taglines in reaching those who would otherwise not know about services to help them access health care. The elimination was arbitrary and capricious.

IV. HHS's Narrowing of Section 1557 Covered Entities Contravenes Statutory Intent.

As enacted by Congress, Section 1557 protects individuals from discrimination in any "health program or activity," any part of which is receiving Federal financial assistance; or any program or activity administered by the Executive, or any entity

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established under Title I of the ACA. 42 U.S.C. § 18116(a). Contrary to the language of Section 1557, the 2020 Revised Rule only applies the non-discrimination protections to health programs or activities that receive federal financial assistance from HHS; programs or activities administered by HHS under ACA Title I; and entities established under Title I of the ACA. 85 Fed. Reg. at 37,167-71. This definition and the incorporated narrow definition of health program or activity and Federal financial assistance is not supported by the plain meaning of Section 1557 or the ACA. Am. Med. Ass'n., Comment ID HHS-OCR-2013-0007-137131, at 2-3; Cities of New York et al., Comment ID HHS-OCR-2013-0007-147950, at 16-18; NHeLP at 9-17.

The ACA does not define the term "health program or activity," but uses the term health program at least 30 times to reference the provision both of care and of insurance. *See, e.g.*, 42 U.S.C. § 18051; *id.* § 299b-31 (cross-referencing 42 U.S.C. § 1320a-7b); 25 U.S.C. § 1623. Under the ACA, health program or activity is a broad, inclusive term. In the 2020 Revised Rule, HHS's cramped interpretation carves out many entities and defines health care to separate health care services from paying for those services. 85 Fed. Reg. at 37,172-73. Using this distinction, HHS's conclusions about who is a "health program or activity" leads to an absurd result not consistent with the ACA, as it would lead to many health care programs—Federal or private—not being covered entities because it is rare that any program directly provides services rather than paying for services provided. Sharply reducing the types of covered entities creates significant harm to individuals served by those entities who may now have very

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limited recourse for addressing discrimination in those programs, including many Federally funded programs and private insurance plans, such as employer sponsored plans. *See, e.g.,* ACLU Foundations of California at 10; NHeLP at 11-15; *see generally* Brief of Northwest Health Law Advocates et al. as Amicus Curiae, ECF No. 30-1.

In addition, the language of Section 1557, including that regarding Federal financial assistance, reflects that of similar remedial statutes such as Section 504 of the Rehabilitation Act of 1973 that apply coverage broadly. *See* 29 U.S.C. § 794; *but see* 85 Fed. Reg. at 37,171 (HHS asserting the statute is different and ignoring the language similarities). The cramped reading of Section 1557 is contrary to the statute, including the provision of Section 1554 limiting HHS's rulemaking authority. 42 U.S.C. § 18114.

CONCLUSION

The ACA reforms addressed discriminatory practices in nearly all health programs, both public and private. The 2016 Final Rule reflected this broad view of protecting individuals from discrimination in health programs and activities. The 2020 Revised Rule seeks to return to a more recessive understanding of discrimination in health care. HHS's new interpretation is contrary to the ACA's approach to health care.

The 2020 Final Rule is contrary to law, arbitrary and capricious, and harmful to individuals who are protected by Section 1557. For the forgoing reasons and those set forth in the State's memorandum in support of this motion, this Court should grant Washington's request for a preliminary injunction.

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DATED: August 14, 2020.

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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, causing it to be served on all counsel who have entered an appearance.

DATED: August 14, 2020, at Sacramento, California.

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