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The Honorable Alex M. Azar II Secretary U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Mr. Roger Severino
Director
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Ave. S.W.
Washington, DC 20201

Re: Nondiscrimination in Health and Health Education Programs and Activities (Section 1557 NPRM), RIN 0945-AA11

Dear Secretary Azar and Mr. Severino:

The National Health Law Program (NHeLP) appreciates the opportunity to comment on the proposed rule (NPRM) on Section 1557 of the Patient Protection and Affordable Care Act (ACA) ("Health Care Rights Law" or "Section 1557"). For over fifty years, NHeLP has worked to improve health access and quality through education, advocacy and litigation on behalf of low-income and underserved individuals. Given both our history and our decade of work ensuring Section 1557 is implemented according to Congressional intent, we are especially concerned with the proposed changes sought by HHS.

Section 1557 is the key nondiscrimination provision of the Affordable Care Act (ACA).¹ It prohibits discrimination in health programs and activities receiving federal financial assistance, health programs and activities administered by the executive branch, as well as entities created under the ACA, including the Marketplaces and health plans sold through the Marketplaces. Section 1557's protections extend to discrimination on the basis of race, color, national origin (including language access), sex, age, and disability by building on existing civil rights laws.² It is the first federal law to ban sex discrimination in health care. Section 1557 recognizes that individuals may be part of multiple protected classes and may face discrimination because they belong to one or more of these classes.

The Department of Health and Human Services (HHS) underwent an extensive process to develop regulations for Section 1557, including a Request for Information, proposed rule, and final rule.³ HHS considered more than 24,875 public comments submitted for the 2016 rule.⁴ This new proposed rule ignores the reasoned process HHS has already undertaken.

As an organization committed to upholding the civil rights of all persons, we strongly oppose the NPRM provisions which seek to eliminate and limit protections for individuals who are limited English proficient, LGBTQ+ persons, women and persons with disabilities and chronic conditions. Section 1557 addresses not only protections for each protected class covered, but the intersection of those protections. As such, an attack on the civil rights of one group in the NPRM is an attack on the civil rights of all. We strongly recommend that HHS not finalize any part of the proposed changes to the

³ U.S. Dep't of Health & Human Servs., *Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities*, 78 Fed. Reg. 46558 (Aug. 1, 2013); U.S. Dep't of Health & Human Servs., *Nondiscrimination in Health Programs and Activities* (Notice of Proposed Rulemaking), 80 Fed. Reg. 54172 (Sept. 8, 2015); U.S. Dep't of Health & Human Servs., *Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Health Programs or Activities Administered by the Department of Health and Human Services or Entities Established under Title I of the Patient Protection and Affordable Care Act, 45 C.F.R. Part 92, 81 Fed. Reg. 31376 (May 18, 2016) (hereinafter "2016 Final Rule").*



¹ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010); 42 U.S.C. § 18116.

² Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d et seq.), Title VII of the Civil Rights Act of 1964 (42 U.S.C. § 2000e et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et seq.), Section 794 of Title 29, or the Age Discrimination Act of 1975 [42 U.S.C. § 6101 et seq.].

Section 1557 regulations as well as the other conforming provisions. HHS should instead leave the 2016 final Section 1557 regulations in place in their entirety.

II. Reasons for the Proposed Rulemaking

- A. Section 1557 of the PPACA Does not Prevent or Limit Reconsideration of the Proposed Rule &
- B. Litigation Challenging the Section 1557 Regulation

Rather than respond individually to each statement under II.A. and II. B. as outlined in the NPRM, we are providing comments for these statements based on our own organization. That said, we believe we have addressed each of these specific statements.

a. HHS posits specious reasons for revising the current Section 1557 regulations

HHS repeatedly cites to the preliminary injunction issued by a federal district court in the *Franciscan Alliance v. Azar* case as its reason for revising or eliminating much of the current Section 1557 regulations.⁵ However, the preliminary injunction issued by Judge Reed O'Connor does not overturn the 2016 Final Rule in whole or in part; nor does it order HHS to revise the rule.⁶ In its discussion of reasons to revise the current regulations, HHS fails to explain why it gives greater weight to Judge's O'Connor's preliminary injunction invalidating Section 1557's regulatory protections against gender identity discrimination, while ignoring the decisions reached by other courts upholding Section 1557's gender identity protections.⁷ It is imprudent for HHS to invest considerable time and resources in a proposed rulemaking process based upon a legally-suspect preliminary injunction.

HHS further states that, in light of Judge O'Connor's preliminary injunction, the repeal or revision of current Section 1557 regulations would "minimize litigation risk." This is an

Prescott v. Rady Children's Hosp., 265 F. Supp. 3d 1090 (S.D. Cal. 2017), Flack v. Wisconsin Dept. of Health Srvs., 18-cv-309, 2018 WL 3574875 (W.D. Wis. Jul. 25, 2018), Flack v. Wis. Dep't of Health Servs., No. 18-cv-309-wmc, 2019 U.S. Dist. LEXIS 68824 *3 (W.D. Wis. Apr. 23, 2019), Boyden v. Conlin, No. 17-cv264-WMC, 2018 (W.D. Wis. September 18, 2018), Tovar v. Essentia Health, No. 16-cv-00100-DWF-LIB (D. Minn. September 20, 2018).
 84 Fed. Reg. 27849.



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⁵ E.g., 84 Fed. Reg. 27848, 27856, 27870.

⁶ See generally *Franciscan Alliance v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016).

absurd contention, since changes in the regulations will increase, rather than decrease, confusion and uncertainty. At the very least, HHS should wait until the pending legal challenges to the 2016 Final Rule are resolved, since even a final ruling from Judge O'Connor would not end litigation.⁹

Even if the ultimate resolution of *Franciscan Alliance* were at hand, current regulations for Section 1557 provide for the severability of any provision upon a holding of "utter invalidity or unenforceability."¹⁰ The proposed rule not only ignores this provision, but eliminates it without explanation.

HHS fails to provide explanation, evidence, or reasoning when in its proposal to eliminate significant portions of the current Section 1557 regulations. HHS repeatedly cites to "independent" analyses apart from the proposed rule's Regulatory Impact Analysis ("RIA") and which are not specified or the underlying data and methodology of which are not publicly available. ¹¹ In addition, as described in more detail below (*infra*, Section VI), HHS bases its RIA on a number of assumptions without providing any explanation or evidence of their bases. ¹² We are therefore unable to fully comment on many aspects of HHS' revision and rollback of key regulatory protections.

Instead of providing, as HHS predicts, "finality, predictability, administrability (*sic*), consistency, relief of burdens, and clarity," the proposed rule, if finalized, would create confusion, uncertainty, noncompliance, and, without a doubt, legal challenges. ¹³ Of greater concern, however, are the countless individuals who will denied access to medically necessary care, or avoid seeking care altogether, because of ongoing, unchecked discriminatory practices by insurers and providers.

¹³ 84 Fed. Reg. 27849.



⁹ Since his confirmation to the federal bench in 2007, Judge O'Connor has issued final verdicts in only 1% of more than 3,000 cases heard. Of those decisions, one in five has been reversed, remanded, or vacated. See *Litigation Analytics Report for Hon. Reed O'Connor*, Westlaw Edge (last visited July 15, 2019),

https://1.next.westlaw.com/Analytics/Profiler?docGUID=I2005BD7E1DD211B2BA18A50062060 E54&contentType=judge&view=profile&dataOrchGUID=68f821f1f9404fdf986029b7644666ca&tr ansitionType=LegalLitigation&contextData=(sc.Default)#/judge/I2005BD7E1DD211B2BA18A50 062060E54/profile.

¹⁰ 45 C.F.R. § 92.2(c).

¹¹ See *e.g.*, 84 Fed. Reg. 27858.

¹² See e.g., 84 Fed. Reg. 27876.

Given these fundamental flaws in HHS reasoning for rolling back critically important regulations protecting against discrimination, we strongly urge HHS to withdraw this ill-conceived and haphazard "deregulatory action." ¹⁴

b. The 2016 Final Rule properly blended substantive requirements and enforcement mechanisms of the referenced statutes

The proposed rule selectively cites to court cases involving Section 1557, offering an incomplete and distorted version of developing case law for enforcing Section 1557. The NPRM cites *SEPTA v. Gilead Sciences, Inc.,* a district court case out of Pennsylvania, for the notion that the statute imported the "various different standards and burdens of proof" into Section 1557, "depending on the protected class at issue." The NPRM suggests that courts are settled on the issue and have clear standards for Section 1557 cases, when courts certainly are not. 16

The NPRM largely ignores the decision of *Rumble v. Fairview Health Services* and subsequent case law in its discussion of enforcement mechanisms under Section 1557.¹⁷ Its only mention of *Rumble* mischaracterizes its holding and provides the wrong year in its citation.¹⁸ HHS suggests that the *Rumble* opinion aligns with *SEPTA*, despite the fundamental conflict between the two decisions.¹⁹

Rumble concludes that Section 1557's text provides a "new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status." *Rumble* has been repeatedly cited by federal courts for the interpretation that Section 1557 has a private right of action.²¹ The *Rumble* court

²¹ See, e.g., Callum v. CVS Health Corp., 137 F.Supp.3d 817, 845 (D.S.C. 2015); Esparza v. Univ. Med. Ctr. Mgmt. Corp., No. CV 17-4803, 2017 WL 4791185, at *4 (E.D. La. Oct. 24,



¹⁴ *Id*.

¹⁵ 102 F. Supp. 3d 688, 698–99 (E.D. Pa. 2015).

¹⁶ See, e.g., *Doe One v. CVS Pharmacy, Inc.*, 348 F. Supp. 3d 967, 981 (N.D. Cal. 2018) (stating that "[n]o consensus has yet emerged as to the standard for assessing ACA anti-discrimination claims" and describing the different standards of *Rumble* and *SEPTA*). Only one appellate decision has addressed this question to date, so there is also no consensus from the appellate courts. *See Doe v. BlueCross BlueShield of Tennessee, Inc.*, 926 F.3d 235, 241 (6th Cir. 2019).

¹⁷ Rumble v. Fairview Health Servs., 2015 WL 1197415 at *11 (D. Minn. 2015).

¹⁸ See 84 Fed. Reg. 27873, citing to a nonexistent 2017 ruling. Presumably, HHS is referring to the 2015 decision cited above.

¹⁹ *Id*.

²⁰ Rumble v. Fairview Health Servs., 2015 WL 1197415 at *11 (D. Minn. 2015).

further explains that allowing disparate impact actions for some plaintiffs but not others, depending on their protected class, would be an "absurd inconsistency" that would also leave courts with no clear standard when a plaintiff alleging discrimination belonged to more than one protected class.²²

HHS also overstates the impact of pre-ACA cases and misrepresents their holdings when arguing that disparate impact claims are not available under Section 1557.²³ For example, the NPRM cites to *Crocker* for support, yet *Crocker* refused to make a decision on whether there was a private right of action for disparate impact discrimination under Section 504 and discussed the issue only in dicta.²⁴ HHS then makes a second leap that the *Crocker* dicta applies to Section 1557 claims.²⁵ In its analysis, HHS also fails to recognize that Congress passed Section 1557 as a key component of the ACA, a set of sweeping reforms that changed what health care and health insurance practices were acceptable and banning discriminatory activities that courts had previously allowed. Cases cited in the NPRM have overly relied on interpretations of the underlying statutes without recognizing the inherent shifts that ACA made in the health care realm. If Section 1557 were limited by the constraints of the referenced statutes, its passage would have been largely unnecessary, as the four civil rights statutes already apply to organizations "in the business of providing . . . health care."²⁶

HHS' reliance on select case law to support regulatory changes is misleading and presents a distorted picture of Section 1557's enforcement mechanisms. The changes suggested in the proposed rule will not clarify the law, and may make it harder for people who experience discrimination to enforce their rights through administrative and judicial complaints.

²⁶ See, e.g., 29 U.S.C. § 794 (2018) (Rehabilitation Act).



^{2017);} *Griffin v. Gen. Elec. Co.*, No. 1:15-CV-4439-AT, 2017 WL 8785572, at *3 (N.D. Ga. Dec. 6, 2017), aff'd, 752 F. App'x 947 (11th Cir. 2019); *Audia v. Briar Place, Ltd.*, No. 17 CV 6618, 2018 WL 1920082, at *3 (N.D. III. Apr. 24, 2018); *Ass'n of New Jersey v. Horizon Healthcare Servs., Inc.*, No. CV 16-08400(FLW), 2017 WL 2560350, at *4 (D.N.J. June 13, 2017); *York v. Wellmark, Inc.*, 2017 WL 11261026, at *16 (S.D.lowa Sep. 06, 2017); *Briscoe v. Health Care Serv. Corp.*, 281 F.Supp.3d 725, 737 (N.D. III. 2017).

²² Rumble at *11-12.

²³ 84 Fed. Reg. 27851.

²⁴ Crocker v. Runyon, 207 F.3d 314 (6th Cir. 2000).

²⁵ 84 Fed. Reg. 27851.

c. The current regulations are already consistent with the regulations of HHS and other agencies

HHS vastly overstates the need for the Section 1557 regulations to be consistent with other HHS regulations and the regulations of other agencies, and the extent to which the current Section 1557 regulations are inconsistent with other regulations.

The current regulations underwent extensive review for consistency with the regulations of HHS and other agencies before they were promulgated. As HHS notes, Executive Order 12250 § 1-201 requires the Attorney General to "coordinate the implementation" and enforcement of [Title VI, Title IX, Section 504 and a]ny other provision of other provision of Federal statutory law which provides, in whole or in part, that no person in the United States shall, on the ground of race, color, national origin, handicap, religion, or sex, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance."27 In the case of the current Section 1557 regulations, DOJ did indeed review the rule before it was published. Another Executive Order, Executive Order 12866, explicitly requires that: "Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies."28 As required by that executive order the current Section 1557 rule was vetted by OMB/OIRA and deemed consistent with other regulations by HHS and other agencies.²⁹. Despite HHS's suggestion to the contrary, the current Section 1557 rule was extensively reviewed by the executive branch for consistency with other regulations before it was finalized. HHS provides no explanation for why these review processes were not sufficient or failed to identify purported inconsistencies.

In the preamble to this proposed rule, HHS also cites 42 U.S.C. § 6103(a)(4) requiring consistency with other regulations.³⁰ That part of the Age Discrimination Act requires:

the head of each Federal department or agency which extends Federal financial assistance to any program or activity by way of grant, entitlement, loan, or contract other than a contract of insurance or guaranty, shall transmit to the Secretary and publish in the Federal Register proposed regulations to carry out

³⁰ Cited at 84 Fed. Reg. 27851 n. 28.



²⁷ Cited at 84 Fed. Reg. 27851 n. 28.

²⁸ Executive Order 12866 § 1(b)(10).

²⁹ See Executive Order 12866 §§ 2(b), 3(f)(2), 4(c)(5); see also Executive Order 13563 § 1(a).

the provisions of section 6102 [prohibiting age discrimination] and to provide appropriate investigative, conciliation, and enforcement procedures. Such regulations shall be consistent with the final general regulations issued by the Secretary [of HHS], and shall not become effective until approved by the Secretary.³¹

Since the 1557 final rule was promulgated by HHS, by the terms of this statutory provision, it did not need to undergo separate HHS review. Thus, this provision is simply not relevant to the question of consistency, since it only applies to other agencies besides HHS, and applies in the specific context of applying the provisions of the Age Discrimination Act. In any event, HHS drafted the final rule with knowledge of its prior regulations on age discrimination and crafted the rule to be consistent with its other regulations.

Moreover, the specific examples of purported inconsistencies given by HHS in the preamble are not actually inconsistent with the current Section 1557 regulations. For example, the fact that NIH has a policy that its grants should explain certain differences between males and females based on biological factors is not inconsistent with the current Section 1557 regulations' determination that discrimination on the basis of sex encompasses discrimination on the basis of gender identity.³² Making a clinical distinction between two sexes based on factors such as sex chromosomes, gonads, sex hormones, and non-ambiguous internal and external genitals in no way negates the experience of discrimination by transgender people, whose gender identity does not match the sex they were assigned at birth. Nor does the fact that OCR has separately defined "gender" and "sex" separately in certain regulations imply that "gender" is a concept wholly unrelated to sex, such that discrimination on the basis of sex can never include discrimination based on gender identity or transgender status.³³ And the position taken by DOJ in Title VII litigation and an internal memo as to whether discrimination on the basis of sex includes discrimination on the basis of gender identity is completely irrelevant to the question of whether Section 1557 protects against discrimination on the basis of gender identity.³⁴ Rather, as described in more detail *infra* Section III.B, the current regulations that protect against discrimination on the basis of gender identity

³⁴ 84 Fed. Reg. 27856-57. *See Kisor v. Wilkie*, 139 S. Ct. 2400 (2019) ("[A]n agency's reading of a rule must reflect its 'fair and considered judgment,' [so a] court should decline to defer, for example, to a merely 'convenient litigating position,' . . . or to a new interpretation that creates 'unfair surprise' to regulated parties.") (citations omitted).



³¹ 42 U.S.C. § 6103(a)(4).

³² See 84 Fed. Reg. 27853-54.

³³ 84 Fed. Reg. 27854.

appropriately implement Section 1557. In any event, the proposed changes to the regulations create just as many, if not more inconsistencies with current regulations as described throughout our comments below. This supposed basis for completely overhauling the current regulations is unsupported and unsound.

d. The Costs of the Final Rule Were Unnecessary and Unjustified

Please see our discussion under III.B regarding repealing the notice and tagline requirements as well as our comments regarding the Regulatory Impact Analysis.

III. Nondiscrimination in health programs or activities

<u>Proposed Subpart A – General Provisions</u>

§ 92.2 Nondiscrimination Requirements & § 92.3 Scope of Application

a. The ACA's nondiscrimination protections have broad applicability and scope

Prior to the ACA, health insurance companies routinely discriminated by denying coverage to individuals with pre-existing conditions. Insurance companies charged women higher premiums than men, and often imposed annual and lifetime caps on benefits, which disproportionately affected people living with serious, chronic, or lifethreatening medical conditions.

Congress passed the ACA to put an end to these discriminatory practices. The ACA requires guaranteed issue of coverage in the individual and small group health insurance markets so that no one can be denied health insurance due to a preexisting condition.³⁵ Health insurers may no longer exclude coverage of a preexisting condition.³⁶

The ACA further prohibits discrimination against individual participants and beneficiaries based on health status or medical condition, and it prevents insurers from imposing annual or lifetime limits on benefits.³⁷ The ACA also sought to end discrimination in the types of health benefits offered by requiring most individual and small group health

³⁷ 42 U.S.C. §§ 300gg–4; 300gg-11.



³⁵ 42 U.S.C. § 300gg-1.

³⁶ *Id*.

plans to provide comprehensive health benefits in ten broad categories of coverage, known as Essential Health Benefits, or EHBs.³⁸

In the 2016 Final Rule, HHS acknowledged the invidious nature of discrimination prior to the ACA:

Prior to the enactment of the ACA, insurance companies were allowed to impose higher premiums on women or deny women coverage altogether. If issuers did cover women, they frequently did not cover a number of women's health services, including routine preventive services, such as pap smears or mammograms. Insurance premiums previously could differ by sex, and were often higher for females relative to males. The ACA prohibits differential treatment based on sex, includes maternity coverage essential health benefits, and requires non-grandfathered plans to cover women's preventive services without copays, among other benefits.³⁹

In the 2016 Final Rule, HHS further highlighted the purposes of the ACA and how Section 1557's protections are inexorably linked to broader ACA coverage requirements and other protections: "a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country." This interpretation is consistent with the Supreme Court's recognition of the broader purpose of the ACA to "expand insurance coverage. . . . [and] ensure that anyone can buy insurance." ⁴¹

Congress has repeatedly rejected attempts to repeal the ACA.⁴² The ACA's protections, including Section 1557, remain vitally important for persons with preexisting conditions and those who experience discrimination by health insurance companies and providers. HHS' proposal to rewrite or eliminate regulations implementing Section 1557 is nothing less than an end run around the ACA's statutory protections against discrimination.

⁴² See C. Stephen Redhead & Janet Kinzer, *Legislative Actions in the 112th, 113th, and 114th Congresses to Repeal, Defund, or Delay the Affordable Care Act,* Congressional Research Service (Feb. 7, 2017), https://fas.org/sqp/crs/misc/R43289.pdf.



³⁸ 42 U.S.C. § 18022.

³⁹ 81 Fed. Reg. 31460.

⁴⁰ 81 Fed, Reg. 31379.

⁴¹ King v. Burwell, 135 S. Ct. 2480, 2493 (2015).

b. The proposed rule contravenes Congress' intent to broadly apply the ACA's nondiscrimination protections

Section 1557, according to the statute and current regulations, applies to health care programs and activities receiving federal financial assistance or funding; programs administered by the federal government, including Medicare and the Indian Health Service (IHS); and entities created under Title I of the ACA. Covered entities include hospitals, clinics, and health care provider's offices and issuers selling health insurance plans within and outside of the ACA Marketplaces.⁴³ If an entity is principally engaged in providing or administering health services or health insurance coverage, the current regulations state that all of its activities are covered by Section 1557 if any part receives federal financial assistance.⁴⁴

The current regulations are consistent with Congress's intent in enacting Section 1557. Congress's intended Section 1557 to build and expand upon existing civil rights laws, while providing broad protection against discrimination in health care. Moreover, Congress has repeatedly expressed that it intends civil rights laws to be broadly interpreted in order to effectuate their remedial purposes.⁴⁵

The proposed rule seeks to significantly narrow the scope and applicability of Section 1557 contrary to the plain meaning of the statute and well-established implementation of civil rights laws.

c. HHS proposed definition of federal financial assistance is overly narrow and inconsistent with other regulations

HHS proposes to eliminate the current definition of federal financial assistance (FFA) under Section 1557, and to construe narrowly what entities qualify as a recipient of FFA. This proposed interpretation is inconsistent with Section 1557, and with other HHS regulations defining FFA recipients. For example, in the health care refusals rule *Protecting Statutory Conscience Rights in Health Care* finalized in May 2019, HHS defined FFA broadly as:

1) grants and loans of Federal funds;

⁴⁵ See Kang v. U. Lim Am., Inc., 296 F.3d 810, 816 (9th Cir. 2002); see also H. Rep. No. 102–40(I), at 88, U.S. Code Cong. & Admin. News at 626 (stating that "remedial statutes, such as civil rights law[s], are to be broadly construed").



⁴³ 42 U.S.C. § 18116(a); 45 C.F.R. §§ 92.2(a), 92.4.

⁴⁴ 45 C.F.R. § 92.4.

- 2) "the grant or loan of Federal property and interests in property:
- 3) the detail of Federal personnel;
- 4) "the sale or lease of, and the permission to use (on other than a casual or transient basis), Federal property or any interest in such property without consideration or at a nominal consideration [...]; and
- 5) "any agreement or other contract between the Federal government and a recipient that has as one of its purposes the provision of a subsidy to the recipient.⁴⁶

HHS explained that this definition "mirrors the definition used in the Department's regulations implementing Title VI, and is intended to carry the same meaning as it has traditionally been understood to carry in the application of those regulations."⁴⁷ HHS further argues that modelling the health care refusals' FFA definition on Title VI regulations will make compliance easier since entities subject to this regulation "will be sufficiently familiar with that meaning to understand its application in this final rule."⁴⁸

The 2016 Final Rule defines FFA in the same way – adding only clarifications regarding subsidies and contracts as required by statute and reiterating FFA includes "grants, loans, and other types of assistance in accordance with the definition of Federal financial assistance in the regulations implementing Section 504 and the Age Discrimination Act... and Title IX."⁴⁹ This interpretation flows from the text and context of Section 1557, and is correct.

HHS now proposes to eliminate all definitions under Section 1557, including FFA and recipients, and to instead interpret both FFA and recipients narrowly. As justification, HHS contends that the 2016 Final Rule exceeded the bounds of the statute by describing FFA which HHS has a primary responsibility for administering, as well as FFA in which HHS "plays a role in administering." (See further discussion on FFA in which HHS "plays a role" in subsection (d) below). Not only is this interpretation inconsistent with Section 1557, but it is inconsistent with HHS's own regulations. The 2019 health care refusals rule does not limit applicability to assistance HHS has a

⁵⁰ 84 Fed. Reg. 27861, citing 45 C.F.R. § 92.4.



⁴⁶ 45 C.F.R. § 88.2.

⁴⁷ 84 Fed. Reg. 23193.

⁴⁸ *Id.* citing to 45 C.F.R. § 80.13(f).

⁴⁹ 81 Fed. Reg. 31467. In the 2016 Final Rule, HHS relies on Title IX regulations to establish that premium tax credits, while paid to the individual (and for the benefit of the individual) amount to financial assistance for the institution (e.g., insurers and the QHPs they provide) – just as student loans or grants are for the student, but ultimately paid to the institution. 81 Fed. Reg. 31383.

primary responsibility for administering, but instead broadly encompasses "grants and loans of Federal funds" as part of its definition of FFA.⁵¹

In the Section 1557 proposed rule, HHS does not explain why it defines FFA very broadly for the purposes of allowing providers to deny medically necessary care based upon religious or moral grounds in one regulatory context, yet defines FFA very narrowly for purposes of nondiscrimination in this proposed rule. The proposed, narrow interpretation of FFA is unjustified, and inconsistent with its other regulations defining FFA and is certain to cause confusion about Section 1557's applicability.

Further, if this change were nevertheless implemented, it would have significant consequences, particularly for consumers who purchase short-term limited duration insurance ("STDLI"). If implemented, the proposed rule would generally not apply to STDLI plans because insurers are no longer considered health care entities, and these specific plans do not receive federal financial assistance. Exempting STDLI plans from Section 1557's protections is not consistent with Congress's intent to provide broad protection against discrimination in health care.

We oppose eliminating the current regulation defining FFA, because HHS' selective interpretation that FFA applies narrowly under Section 1557 is incorrect.

d. Section 1557 extends to federal financial assistance in which HHS "plays a role"

The 2016 Final Rule recognizes that premium tax credits constitute FFA which subjects Qualified Health Plans (QHPs) and their issuers to Section 1557 protections.⁵² However, the proposed rule says that only FFA administered by HHS constitutes FFA for purpose of the applicability of the rule, since premium tax credits are ultimately provided by the Internal Revenue Service (IRS).⁵³ The proposed rule also eliminates language in the current rule saying it applies to FFA that HHS "plays a role" in administering.⁵⁴

HHS' proposal would create confusion and seemingly attempts to exempt key parts of ACA Marketplace coverage from Section 1557 regulations. HHS states that QHPs "may" still be subject to HHS regulations and enforcement for Section 1557 on "other

⁵⁴ 84 Fed. Reg. 27859.



⁵¹ 45 C.F.R. § 88.2.

⁵² See 45 C.F.R. § 92.4.

⁵³ 84 Fed. Reg. 27861.

grounds."⁵⁵ Later, HHS says QHPs are subject to HHS regulations as Title I entities (see discussion in subsection (e) below).⁵⁶

Under the proposed rule, the Marketplaces would presumably be covered as entities created under Title I of the ACA. However, premium tax credits and other functions, such as income, identity, and other verifications performed through the data hub might not be. The result would be confusion and fragmentation in applicability of Section 1557.

e. The proposed rule creates confusion regarding its applicability to Title I entities

In the proposed rule, HHS says that "exchange plans" *may* be subject to Section 1557; and QHPs *are* subject to Section 1557 because they are sold through exchanges created by Title I.⁵⁷ The ACA defines QHPs, stating that they must meet certification standards established by the exchange "through which such plan is offered."⁵⁸ However, stand-alone dental plans and catastrophic plans are also sold through exchanges created by Title I. HHS does not explain why or when an "exchange plan" that is not a QHP would be exempt from Section 1557.

QHPs and other plans sold through exchanges are subject to Section 1557 in two ways – they receive FFA and are entities created under Title I. Instead of adding clarity, HHS' proposed rule creates considerable confusion by suggesting that some exchange plans are subject to Section 1557 while others are not.

f. HHS seeks to exempt itself and other federal programs and agencies from Section 1557's nondiscrimination requirements

The plain language of Section 1557, as well as the 2016 Final Rule, establishes that any health "program or activity" administered by an Executive agency is subject to the law's provisions. ⁵⁹ However, the proposed rule seeks to exempt from Section 1557 most federal health programs and agencies administering those programs. HHS imagines that Congress sought to limit application Section 1557 only to federal health programs or activities created under Title I of the ACA. This theory stands contrary to the statutory text, design, and intent of Section 1557 and the ACA.

⁵⁹ 42 U.S.C. § 18116 (a); 42 C.F.R. §§ 92.1, 92.2, 92.4.



⁵⁵ 84 Fed. Reg. 27861.

⁵⁶ *Id*.

⁵⁷ 84 Fed Reg. 27861 (emphasis added).

⁵⁸ 42 U.S.C. § 18021(a)(1)(A).

HHS' new interpretation of Section 1557 in effect changes the word "or" to "and," specifying that the law applies to health programs or activities administered by an Executive agency "and" created under Title I.⁶⁰ This reading of statute would create a surplusage. If Congress had intended to limit Section 1557 only to those entities created under Title I, it would not have included the clause pertaining to executive agencies. See, e.g., Colautti v. Franklin, 439 U.S. 379, 392 (1979) ("Appellants' argument . . . would make either the first or the second condition redundant or largely superfluous, in violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative.").⁶¹

Moreover, if implemented, it would lead to a situation whereby recipients of FFA would be subject to Section 1557, but the programs themselves, and the agencies administering them, would be exempt. For example, under HHS new interpretation, state Medicaid programs would be subject to Section 1557 as recipients of FFA, but the Centers for Medicare & Medicaid Services, which administers these programs, would be exempt. Such an interpretation is not only inconsistent with the plain meaning of Section 1557, but it is also inconsistent with section 504, and therefore likely to cause significant confusion. HHS and all its components, including CMS, the Health Resources Services Administration (HRSA), the Centers for Disease Control and Prevention (CDC), and the Substance Abuse and Mental Health Services Administration (SAMHSA), are subject to section 504's prohibition on discrimination. 62

We strongly urge HHS to retain the current regulations addressing the applicability of Section 1557 and not finalize the proposed 45 C.F.R. § 92.3.

g. Health insurance is health care

The current definition of "health program or activity" promulgated by HHS in the 2016 Final Rule cites to the Civil Rights Restoration Act's ("CRRA") definition of "program or activity" as including "all of the operations of an entity [that is] principally engaged" in a covered service. 63 HHS explained that its interpretation of "principally engaged" follows the approach of the CRRA, which it says Congress included in Section 1557 via the four

⁶³ 81 Fed. Reg. 31385.



^{60 84} Fed. Reg. 27862.

⁶¹ See also, *Yates v. United States*, 135 S. Ct. 1074, 1085 (2015) (plurality opinion) (declining to read statute so as to "significantly overlap" with a distinct statute, resisting a reading that would "render superfluous an entire provision passed in proximity as part of the same Act").

^{62 29} U.S.C. § 794; 45 C.F.R. Part 85.

civil rights statutes referenced therein.⁶⁴ HHS acknowledges that under the CRRA, "the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance."⁶⁵ HHS reasonably concluded because "Congress adopted a similar approach with respect to the scope of health programs and activities covered by Section 1557. If any part of a health care entity receives Federal financial assistance, then all of its programs and activities are subject to the discrimination prohibition."⁶⁶

However, in the proposed rule, HHS seeks reverse the current rule, positing that providing health care "differs substantially" from providing health insurance coverage. ⁶⁷ As such, HHS seeks to exempt a broad swath of health insurance companies from the application of Section 1557. This nonsensical result would, if fully implemented, would significantly reduce the application of the law through regulation. Moreover, it is inconsistent with the plain language of Section 1557 and Congress's intent.

HHS provides no support for its tortured interpretation that health insurance is not a health program or activity within the meaning of Section 1557. An insurer does not simply process claims. Insurers design benefits, establish formularies, payment structures, and networks. Insurers conduct prior authorization, and establish and evaluate other clinical coverage criteria. Insurers exercise considerable control over the health care of enrollees — deciding what providers a patient may see, what hospitals they may visit, and what treatments or medications they may receive. ⁶⁸ In the 2016 Final Rule, HHS directly addressed the responsibility of insurers to comply with Section 1557 when insurers act as third party administrators for self-insured plans. ⁶⁹

HHS' new interpretation, that health insurance is not health care, is not only contrary to the design and intent of the ACA but is contrary to the plan language of Section 1557 which applies to "any health program or activity." Thus, at a minimum, Section 1557's

⁷⁰ 42 U.S.C. § 18116(a) (emphasis added).



⁶⁴ Id. at 31386.

⁶⁵ *Id*.

⁶⁶ Id. See also 45 C.F.R. § 92.4.

⁶⁷ 84 Fed. Reg. 27850.

⁶⁸ See, e.g., Institute of Medicine, Controlling Costs and Changing Patient Care? The Role of Utilization Management 13 (1989); Joseph B. Clamon, Does My Health Insurance Cover It - Using Evidence-Based Medicine and Binding Arbitrator Techniques to Determine What Therapies Fall under Experimental Exclusion Clauses in Health Insurance Contracts, 54 Drake L. Rev. 473, 508 (2006).

⁶⁹ 81 Fed Reg. 31432.

applicability all of the operations of an entity principally engaged in health care, including health insurers, is the only plausible reading of the CRRA and Section 1557.

As HHS emphasized in the 2016 Final Rule, applying Section 1557 to all the operations of a health insurer, or any other health program or activity, if any part receives FFA, is the very purpose of the ACA and its nondiscrimination protections:

This interpretation serves the central purposes of the ACA and effectuates Congressional intent, by ensuring that entities principally engaged in health services, health insurance coverage, or other health coverage do not discriminate in any of their programs and activities, thereby enhancing access to services and coverage.⁷¹

The proposed rule makes no mention of the potential consequences to millions of people if health insurance companies were exempt from Section 1557.

However, in the 2016 Final Rule, HHS explained:

One of the central aims of the ACA is to expand access to health care and health coverage for all individuals. Equal access for all individuals without discrimination is essential to achieving this goal. Discrimination in the health care context can often lead to poor and inadequate health care or health insurance or other coverage for individuals and exacerbate existing health disparities in underserved communities. Individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care; individuals who are subject to discrimination are denied opportunities to obtain health care services provided to others, with resulting adverse effects on their health status. Moreover, discrimination in health care can lead to poor and ineffective distribution of health care resources, as needed resources fail to reach many who need them. The result is a marketplace comprised of higher medical costs due to delayed treatment, lost wages, lost productivity, and the misuse of people's talent and energy.⁷²

Without question, Congress intended the ACA and its key nondiscrimination provision, Section 1557, to broadly provide protections against insurance company abuses. The very notion that HHS would seek to exempt insurers from nondiscrimination requirements defies rational explanation. We oppose proposed § 92.3.

⁷² 81 Fed. Reg. 31444.



⁷¹ 81 Fed. Reg. 31386.

§ 92.4 Assurances required

We strongly support having assurances required for compliance with Section 1557 for those receiving federal funds.

§ 92.5 Enforcement Mechanisms

We oppose the proposed changes to § 92.301 as newly designated § 92.5. HHS's proposed rule incorrectly limits the remedies available under Section 1557. Congress intentionally designed Section 1557 to build and expand on prior civil rights laws such that individuals seeking to enforce their rights would have access to the full range of available civil rights remedies and not be limited to only the remedies provided to a particular protected group under prior civil rights laws. Section 1557 expressly provides individuals access to any and all of the "rights, remedies, procedures, or legal standards available" under the cited civil rights statutes, regardless of the type of discrimination. Rather than recognizing that the statute creates a single standard for addressing health care discrimination, HHS's interpretation of the statute in these regulations as amended and re-designated would instead create multiple piecemeal legal standards and burdens of proof derived from different statutory contexts. HHS's interpretation is contrary to the statutory language and Congress's intent.

The proposed language is not a valid interpretation of Section 1557. While the statute expressly sets out the grounds for discrimination by reference to the cited civil rights statutes, it does not set forth separate remedies, legal standards, and burdens of proof applicable to each prohibited basis of discrimination based on the statutes from which each was incorporated.⁷³ To the contrary, Congress specified that "[t]he enforcement mechanisms provided for and available under such title VI, title IX, section 504, *or* such Age Discrimination Act shall apply for purposes of violations of this subsection."⁷⁴ The use of the disjunctive "or" indicates that any of the enforcement mechanisms applicable under any of the incorporated statutes are available to every claim of discrimination under Section 1557, regardless of the particular type of discrimination triggering the claim. Applying standard rules of construction, all the enforcement mechanisms provided for and available under each of the referenced statutes in Section 1557 are available to every claim of discrimination under Section 1557.

⁷³⁷³ See Sarah G. Steege, *Finding A Cure in the Courts: A Private Right of Action for Disparate Impact in Health Care*, 16 MICH. J. RACE & L. 439, 462 (2011) ("[T]here is no indication in § 1557 that each listed statute's enforcement mechanisms apply only to its own protected classes.").

⁷⁴ 42 U.S.C. § 18116(a) (emphasis added).



It is also necessary to read Section 1557 as establishing a single standard for addressing health care discrimination to avoid "patently absurd consequences." HHS's reading of Section 1557 in this proposed section "would lead to an illogical result, as different enforcement mechanisms and standards would apply to a Section 1557 plaintiff depending on whether the plaintiff's claim is based on her race, sex, age, or disability."⁷⁶ Moreover, courts would be left without guidance on how to address intersectional claims—should a person who alleges discrimination on the basis of both race and age be subject to the standards and enforcement mechanisms under a title IX analysis or the Age Discrimination Act? Section 1557 recognizes the reality that discrimination "may occur not solely because of the person's race or not solely because of the person's sexual orientation or gender identity, [disability status, or national origin], but because of the combination."⁷⁷ Thus, the law aimed to make it easier for people to file complaints of intersectional discrimination in one place. The proposed rule will only make it harder for people to file complaints. Congress explicitly adopted one provision to prohibit all discrimination in health care. It strains the imagination to read that one provision would require agencies and courts to apply a hodgepodge of standards and enforcement mechanisms.

Further, the proposed changes to the regulation do not comport with congressional intent. Congress did not intend that the enforcement mechanisms and standards available under Section 1557 be tethered to the nature of the claim. Rather, in enacting Section 1557, Congress sought to "create a new right and remedy in a new context without altering existing laws." Congress has repeatedly expressed that it intends civil rights laws to be broadly interpreted in order to effectuate their remedial purposes. By narrowly limiting the legal standards and burdens of proof that apply to those who have experienced health care discrimination, HHS's interpretation in the proposed rule would ignore Congress's intent to provide broad remedies to address discrimination. HHS should not finalize the proposed language in § 92.5.

⁷⁹ See Kang v. U. Lim Am., Inc., 296 F.3d 810, 816 (9th Cir. 2002); see also H. Rep. No. 102–40(I), at 88, U.S. Code Cong. & Admin. News at 626 (stating that "remedial statutes, such as civil rights law[s], are to be broadly construed").



⁷⁵ United States v. Brown, 333 U.S. 18, 27 (1948).

⁷⁶ See *Rumble*, 2015 WL 1197415, at *11.

⁷⁷ Brief for National LGBTQ Task Force as Amici Curiae Supporting Respondents, *Masterpiece Cakeshop v. Col. C.R. Comm'n*, 137 S.Ct. 2290 (2017), http://www.thetaskforce.org/wp-content/uploads/2017/10/16-111-bsac-LGBTQ-Task-Force.pdf.

⁷⁸ Rumble v. Fairview Health Servs., No. 14-CV-2037 SRN/FLN, 2015 WL 1197415, at *11 n.6 (D. Minn. Mar. 16, 2015).

As HHS notes, some courts have interpreted Section 1557 to apply different enforcement mechanisms and standards depending on whether someone's claim is based on race, sex, age, or disability. These cases rely on the fact that Congress incorporated the enforcement mechanisms from the four cited civil rights statutes to interpret Section 1557 to limit the standards and enforcement mechanisms available based on the statute that defines the grounds for discrimination.⁸⁰ But the courts in these cases miscomprehend the statutory language and context. As discussed above, Section 1557 expressly provides for broad and uniform enforcement, consistent with Congress's intent that civil rights laws provide broad remedies. While Congress could perhaps have more clearly articulated its intent to establish a single statutory standard for determining discrimination and enforcing Section 1557, its failure to perfectly articulate such a standard does not necessitate the narrow reading of the statute articulated in the proposed rule and the cases it cites.⁸¹ These cases overly rely on interpretations of the underlying statutes without recognizing the inherent shifts that ACA made in the health care realm.82 If Section 1557 were limited by the constraints of the referenced statutes, its passage would have been largely unnecessary, as the four civil rights statutes already apply to organizations "in the business of providing . . . health care."83 HHS's interpretation of the statute is incorrect and proposed § 92.5 should not be finalized.

Section 1557 is the law. The proposed rule's inconsistency with the statute itself would cause confusion for both health care entities and patients, ultimately increasing confusion about what the law requires and who is protected under it and making it harder for those who are discriminated against to enforce their rights. Many people who

⁸³ See, e.g., 29 U.S.C. § 794 (2018) (Rehabilitation Act).



<sup>See, e.g., Southeastern Pennsylvania v. Gilead, 102 F. Supp. 3d 688, 699 n.3 (E.D. Pa. 2015); Briscoe v. Health Care Serv. Corp., 281 F. Supp. 3d 725, 738 (N.D. III. 2017); see also, e.g., Doe v. BlueCross BlueShield of Tennessee, Inc., 926 F.3d 235, 241 (6th Cir. 2019).
See King v. Burwell, 135 S. Ct. 2480, 2492 (2015) (noting that the ACA "contains more than a few examples of inartful drafting" and thus emphasizing the importance of considering the broader context of the statute).</sup>

⁸² The Supreme Court has recognized that the broader purpose of the ACA is to "expand insurance coverage. . . . [and] ensure that anyone can buy insurance." *King*, 135 S. Ct. at 2493. An expansive prohibition on discrimination in health care is key to ensuring that *anyone* can buy insurance. Thus other courts have properly concluded that a single standard and burden of proof apply under Section 1557: "looking at Section 1557 and the Affordable Care Act as a whole, it appears that Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status." *Rumble*, 2015 WL 1197415, at *10.

experience discrimination cannot access the court system due to cost.⁸⁴ When people can afford to bring judicial actions, they generally receive little in the form of compensatory relief.⁸⁵ This could make it even more expensive for people to enforce their rights, deterring them from filing complaints of discrimination.

Thus, we particularly oppose HHS's proposal to replace current § 92.301(b) with proposed § 92.5(b). Every court that has ruled on the question has found that the statutory language of Section 1557 confers a private right of action for monetary damages. The existence of such a right is clear from the statutory language in Section 1557, which explicitly references and incorporates the "enforcement mechanisms" of the four civil rights laws listed—all of which contain a private right of action. Once again, this understanding is also consistent with Congress's intent that civil rights laws be broadly interpreted to effectuate the remedial purposes of those laws. Removing the regulatory language that makes clear that private right of action and monetary damages are available to redress violations of 1557 will serve only to confuse. HHS should not finalize proposed § 92.5(b).

§ 92.6 Relationship to Other Laws

HHS proposes to re-designate and combine current § 92.2 and § 92.3 into a new § 92.6, titled "Relationship to Other Laws." These changes are unnecessary, and the proposed revisions conflict with the statutory language and congressional intent.

a. The deletion of current § 92.3(a) and amendments to current § 92.3(b) are unnecessary and confusing

HHS proposes to entirely delete what is now § 92.3(a), which provides a rule of interpretation for Section 1557. HHS also proposes to amend current § 92.3(b) and redesignate the amended language as § 92.6(a). These proposed changes are unnecessary and should not be finalized. The deletion of current § 92.3(a) is likely to cause confusion, since it will leave both entities and courts with less information about

See Brittany Kauffman, Study on Estimating the Cost of Civil Litigation Provides Insight into Court Access, Inst. for the Advancement of the Am. Legal System (Feb. 26, 2013), https://iaals.du.edu/blog/study-estimating-cost-civil-litigation-provides-insight-court-access;
 Michelle Chen, One More Way the Courts Aren't Working for the Poor, The Nation (May 16, 2016), https://www.thenation.com/article/one-more-way-the-courts-arent-working-for-the-poor.
 Maryam Jameel & Joe Yerardi, Workplace discrimination is illegal. But our data shows it's still a huge problem, Vox (Feb. 18, 2019), https://www.vox.com/policy-and-politics/2019/2/28/18241973/workplace-discrimination-cpi-investigation-eeoc.



HHS's intent with respect to Section 1557. The current provision makes clear that the four pre-existing civil rights laws referenced by Section 1557 set the floor in terms of the scope of protections afforded by Section 1557. This is consistent with Congress's intent that Section 1557 build and expand upon these existing civil rights laws, while providing broad protection against discrimination in health care. We share HHS's objective of providing clear guidance on Section 1557's scope and application to covered entities and other stakeholders to reduce unnecessary litigation. The deletion of this provision will have the opposite result; creating more confusion among stakeholders that is likely to lead to more litigation over the scope and interpretation of Section 1557. HHS should not finalize the proposed revisions.

b. Section 1557 does not incorporate exemptions beyond those expressly enumerated in the ACA

HHS proposes to substantially amend current § 92.2 and re-designate the amended language as § 92.6(b). We oppose this change. Nothing in the legislative history or language of the regulation itself permits exceptions to Section 1557's prohibition on discrimination. Moreover, existing statutes that allow individuals and entities to refuse to provide certain services are more than sufficient to accommodate any religious objections. HHS's attempt to import some of these statutes into Section 1557 by regulation goes too far. The proposed new language is inconsistent with the statutory text of Section 1557, conflicts with the purpose of the ACA, and will cause confusion among entities.

The proposed rule would impose exemptions, rights, and protections from the following laws into Section 1557:

- Section 1553 of the Patient Protection and Affordable Care Act (42 U.S.C. 18113);
- Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023);
- Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.);
- Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.);
- The Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.);
- Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794);
- Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.);
- The Architectural Barriers Act of 1968 (42 U.S.C. 4151 et seq.);
- The Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008 (42 U.S.C. 12181 et seq.);



- Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d);
- The Coats-Snowe Amendment (42 U.S.C. 238n);
- The Church Amendments (42 U.S.C. 300a-7);
- The Religious Freedom Restoration Act (42 U.S.C. 2000bb et seq.);
- The Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115-245, Div. B sec. 209 and sec. 506(d) (Sept. 28, 2018)); and
- Any related, successor, or similar Federal laws or regulations.

Neither statutory nor legislative history supports adding exemptions to Section 1557, and the only exceptions to Section 1557's broad nondiscrimination mandate are specifically and explicitly contained in Title I of the ACA, including §§ 1553 and 1303.86 Because the exemptions contained in those two provisions are already explicit, there is no need to incorporate them into this regulation.

In addition, while Title VI, Title VII, Title IX, the Age Discrimination Act, and Section 504 of the Rehabilitation Act are referenced in Section 1557, the plain language of the statute does not incorporate any exemptions contained in those statutes. Thus, this regulation goes too far in attempting to import exemptions from these statutes into Section 1557. For example, while it is true that Title IX contains limited exceptions to its protection in certain circumstances, these exceptions are not incorporated into Section 1557. First, because those limited exceptions are not explicitly stated in Section 1557, they cannot be read to apply to it, therefore, Section 1557 does not import any exceptions from Title IX. Section 1557 references Title IX solely for the ground on which it prohibits discrimination, which is sex. 87 Since Title IX has codified pregnancy discrimination as a form of sex discrimination, and in light of Section 1557's expansive and unprecedented antidiscrimination provisions, it is clear that refusals that center on reproductive health care—including contraception, sterilization, abortion, and other reproductive health care services—are not protected under Section 1557, as they comprise a kind of sex discrimination. The sex discrimination provision, therefore, limits the scope of permissible health care refusals.

HHS considered in its 2016 final rule a blanket religious exemption, and determined such an exemption is not needed. In its assessment, HHS concluded that application of

⁸⁷ The Supreme Court held in a similar context that the incorporation by reference of protections from one civil rights statute into another does not mean that the limitations of the first apply to the second. *See Consolidated Rail Corp. v. Darrone,* 465 U.S. 624 (1984) (holding that Section 504's reference to Title VI's remedies, procedures, and rights did not import limitations from Title VI not expressly provided in Section 504).



⁸⁶ See 42 U.S.C. § 18116(a).

Section 1557 would not be required of federally funded programs and entities if doing so would violate existing religious freedom and conscience protections. The Department noted that:

certain protections already exist in Federal law with respect to religious beliefs, particularly with regard to the provision of certain health related services. For example, [the 2016] rule would not displace the protections afforded by provider conscience laws, RFRA, provisions in the ACA related to abortion services, or regulations issued under the ACA related to preventive health services.⁸⁸

Moreover, the proposal fails to specify exactly what exemptions it would incorporate into Section 1557. For example, the Americans with Disabilities Act (ADA) does not contain a defined list of exemptions, so it is completely unclear what the proposed language would include. The ADA has that list of miscellaneous provisions that, among other things, exempts certain people or conditions from definition of disability – but without additional explanation from HHS it is not clear who or what HHS is proposing to exempt. The ADA also explicitly exempts from its application "an insurer, hospital or medical service company, health maintenance organization, or any agent, or entity that administers benefit plans, or similar organizations from underwriting risks, classifying risks, or administering such risks," and for "a person or organization [that] establish[es], sponsor[s], observ[es] or administer[s] the terms of a bona fide benefit plan."89 In addition, Title I of the ADA contains a list of communicable diseases that are exempt from employment protection, and some religious exemptions, and Title III contains other exemptions for private clubs or religious institutions. These exemptions do not appear in Section 1557 and run counter to its purpose. In any event, since HHS has not delineated what exemptions it proposes to import into Section 1557 by referencing the ADA and other statutes, we are not able to provide meaningful comment on this proposal.

Moreover, the Architectural Barriers Act, the ADA, Section 508 of the Rehabilitation Act, the Coats-Snowe Amendment, the Church Amendments, the Religious Freedom Restoration Act, the Weldon Amendment, and any other federal laws are not mentioned at all in Section 1557. Nor is there is anything in the legislative history or language of the ACA that permits additional exceptions to Section 1557's prohibition on discrimination. Any exemption to the antidiscrimination mandate of the ACA would undermine the goal of health reform to combat practices that have negatively and profoundly impacted the health of the protected classes enumerated in Section 1557.

⁸⁹ 42 U.S.C. § 12201(c).



⁸⁸ 81 Fed. Reg. 31379.

The proposed regulation may affect overall access to care for women and others. Because the proposed regulation incorporates Title IX's religious exemption, a religious provider could say that they do not have to comply with sex discrimination protections. Allowing a religious exemption to Section 1557's protection against sex discrimination could have far-reaching consequences. Incorporating Title IX's religious exemption could create new instances in which health care providers and entities could allow their beliefs to determine patient care and open the door to discrimination. If implemented, this could allow religiously-affiliated hospitals and other health care entities to discriminate against people seeking reproductive health services and LGBTQ people. Providers, hospitals, or clinics could also be permitted to refuse to provide health services to a woman who is not married.

We oppose the inclusion of Title IX exemptions since they do not apply to health care situations and settings. As HHS concluded in the 2016 Final Rule:

[S]tudents or parents selecting religious educational institutions typically do so as a matter of choice; a student can attend public school (if K–12) or choose a different college. In the healthcare context, by contrast, individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions. Moreover, the choice of providers may be even further circumscribed in emergency circumstances.

Second, a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results. Thus, 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.⁹⁰

c. HHS may not limit the application of Section 1557 when it violates, departs from, or contradicts other, pre-existing laws

HHS lacks the authority to mandate that any requirements of Section 1557 that "violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections" from the laws listed above that pre-date the ACA will not be imposed. This language sharply deviates from the language in Section 1557 which states that Title I of the ACA should

⁹⁰ 81 Fed. Reg. 31380.



not be "construed to invalidate or limit the rights, remedies, procedures, or legal standards" from only Title VI, Title VII, Title IX, the Age Discrimination Act, and Section 504 of the Rehabilitation Act.⁹¹ This language makes clear that the ACA establishes a floor in terms of civil rights protections that may be exceeded by certain other civil rights laws. HHS's proposed rule would instead establish Section 1557 as a ceiling by permitting its protections to be abrogated or even completely overridden by other federal laws. This interpretation is impermissible.

In the first place, HHS fails to specify what provisions of Section 1557 violate, depart from, or contradict the listed provisions. We are unable to provide meaningful comment without more information.

Further, it is the role of courts, not administrative agencies, to harmonize potentially conflicting laws, especially where Congress has not delegated the agency the authority to interpret those laws. ⁹² In addition, the Architectural Barriers Act, the Americans with Disabilities Act, Section 508 of the Rehabilitation Act, the Coats-Snowe Amendment, the Church Amendments, the Religious Freedom Restoration Act, the Weldon Amendment, and any other federal laws are not mentioned at all in Section 1557. Thus, the plain language of the statute cannot be read to allow those laws to automatically limit or supersede its application.

Rather, if anything, Section 1557 should take precedence to the extent that it violates, departs from, or contradicts a provision of one the listed statutes. The ACA represents a sweeping reform to the U.S. health care system that "comprehensively overhauled" the existing legal landscape on health care rights and discrimination. The non-ACA provisions listed in this proposed regulation involve statutes that are not specific to health care. Thus, to the extent that any part of Section 1557 violates, departs from, or contradicts definitions, exemptions, affirmative rights, or protections that exist elsewhere in the law, it must be read to supersede those laws as they apply in the health care space. Such a reading is necessary, since "reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." HHS's proposed regulation improperly attempts the opposite, purporting to constrain the application of the ACA's reforms by limiting its scope to that of pre-existing laws.

⁹⁴ *Id.* at 453.



⁹¹ 42 U.S.C. 18116(b).

⁹² See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 844 (1984).

⁹³ United States v. Fausto, 484 U.S. 439, 443 (1988).

HHS's proposed rule would lead to absurd results that Congress could not have intended. For example, the ADA currently includes a safe harbor provision for "an insurer, hospital or medical service company, health maintenance organization, or any agent, or entity that administers benefit plans, or similar organizations from underwriting risks, classifying risks, or administering such risks," and for "a person or organization [that] establish[es], sponsor[s], observ[es] or administer[s] the terms of a bona fide benefit plan."95 The ACA was specifically intended by Congress to prohibit discrimination in these areas. HHS cannot incorporate the ADA's safe harbor for insurers and other health care entities into Section 1557 by regulation, contrary to Congress's intent. Similarly, the ADA provides a broad exemption from its application to "religious organizations or entities controlled by religious organizations." 46 At least one court has applied this exemption to a religious hospital. 97 The ACA contains no comparable provisions that exempt entities controlled by religious organizations to be exempt from its prohibitions on discrimination, beyond any such exemptions that are set forth elsewhere in Title I of the ACA. Incorporating these contradictory rules into Section 1557 is contrary to the plain language of the ACA, and will create confusion, rather than clarify, about the scope of protection available under the Section 1557. HHS should not finalize proposed § 92.6(b).

<u>Proposed Subpart B – Specific Application to Health Programs or Activities</u>

§ 92.201 Meaningful Access for individuals with limited English proficiency

Language barriers can impede access to and the quality of care that the estimated 25 million people with LEP in the United States receive. The Joint Commission notes that "[i]ndividuals whose care is inhibited due to a communication barrier. . .may be at risk for poor outcomes." The IOM noted, in its report *Unequal Treatment*,

Language barriers may affect the delivery of adequate care through poor exchange of information, loss of important cultural information, misunderstanding

⁹⁸ Wilson-Stronks, Lee, Cordero, Kopp, and Galvez, *One Size Does Not Fit All: Meeting the Needs of Diverse Populations*, Oakbrook Terrace, IL: The Joint Commission (2008), https://www.jointcommission.org/assets/1/6/HLCOneSizeFinal.pdf.



⁹⁵ 42 U.S.C. § 12201(c).

⁹⁶ 42 U.S.C. § 12187.

⁹⁷ Cole v. Saint Francis Med. Ctr., No. 1:15 CV 98 ACL, 2016 WL 7474988, at *6 (E.D. Mo. Dec. 29, 2016).

of physician instruction, poor shared decision-making, or ethical compromises (e.g. difficulty obtaining informed consent; [citation omitted]).⁹⁹

The cost of these barriers can be deadly. As we found in a study we commissioned in 2010, patients lost their lives and suffered irreparable harm due to language barriers and the failure to provide appropriate language services.¹⁰⁰

Due to the nature and importance of health care and the consequences that can result from language barriers, the current regulations appropriately include specific requirements to ensure that covered entities understand their obligations to ensure meaningful access and have clear instructions on how to comply with those obligations. We support this approach as it builds on yet is consistent with Title VI and existing HHS LEP Guidance and offer additional recommendations. We also emphasize that, consistent with the current rule, discrimination on the basis of national origin, including limited English proficiency (LEP), creates unequal access to health. LEP is often compounded with the "cumulative effects of race and ethnicity, citizenship status, low education, and poverty," resulting in more barriers to access. ¹⁰¹

Visiting health care facilities and agencies that administer health programs and activities are often uncomfortable for individuals with LEP who are "unfamiliar with [the system's] cultural norms, vocabulary, and procedures." ¹⁰² Unfamiliarity with the health care system often results in inaction that could compromise a basic standard of living for individuals and families. Furthermore, the lack of language assistance services negatively impacts communities at large, not just LEP individuals. When interpreter services are inadequate, children often serve as language brokers for their parents. ¹⁰³

¹⁰² Vikki Katz, *Children as Brokers of their Immigrant Families' Healthcare Connections*, at 24 (2014), https://academic.oup.com/socpro/article-abstract/61/2/194/1672037?redirectedFrom=fulltext.

¹⁰³ *Id.* at 31.



⁹⁹ Smedley, Stith, and Nelson, editors, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Board on Health Science Policy, Institute of Medicine, at 17, (2002), available at http://www.nationalacademies.org/hmd/Reports/2002/Unequal-Treatment-Confronting-Racial-and-Ethnic-Disparities-in-Health-Care.aspx.

National Health Law Program, *The High Costs of Language Barriers in Medical Malpractice*, https://healthlaw.org/resource/the-high-costs-of-language-barriers-in-medical-malpractice/.
 Kaiser Family Foundation, *Overview of Health Coverage for Individuals with Limited English Proficiency*, at 3, https://kff.org/disparities-policy/fact-sheet/overview-of-health-coverage-for-individuals-with/.

The cost of these barriers can be deadly. As we found in a study we commissioned in 2010, patients lost their lives and suffered irreparable harm due to language barriers and the failure to provide appropriate language services. 104 Examples of patient experiences that have resulted in malpractice claims are documented in *The High Costs of Language Barriers in Medical Malpractice*, a joint publication by the National Health Law Program and University of California, Berkeley, School of Public Health. 105

Our specific comments on the proposed revisions are outlined below.

a. § 92.101(a) – Obligation

We appreciate that the proposed rule properly makes clear that language assistance services required under paragraph (a) must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. These provisions are consistent with longstanding Supreme Court precedent holding that language assistance services are required to ensure that LEP individuals have meaningful access, and that the denial of such access is a form of national origin discrimination. At least one court has recognized that Section 1557 incorporates this concept of meaningful access. All too often, individuals with limited English proficiency do not understand their rights, and will not know their new rights under Section 1557, and thus believe they have to bring their own interpreter or use a child, other patient, or unqualified individual to interpret. The responsibility for informing individuals must reside with the covered entity. And covered entities should be required to document that this information is provided or it would be assumed the individual with limited English proficiency did not get the information and the covered entity would be not in compliance with Section 1557.

We oppose, however, the proposal in § 92.101(a) to inappropriately switch the emphasis from "each individual with limited English proficiency" as provided in the 2016 Final Rule to the covered entity's program or activities. In Section 1557, Congress declared "an *individual* shall not" be subject to discrimination (emphasis added). Section 1557 regulations cannot offer less protection than the statute that authorizes such

¹⁰⁷ See Esparza v. Univ. Med. Ctr. Mgmt. Corp., No. CV 17-4803, 2017 WL 4791185, at *17 (E.D. La. Oct. 24, 2017).



¹⁰⁴ National Health Law Program, The High Costs of Language Barriers in Medical Malpractice (2010) https://healthlaw.org/resource/the-high-costs-of-language-barriers-in-medical-malpractice/.

¹⁰⁵ *Id.*

¹⁰⁶ See Lau v. Nichols, 414 U.S. 563, 568 (1974).

regulations. Therefore, the correct emphasis in the 1557 regulations must be on each individual and not programs. As such, this NPRM would weaken meaningful access and runs counter to Congressional intent and the thorough administrative record supporting the 2016 Final Rule. We oppose these changes.

b. § 92.101(b)(1) – Specific applications -- Enforcement Discretion

As recognized in the current regulation, the enforcement standards balance two core principles critical in effectuating Section 1557's prohibition of national origin discrimination. The first principle, as outlined in HHS' 2003 LEP Guidance, is that the Department must "ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English."108 Safe and quality health care requires an exchange of information between health care provider and patient for purposes of the diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insured coverage of healthrelated services. This exchange of information is jeopardized when the provider and the patient speak different languages, which may result in adverse health consequences and even death. Indeed, as recognized in the original Section 1557 NPRM, the provision of health care services, by its "very nature[,] requires the establishment of a close relationship with the client or patient that is based on sympathy, confidence and mutual trust." Provider-patient communication is essential to the concept of patient centeredness, which is a core component of quality health care and has been shown to improve patients' health and health care.

The second principle is that the level, type and manner of language assistance services required should vary based on the relevant facts, which may include the operations and capacity of the covered entity. For these reasons, current regulations provide factors that the Director will evaluate to determine whether a covered entity has met the requirement in paragraph (a). Current § 92.201(b)(1) requires the Director to consider, and give substantial weight to, the nature and importance of the health program or activity, including the particular communication at issue. Both Title VI and Section 1557 prohibit national origin discrimination against each person, not based on the total

¹⁰⁹ Notice of Proposed Rulemaking: Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54183 (Sep. 8 2015), https://www.govinfo.gov/content/pkg/FR-2015-09-08/pdf/2015-22043.pdf.



¹⁰⁸ Policy Guidance Document: Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Individuals (HHS LEP Guidance), 68 Fed. Reg. 47312 (Aug. 8, 2003), https://www.govinfo.gov/content/pkg/FR-2003-08-08/pdf/03-20179.pdf.

number of people. Neither Title VI nor Section 1557 protections are conditioned on the number of people who experience discrimination, and thus utilizing the four factors is insufficient both for entities to determine how to comply with Title VI and Section 1557 and also for HHS to evaluate compliance.

The proposed regulations would change the mandatory "two factor" mandatory test into a "four factor" optional test. We strongly oppose these changes, which are not consistent with Section 1557's intent. The current regulation at § 92.201(b) provides a modified version of the pre-existing four-factor balancing test, first focusing on the existing factor of the "nature and importance of the health program or activity" and requires that the Director evaluate and give substantial weight to that factor. We support beginning the fact-dependent inquiry of what type of meaningful access must be provided by starting with and giving substantial weight to the nature and importance of the health program or activity and the communication at issue. Beginning the inquiry with this factor properly balances Title VI and Section 1557 obligations to ensure LEP persons are meaningfully served by health programs or activities. This approach is consistent with an understanding of the consequences that can result in lack of access to services or information in the health care setting by individuals with LEP, as intended by Congress when it enacted the ACA.

In evaluating comments submitted on the Section 1557 proposed rule in 2015, HHS revised the final Section 1557 regulation (the regulations currently in place) to eliminate the illustrative four factors and to articulate only one factor: whether a covered entity has developed and implemented an effective written language access plan appropriate to its circumstances. HHS stated that it agreed with commenters' concerns that including multiple illustrative factors – such as the four factors – in the regulatory text may create the erroneous impression that the Director will not consider relevant factors absent from § 92.201(b)(2).

In 2016, HHS also demonstrated that the two-factor test imposes no new burden on covered entities. As it stated in the preamble to the final Section 1557 regulations:

This is because, with regard to recipients of Federal financial assistance, the proposed rule adopted recipients' existing obligations under Title VI to take reasonable steps to provide meaningful access to individuals with limited English proficiency and codified standards consistent with long-standing principles from the HHS LEP Guidance regarding the provision of oral interpretation and written translation services. . .Thus, we do not believe this rule will impose a greater



burden regarding the costs of language assistance services than exist under Title VI.¹¹⁰

Further, HHS specifically addressed why it chose to provide implementing regulations for Section 1557 on the national origin prong in light of Title VI:

OCR considered remaining silent on covered entities' obligations to comply with Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. We rejected this approach because we were concerned that OCR's silence would create ambiguity about covered entity's obligations to individuals with limited English proficiency and could jeopardize the access of individuals with limited English proficiency to covered entities' health programs and activities. Clearly explaining the standards also promotes compliance and reduces enforcement costs."

As clearly stated in these quotes, HHS has already considered and rejected using the four-factor test in evaluating compliance with Section 1557 because the four-factor test failed to adequately implement Section 1557's protections against discrimination on the basis of national origin. Now in the NPRM, HHS fails to adequately explain why it is moving away from the two-factor test and back to the four-factor test. It also fails to explain why it would make the four-factor test optional – the Director "may assess how such entity balances the following four factors" (emphasis added) – rather than mandatory as under the current regulations.

The proposed rule fails to recognize that flexibility covered entities have under Section 1557 is not be an assessment of *whether* to provide meaningful access, but *how* to provide such language assistance. Because "meaningful access" is already a subjective standard, adding the four factors as an optional enforcement discretion adds an excessive layer of ambiguity and therefore makes meaningful language access all the more remote for individuals with LEP. As HHS has previously reiterated from the Department of Justice's LEP Guidance, Title VI policies advance the longstanding principle that "federally assisted programs aimed at the American public do not leave some behind simply because they face challenges communicating in English." This regulation must do the same yet the proposed changes fail to recognize this important principle.

¹¹² HHS LEP Guidance, 68 Fed. Reg. 47312.



¹¹⁰ 81 Fed. Reg. 31453-4.

¹¹¹ *Id.* at 31461-2.

Further, the proposed section deletes a specific reference to those "eligible to be served" by an entity. The shift again moves away from an individual assessment to a program/activity assessment. Yet both Title VI and Section 1557 require that covered entities not discriminate against any individual. Thus, if an entity determined, using the four factors that it did not have to provide language services it would indeed be in violation of both Title VI and Section 1557. Further, it is insufficient for an entity to only provide language services to those who actually walk in its door (or call its office). Instead, a covered entity must be prepared to provide language services to all those eligible to be served, as has been recognized at least since HHS' 2003 LEP Guidance. That guidance states:

Ordinarily, persons "eligible to be served, or likely to be directly affected, by" a recipient's program or activity are those who are served or encountered in the eligible service population . . . In certain circumstances, it is important in conducting this analysis to include language minority populations that are eligible for their programs or activities but may be underserved because of existing language barriers.¹¹³

Unfortunately, by changing the focus from each individual eligible to be served to focus instead on meaningful access to the program or activity, a covered entity may unintentionally discriminate against individuals with LEP.¹¹⁴ Eligible clients/patients will not go to a covered entity if the client/patient perceives the entity is not prepared to assist the client/patient in his/her language. For example, if a hospital is located in an area with a large Hmong population (e.g. in parts of Minnesota), the hospital likely should have the availability of language services in Hmong. Without having materials and services available, it will be discriminating against Hmong patients who reside in its service area, are eligible to be served, but are not yet actually served.

Further, many who have used the four-factor test incorrectly believe that each factor is weighed equally in evaluating compliance. This misinterpretation will arise again with the rescinding of the existing regulations. For example, some covered entities have used the resources and costs factor as a defense to providing language services to a less frequently encountered language group. Indeed the reverse is true; entities must do something but what they must do is determined on a case-by-case basis, a determination supported by the current regulations. For example, if a covered entity has a small number of patients/clients of a less frequently encountered language, an entity may erroneously think it does not have to provide oral interpreting services. While there

¹¹⁴ Compare 45 C.F.R. § 92.201(a) with proposed 45 C.F.R. § 92.101(a), 84 Fed. Reg. 27892.



¹¹³ *Id.* at 47314.

may be some particular dialects or languages which are so infrequently encountered that over-the-phone interpreters are not readily available, advance planning would ensure a covered entity can meet the needs of most LEP individuals.

It is often difficult if not impossible to ascertain when a seemingly "routine" doctor's visit may turn into one that affects an individual's day-to-day existence. How many individuals go to the doctor thinking that they may have high blood pressure, diabetes, cancer, or heart disease? Only by the ability to effectively communicate with a provider and having a provider take a full health history from a patient is it likely that the provider will gather all the information necessary to actually determine if a patient may have a condition that could affect his day-to-day existence. Thus the importance of even a seemingly "routine" healthcare visit in diagnosing potentially life-threatening conditions should weigh heavily in favor of the provision of language services and likely outweigh any concerns about costs and resources, particularly when over-the-phone interpreting services can offer a wide variety of languages at a relatively low cost.

Perhaps most importantly, cost-benefit analyses fail to evaluate how professional and industry or agency culture contribute to racial disparities in health care. Because language assistance services can be measured in cost or resources—money, time, staffing—the cost-benefit analysis is skewed towards the quantifiable and does not capture the immeasurable benefits of language access, increased access and participation in underserved communities, improved health outcomes, and compliance with anti-discrimination laws. The cost-benefit analysis also does not explicitly account for the costs to a consumer who is denied or delayed language assistance.

We also oppose the deletion of consideration of a language access plan from this section. Current regulations do not require development of a language access plan but rather require HHS to take into account whether a covered entity has developed and implemented an effective written language access plan. Many covered entities are already required to evaluate the type of language services they are obligated to provide based on the current HHS LEP Guidance. Doing so ensures that covered entities understand the scope of the populations they serve, the prevalence of specific language groups in their service areas, the likelihood of those language groups coming in contact with or eligible to be served by the program, activity or service, the nature and importance of the communications provided and the cost and resources available. Depending on an entity's size and scope, advance planning need not be exhaustive but is used to balance meaningful access with the obligations on the entity.

¹¹⁵ Ikemoto, L. C., *Symposium: Racial Disparities in Health Care and Cultural Competency*, 48 St. Louis L.J. 75, 119 (2003).



Our experience is that entities are in a better position to meet their obligations to provide language assistance services in a timely manner when those entities identify, in advance, the types and levels of services available in each of the contexts in which the covered entity encounters individuals who are LEP. The current regulations are also consistent with the encouragement of covered entities to create a language access plan from the HHS LEP Guidance. HHS' 2003 LEP Guidance included elements of an effective language access plan. And as noted in the Preamble to the original Section 1557 NPRM, many organizations already develop such plans based on the model described in HHS LEP Guidance. Doing so need not be burdensome and the size and scope of the plan may vary depending on whether the covered entity is a small provider or a Qualified Health Plan issuer.

Given the longstanding recognition of the benefits of creating a language access plan, we oppose the rescission of § 92.101(b)(2) and recommend that the provision remain as an element OCR can consider in evaluating compliance.

c. § 92.101(b)(2) – Language assistance services requirements

As noted above, we oppose using the four-factor test to determine whether language services must be provided. Oral interpreting services should <u>not</u> be subject to the four-factor test but rather be available as needed and free of charge. It may be reasonable for an entity to determine whether to provide in-person or phone or video interpreting based on a variety of factors but under Section 1557 a covered entity may not deny language services altogether, as implied by the proposed rule. The proposed language for interpreter services does not meet even the minimum existing standards required by Section 1557, and currently stated under Title VI and HHS LEP Guidance. As HHS LEP Guidance notes, oral interpreting "can range from on-site interpreters for critical services provided to a high volume of LEP persons, to access through commercially-available telephonic interpretation services." In addition, covered entities may, depending on when interpreting is needed and what is reasonable, provide interpretation through: hiring bilingual staff, hiring staff interpreters, contracting for interpreters, using a telephonic interpreter line, using community volunteers or other persons, in limited circumstances.

¹¹⁸ HHS LEP Guidance, 68 Fed. Reg. 47311 (Aug. 8, 2003).



¹¹⁶ 80 Fed. Reg. 54185.

¹¹⁷ 68 Fed. Reg. 47319-21.

Oral interpreting services must be provided in all cases where requested or needed to comply with Section 1557 (and Title VI) although the manner of providing these services (in-person, telephonic, video) may differ depending on the entity. Thus, consistent with HHS LEP Guidance, covered entities may provide oral interpreting services through the range of options that are available and evaluate the type and manner using a factdependent inquiry. This avoids an overly prescriptive approach, but provides clarity that some form of oral interpreting services must be provided in all cases where needed to constitute meaningful access. This approach provides a reasonable balance and provides covered entities with needed flexibility by adopting existing standards that are already required for some entities. For example, many smaller covered entities may find that contracting with a telephonic interpreter line, such as that required by the Health Insurance Marketplaces and Qualified Health Plans, can provide meaningful access in some cases, while contracting with interpreters or employing staff interpreters may be necessary where communications are likely to affect the health and well-being of an individual and where the covered entity frequently interacts with LEP persons, such as in a hospital. Lastly, in all circumstances when information cannot be translated into multiple languages, taglines should be used to notify limited English proficient individuals that information is available to be interpreted in their primary language.

d. § 92.101(3) – Specific requirements for interpreter and translation services

We appreciate having specific requirements for interpreter and translation services. It is important to specify the particular knowledge, skills and abilities required of interpreters. We note, however, that § 92.101(b)(2)(ii) refers to the need for a "qualified interpreter" and "qualified bilingual or multilingual staff" yet § 92.101(3) fails to replicate the use of the term "qualified." The inclusion of "qualified" in § 92.101(3) is necessary to reiterate the importance of having trained and competent individuals providing language services and also to reinforce § 92.101(4), and to effectuate Congress's intent to protect LEP individuals from discrimination.

We oppose the removal of technical and training requirements for the use of video remote interpreting services for spoken language interpreting. The type of interpreting during a health care visit should not depend on whether the encounter uses telephonic or video connections. In particular, interpreting for trauma, mental health, or death are often inappropriate for telephonic interpreting. Additionally, an interpreter may miss nonverbal cues via telephone. Even with the higher cost in equipment and training, video interpreting has saved costs from in person interpreting as there are no minimums, travel time, or cancellation risks. Keeping the current standard allows providers to determine which technology is appropriate and when an entity uses video, that it is high quality and without lagging. HHS should not set up a dichotomy between video



interpreting for sign language interpreters and video interpreting for foreign language interpreting; once video interpreting is used, the same standards should apply. That is, while a particular entity may determine whether to provide audio or video interpreting, once video interpreting is selected, the same standards should apply to both sign language and foreign language interpreters. We oppose the proposed changes and support continuation of the current requirements.

e. § 92.101(4) – Restricted use of certain persons to interpret or facilitate communication

We support the provision that restricts covered entities from: 1) requiring individuals with limited English proficiency to provide their own interpreter; and 2) relying on an adult accompanying an individual with limited English proficiency to interpret except in emergency situations or where the individual specifically requests for that adult to interpret. We also strongly support the provision that prevents minor children from interpreting or facilitating communications except in emergency situations involving imminent danger. Research has shown that the ability of a provider to accurately diagnose a patient's condition can be jeopardized by untrained interpreters, such as family and friends, especially minor children, who are prone to omissions, additions, substitutions, volunteered opinions, semantic errors, and other problematic practices.

Further, covered entities should be required to document that it provided information about free interpreting is provided and that individuals with LEP do not have to use family members, friends or other ad hoc interpreters. Otherwise, it would be assumed the individual with limited English proficiency did not get the information and the covered entity would be not in compliance with Section 1557. As we noted in our report on malpractice and language access,

Physicians are taught that if an activity is not documented in the medical record, it did not happen. In reliance on this practice, if the medical chart did not show that a professional interpreter was used, this report concluded that none was used.¹¹⁹

The same concept should apply with regards to covered entities documenting compliance with Section 1557. Covered entities must be required to document the

¹¹⁹ National Health Law Program and University of California, Berkeley School of Public Health, *The High Costs of Language Barriers in Medical Malpractice* (2010) at p. 3, fn. 11, http://www.healthlaw.org/publications/search-publications/the-high-costs-of-language-barriers-in-medical-malpractice#.Vie5GytFpSE.



provision of language services and an individual's decision to use an accompanying adult or it should be presumed not to have happened.

§ 92.102 Effective communication for individuals with disabilities

NHeLP supports HHS' proposal to retain the provisions of 45 C.F.R. § 92.202 (redesignated § 92.102), regarding effective communication for individuals with disabilities. Effective communication is a critical component of accessing and receiving quality health care. We often hear about entities refusing to provide effective communication or relying on communication methods that are the preference of the entity rather than the choice of the individual. Therefore, we commend HHS for holding all covered entities to the higher ADA Title II standards found at 28 C.F.R. §§ 35.160–35.164. Giving primary consideration to the choice of aid or service requested by the individual with a disability helps to ensure actual effective communication and thus equal opportunity in the health care setting.

We are, however, concerned with HHS' proposed changes to the definitions relating to the effective communication regulation. First, we object generally to the deletion of the definitions section at 45 C.F.R. § 92.4. The elimination of this section will cause confusion for covered entities and risk inconsistency among the various Section 1557 regulations. It also makes it more difficult to amend definitions as needed, which is especially important in the context of effective communication, as auxiliary aid technologies are constantly evolving. Second, while we appreciate HHS' efforts to incorporate many of the current ADA definitions, including the definitions of disability, auxiliary aids and services, qualified interpreter, and video remote interpreting, we note that HHS has erred in tracking the language of these longstanding definitions. The problems we have identified are as follows:

• The definition of auxiliary aids and services at proposed § 92.102(b)(1) excludes "acquisition or modification of equipment and devices" and "[o]ther similar services and actions," despite these two items being found in the ADA definition at 28 C.F.R. § 35.104 and the current Section 1557 definition at 45 C.F.R. § 92.4. HHS states in its NPRM that "[t]he list of auxiliary aids and services from 28 CFR 35.104 is incorporated into the proposed rule at § 92.102(b)(1)" and in general that "[t]hese provisions are drawn from regulations implementing Title II of the Americans with Disabilities." This list is incomplete and HHS' statements are misleading. Parts of 28 C.F.R. § 35.104 are incorporated into the NPRM, but the above-quoted language regarding the "acquisition or modification of equipment"

¹²⁰ 84 Fed. Reg. 27866, 27867, n. 123.



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and devices" and "other similar services and actions" is missing. This deletion alters what was an open-ended functional definition, and takes what is clearly a list of examples of auxiliary aids and services in the current regulations and turns it into an exhaustive list in the proposed regulation. Moreover, to the extent that HHS claims it seeks to eliminate inconsistent applications of the law, such as change is neither prudent nor consistent with the law. We strongly oppose these deletions.

The definition of auxiliary aids and services at proposed § 92.102(b)(1) also excludes the term "Qualified" before "Interpreters" in subsection (i) and before "Readers" in subsection (ii), despite this critical adjective being found in the ADA definition at 28 C.F.R. § 35.104 and the current Section 1557 definition at 45 C.F.R. § 92.4. While we appreciate that HHS does track the content of the ADA definition of *qualified* interpreters at proposed § 92.102(b)(2)–(3), we believe it will enable greater clarity and consistency with the ADA regulations to keep the term "Qualified interpreters" in the auxiliary aids definition at proposed § 92.102(b)(1)(i). Moreover, the word "Qualified" has also been deleted from "readers" in proposed § 92.102(b)(1)(ii), yet the proposal fails to incorporate the ADA definition of qualified readers. We strongly encourage HHS to both include the word "Qualified" in proposed § 92.102(b)(1)(ii), and incorporate the ADA definition of this term, see 28 C.F.R. § 351.04 ("Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary."). The change here is not merely theoretical. Covered entities should not, for example, be free to assign the task of reading personal information about healthcare status, medical procedures, and bills to a high school student hired to help with receptionist duties over the summer. The requirement for a defined "qualified reader" helps to ensure effective communication and healthcare for people with disabilities.

NHeLP is also concerned with the narrowing of the "free of charge" and "timely manner" provision at proposed § 92.102(b)(2). The current Section 1557 regulations provide that a covered entity must provide appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner . . ."121 This language echoes the ADA Title II regulations, which provide that covered entities "may not place a surcharge on a particular individual with a disability or any group of individuals with disabilities to cover the costs of measures, such as the provision of auxiliary aids or program

¹²¹ 45 C.F.R. § 92.8.



accessibility... "122 In proposed § 92.102(b)(2), HHS significantly narrows this provision by only stating that "interpreting service shall be provided to individuals free of charge and in a timely manner" (emphasis added). We strongly oppose this change and encourage HHS to replace the words "interpreting service" with "auxiliary aids and services" to be consistent with the ADA and prevent unnecessary confusion over the requirement. Covered health care entities may not legally charge for *any* auxiliary aid provided; this pre-existing legal requirement should be made clear.

Finally, HHS requests comment on whether it should add an exemption from the effective communication requirements for covered entities with fewer than 15 employees. 123 NHeLP strongly opposes this exemption. HHS has not applied such an exemption in nearly 20 years and to apply it now would roll back the clock on the enforcement of effective communication for people with disabilities. To be clear, effective communication requirements profoundly impact threshold access to and the quality of health care that a person with a disability receives. Breakdowns in communication between a health care provider and a patient with a disability are reported across all types of disabilities, 124 and the lack of accurate and effective communication can lead to misdiagnosis, erroneous treatment, and ultimately a negative impact on the health of the patient. 125 The lack of positive health care communication experiences can also lead to a loss of trust or fear of health care providers, leading some people with disabilities to feel as if they have no choice but to rely upon self-diagnosis and treatment. 126 The provision of appropriate auxiliary aids and services can help remedy some of these health care disparities. For example, the provision of ASL interpreters to Deaf patients preferring this type of communication

available at http://nationalacademies.org/hmd/Activities/SelectPops/ HealthDisparities/Commissioned-Papers/Compounded-Disparities, at 43–44 (summarizing and analyzing the abundance of research on this point).

126 Id.



¹²² 28 C.F.R. § 35.130(f).

¹²³ See 84 Fed. Reg. 27867.

¹²⁴ See, e.g., Thilo Kroll, et al., *Primary Care Satisfaction Among Adults with Physical Disabilities: The Role of Patient-Provider Communication*, 11 Managed Care Q., no. 1, 11–19 (2003); Melinda Neri & Thilo Kroll, *Understanding the Consequences of Access Barriers to Health Care: Experiences of Adults with Disabilities*, 25 DISABILITY & REHAB., no. 2, 85–96 (2003); Sara Bachman, et al., *Provider Perceptions of Their Capacity to Offer Accessible Health Care For People With Disabilities*, 17 J. DISABILITY POL'Y STUD., no. 3, 130–36 (2006); Elizabeth H. Morrison, et al., *Primary Care for Adults with Physical Disabilities: Perceptions from Consumer and Provider Focus Groups*, 40 FAM MED., no. 9, 645–51 (2008).

¹²⁵ See Silvia Yee, Mary Lou Breslin, et al., *Compounded Disparities: Health Equity at the Intersection of Disability, Race, and Ethnicity*, NAT'L ACADS. SCI., ENG'G, & MED. (2017), available at http://pationalacademies.org/hmd/Activities/SelectPops/

accommodation has been linked with significantly higher utilization rates of preventative care, including cholesterol screens, colonoscopy, and influenza vaccines.¹²⁷ While there are still many improvements to be made, requiring all covered entities to provide effective communication is a vital first step towards ensuring health care equity.

Provider offices with fewer than 15 employees should not be exempted from this basic civil rights requirement. People with disabilities often obtain their health care from local providers or specialists with only a few employees. This is especially true in rural areas, where providers are more likely to have smaller practices, and there may only be one appropriate specialist within a reasonable distance. This exemption could thus function to exclude many people with disabilities from accessing the health care they need. The American Medical Association's (AMA's) Physician Practice Benchmark Survey in the period from 2012-16 found that a majority of physicians still work in small practices, with 57.8% in practices of 10 or fewer physicians, and 37.9% working in practices with fewer than 5 physicians in 2016. 128 Physicians in single specialty practices were even more likely to be in smaller practices. A practice with 10 physicians may or may not have 15 or fewer employees, but a practice with 5 physicians is very likely to have fewer than 15 employees. Exempting these small practices means that people with disabilities will have significantly more difficulty obtaining effective communication from both general and specialty physicians, and sends the message that HHS's latest healthcare-specific civil rights regulations make it harder for people with communication disabilities to obtain needed healthcare. Congress surely did not intend such a result in enacting the ACA and Section 1557.

Moreover, in practice, this exemption would make little sense because public accommodations (including hospitals and provider offices) of <u>any</u> size are already required to provide effective communication under Title III of the ADA. Even HHS, when it originally announced that the 15-employee exemption does not apply to entities receiving HHS funds, recognized this reality:

¹²⁷ Michael M. McKee, et al., *Impact of Communication on Preventive Services Among Deaf American Sign Language Users*, 41 AM. J. PREVENTATIVE MED., no. 1, 75–79 (2011).

¹²⁸ Carol K. Cane, *Updated Data on Physician Practice Arrangements: Physician Ownership Drops Below 50 Percent*, Policy Research Perspectives 4-5, AMA (2017), *available at https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/health-policy/PRP-2016-physician-benchmark-survey.pdf*. The Benchmark surveys are of practicing physicians who provide a minimum of 20 hours of patient care/week in one of the 50 states or the District of Columbia, and who are not employed by the federal government.



This is not a new requirement; Title III of the Americans with Disabilities Act (ADA) already requires public accommodations of all sizes to provide auxiliary aids and services to persons with disabilities where necessary to ensure effective communication and Title II of the ADA extends the same requirement to state and local government entities. The vast majority of entities that receive federal financial assistance from HHS thus are already required to provide auxiliary aids and services to persons with disabilities where necessary to ensure effective communication. 129

If HHS intends to protect small entities from costs, then the appropriate mechanisms to do so is already in 45 C.F.R. § 92.202, which incorporates the ADA Title II exemptions found in 28 C.F.R. § 35.164 by explicit reference. Adding an exemption for small entities will harm people with disabilities and is not the proper solution.

In summary, HHS should clarify that the list of auxiliary aids and services in proposed § 92.102(b)(1) is not exhaustive by adding the following after subsection (ii):

- (iii) Acquisition or modification of equipment and devices; and
- (iv) Other similar services and actions.

HHS should also put back the term "Qualified" before "Interpreters" in proposed § 92.102(b)(1)(i) and before "Readers" in proposed § 92.102(b)(1)(ii), and it should incorporate the definition of "Qualified readers" found at 28 C.F.R. § 35.104. The requirement to provide services "free of charge and in a timely manner" in proposed § 92.102(b)(2) should be applied to all "auxiliary aids and services," not just "interpreter services." Last, no exemption should be added for covered entities with fewer than 15 employees.



¹²⁹ HHS OCR, Section 504 of the Rehabilitation Act of 1973; Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 Fed. Reg. 79368 (Dec. 19, 2000).

¹³⁰ 28 C.F.R. § 35.164 ("This subpart does not require a public entity to take any action that it can demonstrate would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens. In those circumstances where personnel of the public entity believe that the proposed action would fundamentally alter the service, program, or activity or would result in undue financial and administrative burdens, a public entity has the burden of proving that compliance with this subpart would result in such alteration or burdens.").

§ 92.103 Accessibility standards for buildings and facilities

NHeLP supports HHS' proposal to retain the provisions of 45 C.F.R. § 92.203 (redesignated § 92.103), regarding accessibility standards for buildings and facilities. We agree that the 2010 ADA Standards for Accessible Design ("2010 Standards") are the appropriate architectural standards for any facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange. We appreciate HHS' continued commitment to ensuring that health care facilities and provider offices are physically accessible for people with disabilities.

HHS requests comment on the appropriateness of applying the 2010 ADA Standards' definition of "public building or facility" (i.e., the ADA Title II standards) to all entities covered under Section 1557, specifically with respect to multistory building elevators and text telephone ("TTY") requirements. It is indeed appropriate and *necessary* to hold all health programs and activities that receive federal financial assistance to these standards, and we strongly oppose importing the private multistory building exception found at Section 206.2.3 of the 2010 Standards and the private entity TTY standard found at Section 217.4.3 of the 2010 Standards into Section 1557.

First, by virtue of accepting federal financial assistance from HHS, it is entirely appropriate to hold <u>all</u> covered health programs and activities, including private entities, to the Title II standards. If we look at the ADA in a vacuum, a private entity that operates as a place of public accommodation would only be subject to the lower Title III architectural standards. However, here, the ADA standards function in relation to Section 1557, which notably references and incorporates the grounds of discrimination of Section 504, not the ADA. Section 504 covers programs and activities receiving federal financial assistance. So, in this context, some private health care practices, for example, would be on the hook for not only being a public accommodation under Title III, but also an entity that avails itself to nondiscrimination law (Section 504 and Section 1557) by virtue of choosing to accept federal financial assistance from HHS. This distinction justifies holding private health care entities to a higher standard, which HHS itself recognized in its 2015 NPRM:

[The] entities covered under the proposed rule are health programs and activities that either receive Federal financial assistance from HHS or are conducted directly by HHS. Although OCR could apply Title II standards to States and local entities and Title III standards to private entities, we believe it is appropriate to

¹³¹ See 84 Fed. Reg. 27846, 27867.



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hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. 132

Additionally, it is important to consider the context of the buildings and facilities at issue under Section 1557. While we affirm that architectural access is essential in all contexts, we note that it is particularly crucial for people with disabilities to have equal access to health programs and activities. People with disabilities already face significant barriers in accessing needed health care. People with disabilities already face significant barriers in accessing needed health care. Exempting a health insurance enrollment center or plan benefit counselor from having an elevator or a small health care practice from providing TTY, for example, will only serve to widen the disparities in health access. By choosing to operate a business that is critical to an individual's health and life, and then by choosing to accept HHS funds, private health entities have also assumed a duty to ensure that their buildings and facilities are accessible for all. These are also obligations that are inevitably included in the contracts that health entities enter when they agree to function as a plan or provider with Medicaid, Medicare, or through an Exchange. Watering down this responsibility is unacceptable and unlawful. It will function to reward those few construction or alteration projects that did not have the foresight to take account of the needs of healthcare consumers with disabilities.

As to the two exemptions that HHS specifically requests comment on, NHeLP strongly opposes them both. Section 206.2.3 of the 2010 Standards provides, in relevant part, that "[i]n private buildings or facilities that are less than three stories or that have less than 3000 square feet (279 m²) per story, an accessible route shall not be required to connect stories provided that the building or facility is not . . . the professional office of a health care provider . . . or another type of facility as determined by the Attorney General." This private elevator exemption dates back to the 1991 ADA Standards for Accessible Design, a time period in which the concept of widespread architectural accessibility was still relatively recent and when the construction or addition of accessible elevators was still considered extremely burdensome and costly. Today, private entities have had over 50 years to adjust their architectural designs and consider the needs of people with disabilities.¹³⁴ Requiring a multi-story building or facility to have

¹³⁴ The Architectural Barriers Act, the first federal law requiring that facilities designed, constructed, altered, or leased with certain federal funds be accessible for people with disabilities, was signed into law in 1968. See 42 U.S.C. §§ 4151–57.



¹³² HHS, *Nondiscrimination in Health Programs and Activities; Proposed Rule*, 80 Fed. Reg. 54172, 54186 (Sept. 8, 2015).

¹³³ See, e.g., Yee, et al., supra note 125; H. Stephen Kaye, Disability-Related Disparities in Access to Health Care Before (2008–2010) and After (2015–2017) the Affordable Care Act, 109 Am. J. Pub. Health, no. 7, 1015–21 (July 2019).

an elevator is no longer the foreign concept or perceived burden it once was. Instead, it is required by the law. Rolling back the standards for having an elevator in private health buildings will only serve to erect a new, additional barrier for individuals with disabilities to access needed health programs.

We also oppose lowering the private entity TTY standard. Section 217.4.3 of the 2010 Standards provides, in relevant part, that "[w]here at least one public pay telephone is provided in a *public building*, at least one public TTY shall be provided in the building" (§ 217.4.3.1) and "[w]here four or more public pay telephones are provided in a *private building*, at least one public TTY shall be provided in the building" (§ 217.4.3.2). The lower 4:1 TTY standard for private entities, which originated 15 years ago, ¹³⁵ is now outdated given the current widespread availability and affordability of the technology. It takes little effort or cost for covered entities to provide 1:1 TTY, yet the benefits offered to people who are Deaf or have hearing impairments are significant. It enables people with disabilities to communicate with health care providers, their insurance companies, and other similar entities. HHS should not lower the 1:1 TTY standard that has already been in place for three years.

HHS should continue to apply the 2010 ADA Standards' definition of "public building or facility" to all entities covered under Section 1557. HHS should not incorporate the private multistory building elevator exemption or the private entity TTY standard into Section 1557 regulations.

§ 92.104 Accessibility of information and communication technology

NHeLP supports HHS' proposal to retain the provisions of 45 C.F.R. § 92.204 (redesignated § 92.104), regarding information and communication technology ("ICT") for individuals with disabilities. Like effective communication, access to information, communication, and electronic technologies is important to guaranteeing people with disabilities equal access to health care services—and this fact is even more true as U.S. society increasingly relies on digital and web-based communications. Health care providers and health insurance plans are rapidly developing interactive websites, moving their medical recordkeeping online, and communicating with patients through electronic means. We commend HHS' efforts to ensure that people with disabilities are not left behind as technologies evolve.

¹³⁵ The 4:1 private TTY standard was first adopted in the 2004 ADA Accessibility Guidelines ("ADAAG").



HHS also requests comment on whether it should cross-reference Section 508 and its applicable implementing regulations in proposed § 92.104. NHeLP supports this proposal. Cross-referencing Section 508 and its regulations will help ensure that the Section 1557 stay up-to-date as the Section 508 regulations are amended, and it will ensure consistency across the civil rights laws.

§ 92.105 Requirement to make reasonable modifications

The proposed text of 45 C.F.R. § 92.105 mirrors the current text of 45 C.F.R. § 92.205 and retains the requirement to make reasonable modifications to policies, practices, or procedures. We support this language. This language of "reasonable modification" conforms to other non-discrimination regulations that apply to state and local government, and therefore is consistent with other regulatory schemes applicable to entities subject to 1557. The 2016 Final Rule specifically applies the definition of "reasonable modification" from Title II of the ADA (state and local governments), which continues to be the appropriate standard for recipients of federal financial assistance, programs established under Title I of the ACA, and programs administered by HHS. The concept of "reasonable modification" is not burdensome. The concept has long applied to a broad swath of entities, whether public or private, and therefore it is clear and familiar to most entities covered by Section 1557. There is no reason to make any changes to this language, nor to import unrelated concepts from other regulatory schemes.

HHS has requested comment on whether the following language should be substituted for the proposed 45 C.F.R. § 92.105: covered entities shall make "reasonable accommodation to known physical or mental limits of an otherwise qualified" individual with a disability. HHS also asks whether an exemption for "undue hardship" should be imported from 45 C.F.R. § 84.12 and 28 C.F.R. § 92.205 into proposed § 92.105. The substitute language is from regulations related to employment, and is unnecessary, ill-

¹³⁷ See, e.g., 28 C.F.R. § 35.130(b)(7)("A public entity shall make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, unless the public entity can demonstrate that making the modifications would fundamentally alter the nature of the service, program, or activity.")(Title II of the ADA). Title III also incorporates a requirement that covered entities make "reasonable modifications in policies, practices, or procedures, when the modifications are necessary to afford goods, services, facilities, privileges, advantages, or accommodations to individuals with disabilities, unless the public accommodation can demonstrate that making the modifications would fundamentally alter the nature of the goods, services, facilities, privileges, advantages, or accommodations." 28 C.F.R. § 36.302(a) (Title III).



¹³⁶ 45 C.F.R. § 92.205.

fitting, and inappropriate for a health care context. The answer to both questions is no. HHS should not make any changes to the language at current 45 C.F.R. § 92.205.

As a preliminary matter, in asking about the imported language, HHS states that the language is taken from HHS Section 504 regulations and the "Department of Justice's Section 504 coordinating regulation." However, both citations to the DOJ Section 504 coordinating regulations are to a non-existent portion of the Code of Federal Regulations. These incorrect citations makes it impossible for public to know with certainty what HHS is proposing, nor does it allow the public to analyze the context of proposed imported, or any case law interpreting such, language. Public comment requires transparency, and the source of any imported language is an integral part of transparency.

Furthermore, new exemptions are unnecessary and contrary to Section 1557. The concept of a "reasonable modification" is not boundless—it is already well-defined by regulation and decades of case law. In fact, the definition of "reasonable modification" is so clear that HHS declined to provide additional explanation of the term in the 2016 Final Rules. The 2016 final regulations track Title II of the ADA, requiring covered entities to make a reasonable modification "unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity." Continuing to apply the "reasonable modification" analysis to Section 1557 promotes consistency with pre-existing civil rights statutes, one of HHS' stated goals of their proposed rules. Neither Section 504 nor Title II of the ADA would

¹⁴³ 84 Fed. Reg. 27848.



¹³⁸ 84 Fed. Reg. 27868.

¹³⁹ See 84 Fed. Reg. 27868, citing to 28 C.F.R. § 92.205 two separate times. 28 C.F.R. Part 92 contains regulations regarding the "Office of Community Oriented Policing Services (COPS)," and does not contain a section 92.205.

¹⁴⁰ It appears that HHS seeks to import DOJ's rules for the implementation of Executive Order 12250. See 28 C.F.R. § 41.53. It is also possible that HHS intends to refer to DOJ's rules for reasonable accommodation in employment in federally assisted programs pursuant to Section 504. See 28 C.F.R. § 42.511. Either way, it is incumbent on HHS to accurately explain the source of any regulations it seeks to substitute.

¹⁴¹ See 81 Fed. Reg. 31382 ("OCR believes that defining the terms "reasonable modification" and "accessibility" in this rule is unnecessary, given the meaning that these terms have acquired in the long history of enforcement of Section 504 and the ADA in the courts and administratively. We intend to interpret both terms consistent with the way that we have interpreted these terms in our enforcement of Section 504 and the Age and so decline to add these definitions to the final rule").

¹⁴² 45 C.F.R. § 92.205.

permit an exemption for "undue hardship" in this context, and it is inappropriate to import such an exemption into Section 1557 where none exists in the statute itself.

As noted above, the suggested imported language of "reasonable accommodation," "known physical or mental limitation," and "undue hardship" stems directly from employment-related regulations. Such concepts are ill-fitting in the health care context and cannot be applied under Section 1557. For example, the definition of "undue" hardship" makes little sense when divorced from the employment context, as it requires consideration of factors often irrelevant to the health care context, such as "(1) The overall size of the recipient's program or activity with respect to number of employees, number and type of facilities, and size of budget; (2) The type of the recipient's operation, including the composition and structure of the recipient's workforce; and (3) The nature and cost of the accommodation needed."144 These factors make sense in an employment context; they do not when applied to health care. For example, the composition and structure of a workforce and the number of employees is relevant to common employment-related accommodations, such as changes in job duties or schedules. These factors are much less likely to have bearing on common health care modifications, which may more commonly include requests for alternative evacuation plans for individuals who cannot use stairs, additional training for health care staff on how to provide services to certain individuals, ensuring lab referrals are made to accessible entities when necessary, or altering a policy to allow an individual to remain in a wheelchair and avoid unnecessary transferring while receiving some treatments such as dental care. Because the factors used to analyze "undue hardship" are more appropriate for the employment context, we believe that the appropriate approach is to retain the "reasonable modification" language, which is taken from Title II of the ADA, already applies to many entities subject to Section 1557, and has a clear definition that is flexible enough to provide guidance to health care entities.

We specifically object to the importation of the concept of "known physical or mental limitation" because it could introduce confusion, suggest that covered entities' obligations are limited, and unduly focuses on measures entities must take in response to requests for modifications. Disability discrimination encompasses not just inappropriate responses to requests for modifications, but also a failure of covered entities to take affirmative steps to prevent discrimination. Taken in conjunction with the proposed deletion of Section 92.101 (defining discriminatory actions prohibited), importing the language regarding "known physical or mental limitation" could be read to limit covered entities' obligations. Nothing in Section 1557 permits such limitations, and such a reading would be contrary to the language of Section 1557 and the larger

¹⁴⁴ 45 C.F.R. § 84.12.



Act within which it sits. Nor has HHS provided an explanation of how this concept, which heretofore has been largely limited to the employment context, would be applied in the health care context. Such an application would undermine HHS' stated purpose of the proposed rule, which is to promote consistency in the application of rules and to adhere to the enforcement mechanisms available in the underlying statutes.¹⁴⁵

Furthermore, while we disagree with HHS' statement that Congress only intended to permit disparate impact claims if such claims were permissible prior to 1557, HHS admits that many courts have permitted disparate impact claims under Section 504. Importing language regarding "known" limitations could be interpreted as limiting plaintiffs' ability to bring systemic disparate impact claims, or other substantive claims. If HHS intends to create such a limitation, it must be explicit about its intent, and do so via a transparent rulemaking process. HHS should retain the language in proposed 45 C.F.R. § 92.105.

For the reasons stated above, we urge HHS to retain the language proposed in Section 92.105 as drafted, and not to import any new exemptions or language regarding "reasonable accommodations for known physical and mental impairments."

§§ 92.102 through 92.105

In these four sections, HHS asks broadly whether it has struck the "appropriate balance" with respect to Section 504 rights and obligations imposed on the "regulated community." We agree generally that to the extent that HHS has retained protections from the 2016 Final Regulations, such protections are appropriate. More broadly, however, the question should not be "whether the benefits of these provisions exceeds the burdens imposed by them." Such a balancing exercise is not called for by the statute, and inserts an inappropriate regulatory finesse on a remedial scheme created by Congress and intended to be interpreted broadly and to correct decades of harm. The task of the agency is to interpret and implement the statute. The proposed balancing of interests may be an appropriate role for Congress, but not for the administrative branch.

¹⁴⁷ See, e.g. 42 U.S.C. § 12101 (ADA findings and purposes). The ADA built upon Section 504, and Section 1557 follows in their footsteps.



¹⁴⁵ 84 Fed. Reg. 27849-51.

¹⁴⁶ See, e.g., McWright v. Alexander, 982 F.2d 222, 229 (7th Cir. 1992); Smith v. Barton, 914 F.2d 1330, 1340 (9th Cir. 1990).

Although we disagree with the premise of the question, we do note that the harm that people with disabilities would suffer if Section 1557 and the current regulatory scheme were not upheld is immense. People with disabilities already experience significant disparities in health outcomes and access to health care. For example, adults with disabilities are 58% more likely to experience obesity, three times more likely to be diagnosed with diabetes, and nearly four times more likely to have early-onset cardiovascular disease. Moreover, they are nearly three times more likely to have not accessed needed health care because of cost and twice as likely to have unmet mental health needs. The ACA's reforms worked to reduce some of these disparities by, for example, reducing the uninsurance rate and increasing the likelihood of a person with a disability having a regular health care provider. However, there are still large gaps in health access. Persistent attitudinal and programmatic barriers to care are ongoing. Section 1557 provides an avenue through which people with disabilities can identify and challenge discriminatory policies.

HHS also asks generally whether regulations for Section 1557 are consistent with the regulatory scheme for entities that are not covered by Section 1557 regulations, such as human services grantees, or whether underlying regulations for other civil rights statutes need to be modified. In general, we have commented on contexts where it is inappropriate to import regulations created for the employment into Section 1557's regulatory scheme. While there are clearly other areas of nondiscrimination law where importing or exporting other regulatory regimes would be inappropriate, HHS has not provided sufficient clarity in both the questions and the context to allow us to provide additional meaningful comment outside of the comments raised above.

To propose changes in existing regulations, HHS must provide its own justification for the changes. Given that the public must be provided an opportunity to comment on HHS' alleged explanations and rationale for these proposed changes, HHS' attempt to

¹⁵⁴ See id.; Yee, et al., supra note 125, at 31–32; 39–44.



¹⁴⁸ See generally, e.g. Valarie K. Blake, *An Opening for Civil Rights in Health Insurance After the Affordable Care Act*, 36 B.C. J.L. & Soc. Just. 235 (2016) (describing pre-ACA health insurance discrimination and how the ACA addressed those issues).

¹⁴⁹ See, e.g., Yee, et al., supra note 125.

¹⁵⁰ *Id.* at 32.

¹⁵¹ *Id.* at 31.

¹⁵² Kaye, supra note 133 at 1015–21 (July 2019); Gloria L. Krahn, *Drilling Deeper on the Impact of the Affordable Care Act on Disability-Related Health Care Access Disparities*, 109 Am. J. Pub. HEALTH, no. 7, 956–58 (July 2019).

¹⁵³ See Kaye, supra note 133, at 1019–21 (for example, across the population of people with disabilities, there has been "much greater delayed or forgone care" post-ACA).

solicit feedback on unspecified underlying regulations that it may then use to promulgate unanticipated changes in a final rule violates requirements of public notice and comment as required by the Administrative Procedures Act. These issues would be more appropriate to inform agency decisions prior to issuing an NPRM, such as through a Request for Information, than in response to an NPRM. We thus decline to provide additional feedback on the question of whether Section 1557 is generally aligned with underlying but unspecified regulations, but have provided our explanations, justifications and evidence supporting our comments in the sections above.

III.B. Current Section 1557 Regulations Proposed for Repeal

§ 92.4 Definitions

HHS proposes to eliminate the definitions section of the current regulations and to drastically limit the scope of Section 1557's protections. We strongly oppose these changes. (See also the discussion above on §§ 92.2 Nondiscrimination Requirements & 92.3 Scope of Application).

The scope of Section 1557's protected classes and characteristics extend broadly. The plain text of Section 1557 and the current implementing regulations establish the broad scope of its nondiscrimination protections. This is consistent with Congress's intent that Section 1557 build and expand upon existing civil rights laws, while providing broad protection against discrimination in health care. However, the proposed rule eliminates key definitions describing who is protected under Section 1557 and ignores HHS' own findings in the 2016 Final Rule on the harms of discrimination in health programs or activities. We oppose these proposed changes which seem to be based more on animus than fact or law.

a. Protections based upon gender identity

Twenty-nine percent of transgender individuals were refused to be seen by a health care provider on the basis of their perceived or actual gender identity and the same percent experienced unwanted physical contact from a health care provider.¹⁵⁵

https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-

care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.



Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, Ctr. for American Progress, (Jan. 18, 2018), https://www.americanprogress.org/issues/labt/news/2018/01/18/4/5130/discrimination-

Additionally, the 2015 U.S. Transgender Survey found that twenty-three percent of respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.¹⁵⁶

Under current law and regulations, Section 1557 prohibits discrimination on the basis of sex, including someone's gender identity. In addition, current regulations expressly prohibit coverage exclusions for gender-affirming care, and prohibit plans from imposing limits or restrictions on health services provided to transgender persons, for services traditionally provided to persons of one sex. Is

Despite the stark need for protection against discrimination on the basis of gender identity, however, the proposed rule completely eliminates gender identity as part of the definition of sex discrimination. It also removes sections of the existing regulations that prohibit health plans from excluding gender-affirming care.

HHS argues that gender identity protections and the prohibition of coverage exclusions imposes a new and costly burden for plans. However, issuers have been on notice since 2012 that they are obliged to follow Section 1557's protections against gender identity discrimination.¹⁵⁹ In any case, the 2016 Final Rule did not establish any new obligations that exist separate from Section 1557.

As explained above, HHS provides no rationale for relying on the preliminary injunction issued in *Franciscan Alliance* as the justification for eliminating regulatory protections against discrimination based upon gender identity. In addition, HHS fails to address numerous other court decisions finding that Section 1557's gender identity protections are statutory, instead cherry picking a handful of cases to the contrary. Discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.¹⁶⁰ Numerous federal

¹⁵⁹ 81 Fed. Reg. 31387, citing Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), https://www.nachc.com/client/OCRLetterJuly2012.pdf.

¹⁶⁰ See, e.g., EEOC v. R.G. & G.R. Harris Funeral Homes, No. 16-2424 (6th Cir. Mar. 7, 2018); Whitaker v. Kenosha Unified Sch. Dist., 858 F.3d 1034 (7th Cir. 2017) (Title IX and Equal



¹⁵⁶ Nat'l Ctr. for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey* 5 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf. ¹⁵⁷ 45 C.F.R. § 92.4.

¹⁵⁸ 45 C.F.R. §§ 92.206, 92.207(b)(3)-(5). See, *e.g.*, Rebekah Rollston, MD, MPH, PROMOTING CERVICAL CANCER SCREENING AMONG FEMALE-TO-MALE TRANSMASCULINE PATIENTS, The Fenway Institute (May 22, 2019), https://fenwayhealth.org/wp-content/uploads/TFIP-28_TransMenCervicalCancerScreeningBrief_web.pdf.

courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination. Horeover, the scope of sex discrimination in Title VII is currently pending before the Supreme Court. It is premature to change the regulations now before the Supreme Court has spoken to this precise interpretive issue.

Regardless, it is clear that discrimination based on gender identity or transgender status is sex discrimination because it treats people differently from otherwise similarly situated people based on their transition from one gender to another, because it treats them

Protection Clause); Doddsv. U.S. Dep't of Educ., 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); Barnes v. City of Cincinnati, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); Smith v. City of Salem, 378 F.3d 566 (6th Cir. 2004) (Title VII); Rosa v. Park West Bank & Trust Co., 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); A.H. ex rel. Handling v. Minersville Area School District, 3:17-CV-391, 2017 WL 5632662 (M.D. Pa. Nov. 22, 2017) (Title IX and Equal Protection Clause); Stone v. Trump, ---F.Supp.3d ---, No. 17–2459 (D. Md. Nov. 21, 2017) (Equal Protection Clause); Doe v. Trump, ---F.Supp.3d ---, 2017 WL 4873042 (D.D.C. Oct. 30, 2017) (Equal Protection Clause); Prescott v. Rady Children's Hospital-San Diego, --- F. Supp.3d ---, 2017 WL 4310756 (S.D. Cal. Sept. 27, 2017) (Section 1557); E.E.O.C. v. Rent-a-Center East, Inc., ---F.Supp.3d ---, 2017 WL 4021130 (C.D. Ill. Sept. 8, 2017) (Title VII); Brown v. Dept. of Health and Hum. Serv., No. 8:16DCV569, 2017 WL 2414567 (D. Neb. June 2, 2017) (Equal Protection Clause); Smith v. Avanti, 249 F.Supp.3d 1194 (D. Colo. 2017) (Fair Housing Act); Students & Parents for Privacy v. U.S. Dep't of Educ., No. 16-cv-4945, 2016 WL 6134121 (N.D. III. Oct. 18, 2016) (Title IX); Mickens v. Gen. Elec. Co. No. 16-603, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016) (Title VII); Fabian v. Hosp. of Cent. Conn., 172 F.Supp.3d 509 (D. Conn. 2016) (Title VII); Cruz v. Zucker, 195 F.Supp.3d 554 (S.D.N.Y. Jul. 5, 2016) (Section 1557); Doe v. State of Ariz., No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016) (Title VII); Dawson v. H&H Elec., Inc., No. 4:14CV00583 SWW, 2015 WL 5437101 (E.D. Ark. Sept. 15, 2015) (Title VII); U.S. v. S.E. Okla. State Univ., No. CIV-15-324-C, 2015 WL 4606079 (W.D. Okla. 2015) (Title VII); Rumble v. Fairview Health Serv., No. 14-cv-2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (Section 1557); Finkle v. Howard Cty., 12 F.Supp.3d 780 (D. Md. 2014) (Title VII); Schroer v. Billington, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); Lopez v. River Oaks Imaging & Diagnostic Grp., Inc., 542 F.Supp.2d 653 (S.D. Tex. 2008) (Title VII); Mitchell v. Axcan Scandipharm, Inc., No. Civ.A. 05-243, 2006 WL 456173 (W.D. Pa. 2006) (Title VII); Tronettiv. Healthnet Lakeshore Hosp., No. 03-CV-0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003) (Title VII). ¹⁶¹ See, e.g., Smith v. City of Salem, 378 F.3d 566, 572-75 (6th Cir. 2004); Rosa v. Park West Bank & Trust Co., 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); Schwenk v. Hartford, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act). See also Statement of Interest of the United States at 14, Jamal v. Saks, No. 4:14-cv-02782 (S.D. Tex. Jan. 26, 2015).

¹⁶² See Altitude Exp., Inc. v. Zarda, 139 S. Ct. 1599 (2019); R.G. & G.R. Harris Funeral Homes, Inc. v. E.E.O.C., 139 S. Ct. 1599 (2019).



differently based on sex stereotypes, and because it treats them differently based on gender identity and transgender status. The First, Sixth, Seventh, Ninth, and Eleventh Circuits have found transgender individuals to be protected by Title VII and other federal sex discrimination laws. Numerous district courts have also held that gender identity discrimination is prohibited by Title VII, either as *per se* sex discrimination because it is based on sex stereotypes, or because it is based on their gender transition. Numerous agency administrative decisions and regulations have also made clear that "sex" includes gender identity and transgender status. Includes gender identity and transgender status.

Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., No. 16-3522, 2017 WL 2331751, at *9 (7th Cir. May 30, 2017); Chavez v. Credit Nation Auto Sales, LLC, 641 F. App'x 883, 884 (11th Cir. 2016); Chavez v. Credit Nation Auto Sales, LLC, 641 F. App'x 883, 884 (11th Cir. 2016); Barnes v. City of Cincinnati, 401 F.3d 729, 737 (6th Cir. 2005); Smith v. City of Salem, Ohio, 378 F.3d 566, 575 (6th Cir. 2004); Schwenk v. Hartford, 204 F.3d 1187, 1201-02 (9th Cir. 2000); Rosa v. Park W. Bank & Trust Co., 214 F.3d 213, 215 (1st Cir. 2000).
Fvancho v. Pine-Richland Sch. Dist. 2017 WL 770619, at *13 (W.D. Pa. Feb. 27, 2017);

¹⁶⁴ Evancho v. Pine-Richland Sch. Dist., 2017 WL 770619, at *13 (W.D. Pa. Feb. 27, 2017); Smith v. Avanti, 2017 WL 1284723, at *4 (D. Colo. Apr. 5, 2017); Valentine Ge v. Dun & Bradstreet, Inc., 2017 WL 347582, at *4 (M.D. Fla. Jan. 24, 2017); Baker v. Aetna Life Ins., 228 F. Supp. 3d 764, 771 (N.D. Tex. Jan. 13, 2017); Roberts v. Clark Cty. Sch. Dist., 215 F. Supp. 3d 1001, 1011, 1015 (D. Nev. 2016); Bd. of Educ. of the Highland Local Sch. Dist. v. United States Dep't of Educ., 208 F. Supp. 3d 850, 869 (S.D. Ohio 2016); Mickens v. General Electric Co., 2016 WL 7015665, at *3 (W.D. Ky. Nov. 29, 2016); Fabian v. Hosp. of Cent. Connecticut, 172 F. Supp. 3d 509, 526-27 (D. Conn. 2016); Doe v. Ariz., 2016 WL 1089743, at *2 (D. Ariz. Mar. 21, 2016); Norsworthy v. Beard, 87 F. Supp. 3d 1104, 1119 (N.D. Cal. 2015); E.E.O.C. v. R.G. & G.R. Harris Funeral Homes, Inc., 100 F. Supp. 3d 594, 603 (E.D. Mich. 2015); Rumble v. Fairview Health Servs., 2015 WL 1197415, at *2 (D. Minn. Mar. 16, 2015); Finkle v. Howard Cty., Md., 12 F. Supp.3d 780, 788 (D. Md. 2014); Parris v. Keystone Foods, 959 F. Supp. 2d 1291, 1303 (N.D. Ala. 2013), appeal dismissed, No. 13-14495-D (11th Cir. Dec. 26, 2013); Radtke v. Miscellaneous Drivers & Helpers Union Local #638 Health, Welfare, Eye, & Dental Fund, 867 F. Supp. 2d 1023, 1031 (D. Minn. 2012); Lopez v. River Oaks Imaging & Diagnostic Grp., Inc., 542 F. Supp. 2d 653, 660 (S.D. Tex. 2008); Schroer v. Billington, 577 F. Supp. 2d 293, 305 (D.D.C. 2008); Mitchell v. Axcan Scandipharm, Inc., 2006 WL 456173, at *2 (W.D. Pa. Feb. 17, 2006); Tronetti v. TLC HealthNet Lakeshore Hosp., 2003 WL 22757935, at *4 (W.D.N.Y. Sept. 26, 2003).

¹⁶⁵ See, e.g., Lusardi v. Dep't of the Army, 2015 WL 1607756, at *11 (E.E.O.C. Apr. 1, 2015); Macy v. Holder, 2012 WL 1435995, *10 (E.E.O.C. Apr. 20, 2012) ("Thus, we conclude that intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination 'based on . . . sex,' and such discrimination therefore violates Title VII."); U.S. Department of Education - 34 C.F.R. § 270.7 ("Sex desegregation means the assignment of students to public schools ... without regard to their sex (including transgender status; gender identity; sex stereotypes, such as treating a person differently because he or she does not conform to sex-role expectations because he or she is attracted to or is in a



There is a split of authority whether the rationale of the Title VII cases discussed above extends to the context of Title IX. Courts generally hold that the sex discrimination provisions of Title IX protect transgender individuals from discrimination.¹⁶⁶

For example, in *M.A.B. v. Board of Education of Talbot County*, a transgender male student was required to use "neutral" locker rooms to change his clothes for activities requiring it. 167 Deciding the student's claim under Title IX, the court considered and relied upon Title VII precedents because the operative language is the same in both statutes. The neutral locker room did not have the same amenities as the boys' locker rooms though including a lack of showers and benches. Additionally, the student was the only student in the school that had to use the designated locker room causing embarrassment as other students gave him odd looks when he went to use his designated locker room. Discrimination based on gender identity had to incorporate consideration of the student's biological sex and stereotypes associated with the student's particular biological sex, so gender identity discrimination is unlawful sex discrimination.

HHS acknowledges other cases in which federal courts have upheld gender identity protections under § 1557, but characterizes them as "pending." The court in *Prescott v. Rady Children's Hosp.*, concluded: "Because Title VII, and by extension Title IX,

¹⁶⁸ 84 Fed. Reg. 27855.



relationship with a person of the same sex; ...)...."); U.S. Department of Health and Human Services - 45 C.F.R. § 92.4 ("On the basis of sex includes, but is not limited to, discrimination on the basis of . . . sex stereotyping, and gender identity.").

¹⁶⁶ See *Whitaker v. Kenosha Unified Sch. Dist. No. 1*, 858 F.3d 1034, 1049 (7th Cir. 2017) (granting a preliminary injunction and holding that the plaintiff had established a likelihood of success under Title IX where the school denied a transgender boy access to the boy's restroom); *Prescott v. Rady Children's Hosp.-San Diego*, 265 F. Supp. 3d 1090, 1099 (S.D. Cal. 2017). In *G.G. ex rel. Grimm v. Gloucester Cty. Sch. Bd.*, 822 F.3d 709, 723 (4th Cir.), the Fourth Circuit reversed a district court ruling interpreting Title IX narrowly in contravention of properly-adopted regulations, remanding the case to the district court for the application of proper deference. The United States Supreme Court vacated and remanded the Fourth Circuit's decision, however, 137 S. Ct. 1239, 197 L. Ed. 2d 460 (2017), with instructions to consider the matter further "in light of the guidance document issued by the Department of Education and Department of Justice on February 22, 2017."

¹⁶⁷ 1:16-cv-02622-GLR (D. Md. March 12, 2018).

recognize that discrimination on the basis of transgender identity is discrimination on the basis of sex, the Court interprets the ACA to afford the same protections."¹⁶⁹

In *Flack* v. *Wis. Dept of Health Servs.*, the court held that Wisconsin's coverage exclusions for gender affirming care in Medicaid is "text-book discrimination based on sex." The court explained: "the Challenged Exclusion prevents the [plaintiffs] from getting medically necessary treatments on the basis of both their natal sex and transgender status, which surely amounts to discrimination on the basis of sex in violation of the ACA."

HHS mischaracterized the status of *Flack* in the NPRM, claiming the petition for class certification is still pending.¹⁷¹ The court granted class certification on April 23, 2019, nearly two months before HHS published its NPRM.¹⁷²

In *Boyden v. Conlin*, the court similarly held: "Whether because of differential treatment based on natal sex, or because of a form of sex stereotyping where an individual is required effectively to maintain his or her natal sex characteristics, the Exclusion on its face treats transgender individuals differently on the basis of sex, thus triggering the protections of... the ACA's anti-discrimination provision." ¹⁷³

HHS also misrepresents the current status of *Boyden* in the NPRM. HHS claims the case is still pending appeal with the 7th Circuit.¹⁷⁴ This is false. The U.S. Court of Appeals for the 7th Circuit dismissed the case on March 26, 2019, three months before HHS published its NPRM.¹⁷⁵

In *Tovar v. Essentia Health*, the court concluded: "Because Title VII, and by extension Title IX, recognize that sex discrimination encompasses gender-identity discrimination, the Court concludes that Section 1557 also prohibits discrimination on the basis of gender identity." ¹⁷⁶

¹⁷⁶ 2018 U.S. Dist. LEXIS 16065 (D. Minn., Sept. 20, 2018)



¹⁶⁹ 265 F. Supp. 3d 1090, 1099 (S.D. Cal. 2017). See also *Rumble v. Fairview Health Servs.*, No. 14-CV-2037 (SRN/FLN), 2017 WL 401940, at *2 (D. Minn. Jan. 30, 2017) ("Section 1557 protects plaintiffs who allege discrimination based on gender identity").

¹⁷⁰ 328 F. Supp. 3d 931 (W.D. Wis. 2018).

¹⁷¹ 84 Fed. Reg. 27855.

¹⁷² Flack v. Wis. Dept of Health Servs., 2019 WL 1772403 (2019).

¹⁷³ 341 F. Supp. 3d 979, 997 (W.D. Wis. 2018).

¹⁷⁴ 84 Fed. Reg. 27855.

¹⁷⁵ Order to Dismiss, *Boyden v. Conlin* Nos. 18-3408, 18-3485 (7th Cir.) (March 26, 2019).

The fact that HHS acknowledges these cases, but ignores these courts' conclusions, brings into question the rigor of the agency's analysis and undermines the very premise upon which HHS bases this regulatory rollback. Furthermore, HHS misstates the status of these important federal court cases that upheld Section 1557 protections against discrimination based upon someone's gender identity, which shows that HHS' proposed revision and elimination of current regulations is not based upon fact or law. HHS should not finalize these proposals.

b. Protections against discrimination based on sex stereotyping

According to one survey, eight percent of lesbian, gay, and bisexual individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and seven percent experienced unwanted physical contact and violence from a health care provider. The study *When Health Care Isn't Caring* found that fifty-six percent of LGB people reported experiencing discrimination from health care providers – including refusals of care, harsh language, or even physical abuse – because of their sexual orientation. HHS' Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights." 179

Current Section 1557 regulations protect against discrimination based on sex stereotypes. While regulations do not expressly include discrimination on the basis of sexual orientation, HHS stated that Section 1557's prohibition of discrimination on the basis of sex includes, at a minimum, sex discrimination related to an individual's sexual

¹⁸⁰ 45 C.F.R. § 92.4.



¹⁷⁷ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, Ctr. for American Progress, (Jan. 18, 2018),

https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-

<u>care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.</u>

¹⁷⁸ Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV, 5 (2010),

http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf

¹⁷⁹ Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health, U.S. Dept. Health & Human Serv., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health.

orientation where the evidence establishes that the discrimination is based on sex stereotypes. The definition of sex stereotypes includes stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms or body characteristics. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex. 182

Moreover, it is well-established that sex discrimination encompasses discrimination based on sex stereotypes. Three decades ago, the Supreme Court held that Title VII prohibits discrimination against workers for their failure to conform to sex-based stereotypes in *Price Waterhouse v. Hopkins*. ¹⁸³ In cases since then, courts have concluded that Title VII's nondiscrimination protections based upon sex stereotyping applies to sexual orientation.

In *Oncale v. Sundowner Offshore Services*, the Court recognized that same-sex sexual harassment can constitute discrimination because of sex and thus violate Title VII. ¹⁸⁴ The Court focused on differential treatment of similarly situated men and women, and away from the specific goals of Congress in passing Title VII. *Oncale* has been read to preclude courts from creating their own exceptions to Title VII coverage based on speculation about the primary intent of Congress in passing the legislation. The Court in *Oncale* observed that "[S]tatutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." According to the Court, whatever evidentiary route a plaintiff chooses, so long as a plaintiff's claim "meets the statutory requirements" – i.e., is "discrimination because of sex" – the claim is cognizable.

Since 2015, the Equal Employment Opportunity Commission ("EEOC") has opined that "[s]exual orientation discrimination is sex discrimination because it necessarily entails

¹⁸⁶ *Id.* at 80.



¹⁸¹ *Id*.

¹⁸² *Id*.

¹⁸³ 490 U.S. 228, 251 (1989) ("As for the legal relevance of sex stereotyping, we are beyond the day when an employer could evaluate employees by assuming or insisting that they match the stereotype associated with their group.")

¹⁸⁴ 523 U.S. 75 (1998).

¹⁸⁵ *Id.* at 79.

treating an employee less favorably because of the employee's sex." Numerous federal district courts have agreed. 188

However, the proposed rule eliminates sex stereotyping from the definitions section of the current regulations.¹⁸⁹ It goes even further, by purging references to "sexual orientation" appearing in other HHS regulations, including those preventing discrimination in Essential Health Benefits, Qualified Health Plan marketing and design, outreach and enrollment activities, as well as Medicaid managed care and Programs for All-inclusive Care of the Elderly (PACE).¹⁹⁰

Deleting sex stereotyping and other definitions may set the stage for HHS to refuse to enforce these important nondiscrimination protections. However, the proposed rule cannot eliminate thirty years of case law finding that sex stereotyping is part of nondiscrimination protections based on sex. We urge HHS to maintain current definitions for Section 1557, including sex stereotyping.

¹⁹⁰ Proposal to amend 45 C.F.R. §§ 147.104(e), 155.120(c)(ii), 155.220(j)(2), 156.200(e), 156.1230(b)(3); 42 C.F.R. §§ 438.3(d)(4) 438.206(c)(2), 438.262; 42 C.F.R. §§ 460.98(b)(3), 460.112(a). Note, the EHB nondiscrimination requirements at 45 C.F.R. § 156.125(b) cross reference 45 C.F.R. § 156.200(e).



¹⁸⁷ Baldwin v. Department of Transportation (Federal Aviation Administration), EEOC Appeal No. 0120133080 (July 15, 2015), 2015 WL 4397641, at 5, 10.

^{See Burnett v. Union R.R. Co., No. CV 17-101, 2017 WL 2731284, at *4 (W.D. Pa. June 26, 2017); Philpott v. N.Y., 2017 WL 1750398, at *2 (S.D.N.Y. May 3, 2017); Smith v. Avanti, No. 2017 WL 1284723, at *4 (D. Colo. Apr. 5, 2017); Smith v. Avanti, No., 2017 WL 1284723, at *4 (D. Colo. Apr. 5, 2017); U.S. Equal Employment Opportunity Comm'n v. Scott Med. Health Ctr., P.C., 217 F. Supp. 3d 834, 841 (W.D. Pa. 2016); Tinory v. Autozoners, No. CV 13-11477-DPW, 2016 WL 320108, at *5 (D. Mass. Jan. 26, 2016); Boutillier v. Hartford Pub. Sch., 221 F. Supp. 3d 255, 268 (D. Conn. 2016); U.S. Equal Employment Opportunity Comm'n v. Scott Med. Health Ctr., P.C., 217 F. Supp. 3d 834, 841 (W.D. Pa. 2016); Videckis v. Pepperdine Univ., 150 F. Supp. 3d 1151, 1160 (C.D. Cal. 2015); Isaacs v. Felder Servs., LLC, 143 F. Supp. 3d 1190, 1194 (M.D. Ala. 2015); Hall v. BNSF Ry. Co., 2014 WL 4719007, at *3 (W.D. Wash. Sept. 22, 2014); Koren v. Ohio Bell Tel. Co., 894 F. Supp. 2d 1032, 1038 (N.D. Ohio 2012); Perry v. Schwarzenegger, 704 F. Supp. 2d 921, 996 (N.D. Cal. 2010); Heller v. Edgewater Country Club, 195 F. Supp. 2d 1212, 1223 (D. Or. 2002); Terveer v. Billington, 34 F. Supp. 3d 100, 114 (D.D.C. 2014); Centola v. Potter, 183 F. Supp. 2d 403, 410 (D. Mass. 2002).}

¹⁸⁹ 84 Fed. Reg. 27855, 27869

c. Protections against sex discrimination, including pregnancy and termination of pregnancy

Sex discrimination takes many forms and has the potential to occur at every step in the health care system—from obtaining insurance coverage to receiving a diagnosis and treatment by a provider. Such discrimination has serious adverse impacts on the lives of women, causing them to pay more for health care and to risk receiving improper diagnoses and less effective treatments. The effects of sex discrimination for women of color may be compounded by other forms of discrimination they face, including racial discrimination and discrimination based on limited English language proficiency.

Before the ACA, women experienced pervasive discrimination in health care settings and by insurers. For example, women paid more than men for their insurance and were often unable to find coverage for necessary services, such as maternity care. In 2011, one year before qualified health plans were available in the ACA insurance marketplaces, sixty-two percent of individuals with individual market plans did not have maternity care coverage.¹⁹¹

Section 1557 prohibits discrimination on the basis of sex, including pregnancy status, termination of pregnancy, childbirth and related medical conditions, gender identity, and sex stereotyping. Any discrimination on the basis of pregnancy is specifically prohibited in Title IX regulations, and Section 1557 adopted these same restrictions. Moreover, the 2016 final regulations implementing Section 1557 made clear that Section 1557 did not displace existing federal refusal laws and did not include new refusals. 193

The proposed rule attempts to roll back these protections. Although HHS acknowledges in the preamble to the proposed rule that the prohibition against sex discrimination includes termination of pregnancy, it refuses to state whether the Department would enforce those protections and proposes to rescind the 2016 final rule's clarification that the ban on sex discrimination includes all pregnancy related care. In doing so, the Department illegally attempts to eliminate the express protections that apply to someone who has had an abortion or has experienced a miscarriage or ectopic pregnancy and needs care for those conditions. While the scope of protection under

¹⁹² See 45 C.F.R. § 86.40(b) (prohibiting discrimination on the basis of "pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom").

¹⁹³ 45 C.F.R. § 92.2(b)(2).



¹⁹¹ Sarah Lueck, Ctr. on Budget & Policy Priorities, *If Essential Health Benefit Standards Are Repealed, Health Plans Would Cover Little*, (Mar. 23, 2017), https://www.cbpp.org/blog/if-essential-health-benefits-standards-are-repealed-health-plans-would-cover-little.

Section 1557 is clear, without unambiguous implementing regulations and enforcement, illegal discrimination is likely to flourish.

The proposed rule also seeks to unlawfully incorporate Title IX's "Danforth Amendment", which carves out abortion care and coverage from the ban on discrimination of sex in the education context. Congress did not include the Title IX exceptions, including the Danforth Amendment, either explicitly or by reference, in Section 1557. The proposed rule's unlawful incorporation of the Danforth Amendment is yet another Trump-Pence Administration attack on abortion care. These attacks on abortion access could embolden illegal discrimination that will fall heaviest on those least able to seek health care elsewhere, including women living in rural areas and women of color, who already face disparities in care and provider discrimination during pregnancy.

The impact of these changes could directly harm many people of color. For example, pregnancy-related complications remain one of the ten leading causes of death for Black women aged 15-34 years. Black women are three-to-four times more likely to die from pregnancy related complications than white women. Rescinding portions of the 2016 final rule that expressly define and prohibit sex discrimination based on pregnancy status could put Black women at increased risk of pregnancy-related complications. Similarly, Asian American and Pacific Islander ("AAPI") women could be denied access to crucial services such as emergency contraceptives and prenatal care. AAPI women already face challenges accessing culturally and linguistically appropriate reproductive health care. Some studies show that AAPI women use less effective, but more easily accessible contraceptive methods at higher rates compared to women of other races and ethnicities, placing AAPI women at greater risk of unintended pregnancy. Disparities also exist among AAPI women regarding utilization of prenatal care; Laotian and Cambodian women are less likely than other racial and ethnic groups to receive early and adequate prenatal care.

¹⁹⁶ Jo Jones, et al., U.S. Dep't of Health & Human Servs., *Current Contraceptive Use in the United States, 2006-2010, and Changes in Patterns of Use Since 1995*, 60 Nat'l Health Statistics Report 1, 5 (Oct. 18, 2012), https://www.cdc.gov/nchs/data/nhsr/nhsr060.pdf.

¹⁹⁷ Lora Jo Foo, The Ford Found., Asian American Women: Issues, Concerns, and Responsive Human and Civil Rights Advocacy 106 (2002).



¹⁹⁴ Proposed 45 C.F.R. §86.18 (codifying the abortion exemption in Title IX and "relevant laws" including laws cited in *Franciscan Alliance*, RFRA, the Weldon Amendment, Coats-Snowe, and the Church Amendments).

¹⁹⁵ Cynthia Prather, et al., *The Impact of Racism on the Sexual and Reproductive Health of African American Women*, 25(7) J. Women's Health 664, 664-671 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4939479/.

die from pregnancy-related causes, including embolism and pregnancy-related hypertension. 198 For the Latina and Latinx population, lack of access to comprehensive, affordable insurance coverage means sporadic, if not non-existent, access to desperately needed treatment and services. Due to this and other factors, Latinas experience disproportionately high rates of unintended pregnancy, sexually transmitted infections including HIV, diabetes, asthma, and other health issues. Latinas have the highest incidence of cervical cancer; and Latinas are diagnosed with cervical cancer at nearly twice the rate of non-Latina white women. Immigrant Latinas also experience inequities because they have fewer employment opportunities that provide insurance coverage, may be ineligible for federally funded health coverage, face extreme poverty, and lack culturally and linguistically appropriate health care providers and services. The proposed rule also has the potential to place Native American women at risk of being denied treatment because of illegal pregnancy-based discrimination. According to one study of geographically diverse urban areas, Native American women are already 4.5 times more likely to die during or immediately after pregnancy than non-Hispanic white women. 199 Instead of rolling back nondiscrimination protections that will create more barriers to care, the Trump-Pence Administration should be creating policies that ensure Native women receive all of the pregnancy-related care they need.

We strongly oppose HHS proposal to rollback nondiscrimination protections based on sex, including pregnancy status and termination of pregnancy. This proposal is not consistent with Section 1557.

d. Other Definitions

HHS requested comment on whether definitions should be included in the regulatory text.²⁰⁰ We are concerned about the elimination of an overarching definition section as well as the elimination of specific definitions. Having one section that provides all the relevant definitions for the proposed rule makes it easier for entities and the public to identify relevant definitions rather than having to find definitions within each section. This is especially the case in sections where definitions are not the first subsection of

¹⁹⁹ Adrian Dominguez, et al., Urban Indian Health Inst., Seattle Indian Health Bd., Community Health Profile: National Aggregate of Urban Indian Health Program Service Areas 37 (2016), http://www.uihi.org/wp-content/uploads/2017/08/UIHI_CHP_2016_Electronic_20170825.pdf. ²⁰⁰ 84 Fed. Reg. 27860-1.



¹⁹⁸ Marcus T. Smith, *Fact Sheet: The State of Asian American Women in the United States*, Ctr. for Am. Progress (Nov. 7, 2013, 5:33 PM),

https://www.americanprogress.org/issues/race/reports/2013/11/07/79182/fact-sheet-the-state-of-asian-american-women-in-the-united-states/.

the proposed regulation (e.g. definition of qualified interpreter/translator in § 92.101 and definition of qualified interpreter for individuals with disabilities as well as the definition of auxiliary aids and services in § 92.102).

In particular, we oppose the elimination of the following definitions from the current regulations:

- Covered entity;
- Electronic and information technology;
- Employee health benefit program;
- Federal financial assistance;
- Individual with a disability;
- Individual with LEP;
- National origin;
- Qualified bilingual/multilingual staff;
- · Qualified individual with a disability; and
- Recipient.

HHS says that it eliminates some terms and will interpret them "naturally and consistent" with the Final Rule. This includes "individual with limited English proficiency," "qualified bilingual/multilingual staff," and "individual with a disability." We disagree with this conclusion because it is the very lack of definitions for covered entities that often leads to erroneous determinations about what type of services are required or who can provide those services. For example, in the language access context, we continue to hear about unqualified bilingual/multilingual staff attempting to provide interpreting services or services directly in a non-English language. In our report, *The High Costs of Language Barriers in Medical Malpractice*, we described numerous examples of individuals who believed they had sufficient language skills to communicate with LEP patients but the resulting ineffective communication led to serious patient harm.²⁰¹ In one case detailed in the report:

the patient was a Spanish-speaking pregnant woman in her second trimester who died from complications caused by pork tapeworms. Her neurologist testified that he did not require the use of an interpreter. He admitted that while his Spanish was "somewhat limited," he said that he spoke "medical Spanish" and could take a medical/neurological history in Spanish. He spoke with the patient in Spanish and asked all of his questions in Spanish. Notwithstanding the

²⁰¹ See https://9kqpw4dcaw91s37kozm5jx17-wpengine.netdna-ssl.com/wp-content/uploads/2018/09/Language-Access-and-Malpractice.pdf.



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neurologist's self-assessment of his Spanish-proficiency, Mrs. Garcia still complained that she was unable to effectively communicate her condition to the treating physicians because they did not provide her with an interpreter.²⁰²

An individual may self-assess sufficient fluency in a non-English language to provide services in that language but more often than not, that individual does not have the sufficient fluency for interacting in health care encounters let alone the requisite knowledge of specialized medical terminology essential. Given the goal of Section 1557 to prohibit discrimination and a major goal of the ACA is to reduce disparities, having a definition that clarifies when someone who identifies as bilingual or multilingual can actually provide services directly in a non-English language is critical.

The same reasons support having a definition of individual with a disability, qualified individual with a disability, individual with limited English proficiency and qualified individual with limited English proficiency. Covered entities need to understand the full scope of individuals protected by Section 1557 and for whom assistance in the form of language services or auxiliary aids and services must be provided.

We also support including the definition of "electronic and information technology." Given that the underlying civil rights statutes on which Section 1557 builds were all enacted prior to adoption of much of today's electronic and information technology, we believe it is important that regulations proposed in response to a statute adopted in the 2000's include specific reference to this technology.

Finally, HHS specifically requested comment on whether it should define "recipient" according to the current rule or by incorporation by reference to definitions in the underlying statutes, and whether such a definition of recipient should include subrecipients. We strongly recommend that HHS should define the term recipient and subrecipient according to the covered rule. As we have discussed throughout these comments, Section 1557 has broader applicability than the underlying civil rights statutes on which it builds. Therefore, new entities are subject to Section 1557 and need to understand the full scope of expectations for compliance.

§ 92.7 Designation of responsible employee and adoption of grievance procedures

We oppose the deletion of requirements related to designation of a responsible employee and adoption of grievance procedures. We believe that the requirements for a

²⁰² *Id.* at 14.



responsible employee and adoption of a grievance procedure is very important to holding covered entities responsible for the protections provided by § 1557. Without a designated employee and defined grievance procedure, many individuals protected by Section 1557 may not receive the information needed to prevent discrimination or seek redress for discrimination faced. Other federal civil rights laws require designation of a responsible employee and creation of grievance procedures so many covered entities will already have processes in place; expanding them to cover Section 1557 discrimination should be an easy process and HHS could also determine that processes in place to support Section 1557 are evidence of compliance with other pre-existing requirements.

§ 92.8 Notice Requirements

We strongly support the notice and tagline requirements in current regulations that ensure covered entities inform beneficiaries, enrollees, applicants, or members of the public of the availability of language services and auxiliary aids and services, and that the entity does not discriminate on the basis of race, color, national origin, sex, age or disability. The proposed changes are inconsistent with Section 1557 and should not be finalized.

a. Notices

The elimination of notices is problematic on many levels. The importance of this notice is in part due to Section 1557's recognition of the intersectionality of individuals and the discrimination they may face. Prior to Section 1557, an individual facing discrimination could have different rights and remedies based on the relevant underlying civil rights law covering that discrimination. For example, a woman who is limited English proficient would not have any redress for sex discrimination and would likely only have an ability to file an administrative complaint to address national origin discrimination. One of the goals of Section 1557 was to provide the same rights and remedies to all individuals facing discrimination, whether the discrimination be due to race, color, national origin, sex, disability or age. Having one notice covering all the rights under Section 1557 is critical in informing individuals who may face discrimination due to multiple factors of all their rights in one place and notice.

The proposed elimination of notices compromises and diminishes the primacy of the non-discrimination message of Section 1557. To clearly communicate a covered entity's non-discrimination obligations and consumers' right to access services, a notice must be posted in physical locations, on websites and sent with significant documents as the current regulations provide.



The current required elements of the notice cover a broad range of requirements for compliance with Section 1557. The notice requirement ensures that each covered entity notifies beneficiaries, enrollees, applicants and members of the public of the following:

- (1) The covered entity does not discriminate on the basis covered by Section 1557;
- (2) The covered entity provides auxiliary aids and services for people with disabilities;
- (3) The covered entity provides language assistance services for individuals with LEP:
- (4) How to obtain auxiliary aids and services;
- (5) How to obtain language services;
- (6) The availability of the grievance procedure; and
- (7) How to file a discrimination complaint with OCR.²⁰³

Second, the notice requirements under Section 1557 are not duplicative of any other requirements, especially Section 504 or Title VI. The notice requirements in the current regulations are explicit and designed to adequately inform individuals of the scope of their rights under Section 1557. By not fully explaining why repeal of the notices is necessary, HHS fails to justify the repeal. Further, HHS recognizes that eliminating the notice requirement will result in some individuals not knowing of their rights and how to enforce them. Since the Section 1557 notice is more comprehensive than other requirements, HHS has previously determined that the Section 1557 notice would satisfy the Title VI notice requirement as outlined in 45 C.F.R. § 80.6(d) so that these notices are not duplicative. It has also done so for other required notices as long as the combined notice clearly informs individuals of their rights under Section 1557.²⁰⁴ That is, the current notice requirements provides the most comprehensive yet concise summary of an individual's rights under Section 1557, building on Section 504, Title VI, Title IX and the Age Discrimination Act such that the Section 1557 notice is more comprehensive but not duplicative of other notices.

The notice requirement is also important because Section 1557 applies to a broader array of covered entities than the civil rights laws on which it builds. Section 1557 applies specifically to federally administered programs and activities as well as entities created under Title I of the Affordable Care Act. By eliminating the notice requirements, HHS has effectively exempted a large swath of covered entities from informing individuals about their rights under Section 1557.

²⁰⁴ 45 C.F.R. § 92.8(h).



²⁰³ 45 C.F.R. § 92.8.

Further, the costs of providing this notice are not prohibitive for covered entities. HHS provided a sample notice and translated it into 64 languages, alleviating covered entities of the responsibility and cost of developing one on their own.²⁰⁵ Any burdens of wall space and use of information technology staff and resources to post the notice and include it on a website are greatly outweighed by the benefit of having the notice visible and conspicuous so that consumers may see and access the services promised in the notice.

While we recognize that some covered entities have raised concern about how often they have to send this notice (as well as taglines) with significant documents, the wholesale elimination of the notice is not justified by these concerns. Rather, HHS could consider a variety of options including an explanation of what constitutes significant documents or how often a covered entity has to send a notice if the covered entity sends multiple significant documents to individuals over the course of a year. Indeed, in comments submitted by insurers and medical associations in response to the original NPRM, the overriding question was about the frequency of sending notices or taglines rather than the need to send them at all. This was reiterated during a listening session convened by HHS' Office for Civil Rights in 2017 which we attended, where insurers and provider associations did not request a repeal of tagline requirements but rather sought clarification on the frequency with which notices and taglines should be sent.

HHS did not specifically calculate the costs of providing notices or the costs and harm individuals will suffer by not knowing about their rights. Further, HHS failed to explain why completely eliminating notice requirements is justified given the prior analysis HHS has already undertaken in adopting these requirements just a few short years ago. We thus oppose the repeal of requirements related to notices.

b. Taglines

We strongly support the existing tagline requirements and oppose their repeal. The current regulations requires that the English notice and taglines be included in "significant publications and significant communications targeted to beneficiaries, enrollees, applicants or members of the public."²⁰⁶

²⁰⁵ Appendix A to Part 92 – Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law, *see also* OCR, Translated Resources for Covered Entities, https://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html.

²⁰⁶ 45 C.F.R. § 92.8(f)(1).



As HHS noted in the preamble to the final rule, taglines are important in part because HHS decided not to require translation of notices or other documents. The preamble states:

Given that we are not requiring covered entities to post notices in non-English languages, having taglines available in multiple languages is even more important to provide notice to individuals with limited English proficiency of the availability of language assistance services.²⁰⁷

HHS also considered alternatives to the tagline requirements. HHS declined to adopt these alternatives, stating "We decline to eliminate the tagline requirement because such an approach would not provide adequate notice of language assistance services." It specifically noted that the mere **availability** of language services or auxiliary aids and services does not provide adequate **notice** about the availability of services, how to request services or file a complaint.²⁰⁹

Tagline requirements also exist in other regulations so many of those entities that raised cost concerns with the taglines in the Section 1557 regulations will likely still have to comply with tagline requirements elsewhere. For example, marketplace regulations require taglines on documents and websites.²¹⁰ Qualified health plan issuers must comply with tagline requirements applicable to group health plans and issuers which requires taglines on certain notices and the Summary of Benefits and Coverage.²¹¹

While the Preamble and Regulatory Impact Analysis (RIA) attempt to provide a cost justification for repealing the tagline requirements, much of the data HHS relies on is old and irrelevant. In addition, HHS does not explain the methodology it used to draw these conclusions based on information provided by only a few entities. To the extent we can infer the methodology used by HHS to reach its conclusions, that methodology appears flawed. Additional information provided by a handful of insurers and pharmacy benefit managers cannot be extrapolated to the entire health care system since different entities have different interpretations of what a "significant" document is. Indeed, rather than consider any alternatives – such as clarifying the definition of "significant document" or examining whether taglines could be included in fewer documents if the

²¹¹ 45 C.F.R. § 147.136€(2)(iii), (e)(3); 29 C.F.R. §2590.715-2719(e)(2)(iii), (3).



²⁰⁷ 81 Fed. Reg. 31398.

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ 45 C.F.R. § 155.205(c)(2)(iii)(A).

same document is sent multiple times a year – HHS instead concluded that the costs outweighed any benefit. The repeal of taglines considered in connection with HHS' adoption of the four-factor test for evaluating compliance (which includes consideration of costs) leaves us even more concerned that HHS' enforcement activities will regularly but erroneously conclude that covered entities may not have to provide any language services.

Some of the examples provided to the Office of Management and Budget by entities complaining about the costs of taglines, and which HHS relied on in the RIA, actually go far beyond the expectations and requirements of the Section 1557 regulations. For example, HHS' sample English tagline consists of 19 words (including TTY information in the word count). Some of the taglines provided to OMB and HHS were much longer than HHS' sample and included in many more languages than the 15 expected in the current regulations. The following chart includes the information provided to OMB, extrapolated on the assumption that the length of the tagline would stay relatively similar in different languages (or that the variances would result in similar results across the examples):²¹²

Source	Tagline Length	Language	Number of Taglines	Estimated Total Words ²¹³
§ 1557 Final Rule ²¹⁴	19	English	15	285
Example 1 ²¹⁵	31	Spanish	65	2015
Example 2	85	English	18	1530
Example 3	11	English	66	726
Example 4	36	Spanish	15	540

²¹⁵ These examples are taken from the information submitted to OMB, https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=0945-AA11&meetingId=3184&acronym=0945-HHS/OCR.



²¹² Completed 18166 Meeting, Rin 0945-AA11, May 9, 2018, Handout #1, *available at* https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=0945-AA11&meetingId=3184&acronym=0945-HHS/OCR.

²¹³ Please note that this total is a rough extrapolation as different languages will use more or less words than an English or Spanish tagline. However, we believe it is useful as a guide given the estimates HHS relied on are much longer than what is expected under current Section 1557 regulations.

²¹⁴ This estimate uses the length of HHS' sample tagline included in the Section 1557 final regulation.

Even with this rough estimate, the examples provided consist of two to seven times the number of words expected under the Section 1557 current rule. Thus any cost estimates using those examples would vastly overestimate the costs of providing taglines. While we certainly appreciate the inclusion of a longer, more descriptive tagline in more languages, HHS cannot rely on inflated costs from an extremely small sample as justification to repeal this provision. In the only examples provided, the costs end up inflated because the added length and number of taglines increases the costs to covered entities beyond what HHS originally contemplated. If instead the covered entities utilized a shorter tagline and only provided the tagline in the top 15 languages in the state (which a covered entity likely could do by tailoring notices per state rather than aggregating languages among multiple states), the costs of compliance would be significantly less. It does not seem that HHS conducted any analysis of the costs of using its shorter tagline in only 15 languages.

Additionally, HHS estimates the cost using the current application of the tagline requirement. While we oppose the NPRM's proposed limitations on the scope of Section 1557 as outlined in proposed § 92.2, limiting the number of covered entities, particularly by reducing the number of insurers or products covered, would further reduce the expected costs of providing notices and taglines. That is, HHS currently proposes that only insurers providing health plans in the marketplaces would be covered by Section 1557, excluding these insurer's non-marketplace products (including short-term limited duration plans and employer-sponsored plans). Thus, many fewer entities would be subject to providing taglines to fewer enrollees, further reducing the likely costs.

The combination of inflated costs for providing longer taglines and notices, the reduction in covered entities, and the lack of an independent analysis results in a failure of HHS to accurately estimate and assess the costs and costs savings in proposing to eliminate taglines (as well as notices). As noted by the Center for American Progress, HHS relies solely on selected data provided by insurers and pharmacy benefit managers to make these changes, yet the survey results provided do not contain any information about the reaction individuals with LEP had to the taglines or the impact on this population. In the proposed rule, HHS never mentions receiving input from individuals with LEP and entirely relies on insurance company and pharmacy benefit managers' analyses to determine that notices are not necessary. ²¹⁶ HHS's methods are not sound.

²¹⁶ Center for American Progress, *Attack on the ACA: Undermining Protections for LGBTQ Patients and Language Accessibility Requirements* (July 19, 2019), https://www.americanprogress.org/issues/lgbt/news/2019/07/19/472332/attack-on-the-aca/.



By completely repealing the tagline requirements, HHS failed to consider any alternatives that could balance the potential costs with the need for individuals to be informed about their rights. As HHS noted in the preamble to the final Section 1557 regulations, not having taglines "would not provide adequate notice of language assistance services" and thus would not ensure entities comply with the statutory nondiscrimination requirements of Section 1557. Yet HHS did not consider the costs to individuals with LEP of the loss of taglines or all individuals covered by the protections of Section 1557 who will suffer by the elimination of notices.

As HHS recognized in the Preamble to the Section 1557 final regulations, tagline requirements

may impose some limited burdens on covered entities. However, these burdens 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. Notifying individuals of their rights under Section 1557 and this part, including the availability of language assistance services for individuals with limited English proficiency and the availability of auxiliary aids and services for persons with disabilities, is critical to providing an equal opportunity to access health care and health coverage.²¹⁸

As we mentioned above regarding notices, comments submitted by insurers and medical associations in response to the original NPRM did not generally dispute the tagline requirement but the overriding question was about the frequency of sending notices or taglines. This was reiterated during a listening session convened by HHS' Office for Civil Rights in 2017 which we attended, insurers and provider associations did not request a repeal of tagline requirements but rather sought clarification on the frequency with which notices and taglines should be sent.

HHS has also failed to explain why completely eliminating tagline requirements is justified given the prior analysis HHS has already undertaken in adopting these requirements just a few short years ago.

§ 92.101 Discrimination Prohibited

HHS proposes to delete § 92.101 of the current rule, claiming it will be replaced by "provisions addressing Section 1557's purpose, nondiscrimination requirements, scope

²¹⁸ 81 Fed. Reg. 31401.



²¹⁷ *Id*.

of application, enforcement mechanisms, relationship to other laws, and meaningful access for LEP individuals."²¹⁹ However, § 92.101 contains important prohibitions on discrimination that the NPRM now fails to incorporate.

In the preamble to the current final regulations, HHS noted:

We considered harmonizing each of the specific discriminatory actions prohibited across each civil rights law addressed by Section 1557. We noted that although harmonization could reduce redundancy in the specific discriminatory actions incorporated that are similar to one another, harmonization would likely lead to confusion and unintended differences in interpretation that are subtle yet significant. We therefore proposed that paragraphs (b)(1)–(4) incorporate the specific discriminatory actions prohibited under each civil rights law on which Section 1557 is grounded.²²⁰

Yet the deletion of this section in the current NPRM will cause the very result HHS has previously determined untenable. Both the overall deletion and the deletion of specific protections of each protected class will result in a murkier understanding of Section 1557's scope as well as the protections afforded each protected class.

By deleting § 92.101(b)(1), HHS deletes references to important regulatory definitions of discrimination on the basis of race, color and national origin. For example, the current regulation states that "Each covered entity must comply with the regulation implementing Title VI, at § 80.3(b)(1) through (6) of this chapter."²²¹ The regulations prohibit discrimination on the basis of race, color or national origin such as: denying or providing different services; restricting access or subjecting an individual to segregation or separate treatment; or treating an individual differently than others for the purposes of admission, enrollment, eligibility, membership or other requirement/condition needed to receive a service or other benefit.

The current regulations also provide that no covered entity may aid or perpetuate discrimination against any person by providing significant assistance to any entity/person that discriminates on the basis of race, color or national origin in providing any aid, benefit or service to beneficiaries.²²² Given that many covered entities fail to understand the requirements of Title VI, it is important to reiterate those requirements in

²²² 45 C.F.R. §92.101(b)(1)(ii).



²¹⁹ 84 Fed Reg. 27856, 27860.

²²⁰ 81 Fed. Reg. 31404.

²²¹ 45 C.F.R. § 92.101(b)(1)(i).

this regulation, given that many entities have paid more attention to implementation of the ACA than with complying with longstanding civil rights laws. Thus, having these provisions in the current regulations can bring much needed attention to the pre-existing provisions on which Section 1557 is built.

HHS deletes § 92.101(b)(2) which references important regulatory definitions of disability discrimination, and incorporates the relevant provisions of 504 implementing regulations for federal assisted and federally administered programs and activities. For example, the current regulation states that "Each recipient and State-based MarketplaceSM must comply with the regulation implementing Section 504, at §§ 84.4(b), 84.21 through 84.23(b), 84.31, 84.34, 84.37, 84.38, and 84.41 through 84.52(c) and 84.53 through 84.55 of this subchapter."²²⁴ It also states that

[t]he Department, including the Federally-facilitated Marketplaces, must comply with the regulation implementing Section 504, at §§ 85.21(b), 85.41 through 85.42, and 85.44 through 85.51 of this subchapter.²²⁵

These cross-references clarify that covered entities have an affirmative obligation to ensure that their health care is accessible to individuals with disabilities in a myriad of ways that are not captured in other sections of the NPRM. For example, sections 84.4(b) and § 85.21(b) prohibit discrimination by a variety of factors. These include:

- denying an individual with a disability the opportunity to participate in or benefit from the aid, service, or benefit;
- affording an individual with a disability an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;
- providing an individual with a disability a less effective aid, benefit or service;
- providing an individual with a disability different or separate aids, benefits, or services;
- otherwise limiting a person with a disability in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.²²⁶

²²⁶ 45 C.F.R. §§ 84.4(b), 85.21(b).



²²³ 81 Fed. Reg. 31404.

²²⁴ 45 C.F.R. § 92.101(b) (2) (i).

²²⁵ 45 C.F.R. § 92.101(b)(2)(ii).

It also prohibits covered entities from:

utiliz[ing] criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same State."²²⁷

In short, without the inclusion of § 92.101, the NPRM's description of prohibited discrimination under Section 504 is incomplete. It is also contrary to the statutory language and intent of Section 1557, which explicitly specifies that the grounds for discrimination are defined by reference to Section 504 and other civil rights laws.

HHS also proposes deleting § 92.101(b)(3), which references to important regulatory definitions of sex discrimination. For example, the current regulation states that "Each covered entity must comply with the regulation implementing Title IX, at § 86.31(b)(1) through (8) of this chapter."²²⁸ These regulatory sections outline the specific prohibitions of Title IX, including:

- Treating a person differently in determining whether a person satisfies any requirement or condition for receiving aid, benefit or service;
- Providing different aid, benefits or services (or providing them in a different manner);
- Denying any aid, benefit or service;
- Subjecting any person to separate or different rules of behavior, sanctions, or other treatment;
- Discriminating against any person in the application of any rules of appearance;
- Applying any rule concerning the domicile/residence of a student/applicant, including eligibility for in-state fees and tuition;
- Aiding or perpetuating discrimination against any person by providing significant assistance to any agency, organization, or person which discriminates on the basis of sex in providing any aid, benefit or service to students or employees;
- Otherwise limiting any person in the enjoyment of any right, privilege, advantage, or opportunity.²²⁹

²²⁹ 45 C.F.R. § 86.31(b)(1)-(8).



²²⁷ 45 C.F.R. § 84.4(b); 45 C.F.R. § 85.21(b).

²²⁸ 45 C.F.R. § 92.101(b)(3)(i).

It also states that

a covered entity may not, directly or through contractual or other arrangements, utilize criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex, or have the effect of defeating or substantially impairing accomplishments of the objectives of the program with respect to individuals on the basis of sex.²³⁰

Additional subsections specify that site location may not exclude individuals on the basis of sex and that sex-specific health programs or activities may only be permitted if there is an "exceedingly persuasive" justification. These provisions clarify that covered entities have an affirmative obligation to ensure that their health care is accessible regardless of one's sex (or sex stereotypes or gender identity, per the definition of "on the basis of sex" in the current regulations) in a myriad of ways that is not captured in other sections of the NPRM. Given the fact that sex discrimination is only newly prohibited in health care by Section 1557, since Title IX had only applied to educational contexts, it is extremely important to provide information to health care providers about the scope of Title IX's protections and how to prevent sex discrimination.

By deleting these provisions, the NPRM's description of prohibited discrimination under Title IX, and thereby Section 1557, is incomplete. These provisions are necessary to the statutory language and intent of Section 1557, which explicitly specifies that the grounds for discrimination are defined by reference to Title IX and other civil rights laws.

And by deleting § 92.101(b)(4), HHS deletes references to important regulatory definitions of age discrimination. For example, the current regulation states that "Each covered entity must comply with the regulation implementing the Age Discrimination Act, at § 91.11 of this subchapter." This provision outlines the general rule for protecting against age discrimination as well as specific rules such as not using age to deny benefits or subject an individual to discrimination under any program/activity receiving federal financial assistance and denying or limiting the ability to participate in any program/activity receiving federal financial assistance. In its NPRM, HHS fails to provide any specific information about complying with the Age Discrimination Act and its implementing regulations. Indeed, the only way HHS attempts to recognize the relevance of the Age Discrimination Act for the purposes of Section 1557 is to limit

²³² 45 C.F.R. § 92.101(b)(4)(i).



²³⁰ 45 C.F.R. § 92.101(b)(3)(ii).

²³¹ 45 C.F.R. § 92.101(b)(3)(iii), (iv).

enforcement mechanisms rather than recognize any additional or new requirements for covered entities. The elimination of these provisions is not consistent with Section 1557 and is likely to create confusion.

The current section also contains important information with regard to applicable and non-applicable exceptions as well as how to adopt other regulations' terminology to the context of Section 1557.²³³ These important clarifications have helped covered entities to understand the depth and breadth of Section 1557's application, both where it parallels pre-existing civil rights laws on which it builds but also more importantly where it departs and has a broader application. Eliminating this explicit information leaves covered entities without guidance as to the scope of Section 1557, which is likely to cause confusion, and result in entities engaging in prohibited discrimination. The current provisions are consistent with Section 1557 and should be retained.

§ 92.207 Nondiscrimination in health-related insurance and other health-related coverage

Section 1557 and the 2016 implementing regulations prohibit health insurance companies from discriminating through marketing practices and benefit design. These protections are especially important for people with disabilities and those with other serious or chronic conditions. The proposed rule seeks to exempt most health insurance plans from Section 1557's nondiscrimination protections and eliminates, without explanation, the regulation prohibiting discriminatory benefit design and marketing. This proposed change is contrary to Section 1557's express language and intent.

Before the ACA, health insurers routinely discriminated against people with HIV/AIDS and other serious or chronic conditions by charging them exorbitant premiums, excluding coverage for their conditions, or refusing to provide health coverage at all. Although the ACA ended these practices, some insurers still sought ways to discourage people with significant health needs from enrolling in their plans.

For example, the National Health Law Program and The AIDS Institute filed a complaint with HHS Office for Civil Rights (OCR) charging that four Florida health insurers discriminated against persons living with HIV/AIDS by placing all drugs used in the treatment of HIV, including generics, in the highest cost sharing tiers.²³⁴ Researchers at

²³⁴ National Health Law Program & The AIDS Institute, *Re: Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida, Administrative Complaint filed with*



²³³ 45 C.F.R. § 92.101(c), (d).

the Harvard School of Public Health found that the practice of placing HIV drugs in the highest cost sharing tier, which they called "adverse tiering," to be widespread.²³⁵ The Pharmaceutical Research and Manufacturers Association (PhRMA) contracted for an analysis of the formularies for 123 silver-level Marketplace plans and found similar problems regarding medications for multiple sclerosis and cancer. PhRMA concluded that there was a "lack of adequate formulary scrutiny on the part of state and federal regulators" because "[r]equiring high cost sharing for all medicines in a class is exactly the type of practice the ACA was designed to prevent."

Section 1557 was passed as part of the ACA to specifically address discrimination in benefit design. As an integral component of these reforms, Congress mandated comprehensive health benefit coverage and explicitly prohibited discriminatory practices in the content of those plan designs. Most pertinent, it prohibited limitations or exclusions of benefits based on pre-existing conditions; it mandated coverage, on a nondiscriminatory basis, of ten categories of essential health benefits ("EHBs"); and it prohibited QHP "marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs," among other protections.²³⁷

Section 1557 of the ACA is the key to enforcing these statutory mandates. Section 1557 prohibits discrimination, including discrimination in the design of a benefit package, in health programs or activities receiving federal financial assistance.²³⁸ By statute, it creates a private right of action for individuals to enforce their civil rights in the health care context.²³⁹ The scope of actionable discrimination under Section 1557 logically covers discrimination in enrollment, equal access to benefits, and benefit design.²⁴⁰

the HHS Office for Civil Rights (May 28, 2014), https://healthlaw.org/resource/nhelp-and-the-aids-institute-complaint-to-hhs-re-hiv-aids-discrimination-by-fl/.

²⁴⁰ See, e.g., National Health Law Program & The AIDS Institute, *Re: Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida, Administrative Complaint filed with the HHS Office for Civil Rights* (May 28, 2014), https://healthlaw.org/resource/nhelp-and-the-aids-institute-complaint-to-hhs-re-hiv-aids-discrimination-by-fl/.



²³⁵ Douglas B. Jacobs, ScB, and Benjamin D. Sommers, MD, PhD, *Using Drugs to Discriminate* — *Adverse Selection in the Insurance Marketplace*, N ENGL J MED 2015; 372:399-402 (Jan. 29, 2015).

²³⁶ PhRMA, Coverage Without Access: An Analysis of Exchange Plan Benefits for Certain Medicines, http://www.phrma.org/affordable-care-act/coverage-without-access-an-analysis-of-exchange-plan-benefits-for-certain-medicines#sthash.o0bB3Xh0.pdf.

²³⁷ 42 U.S.C. §§ 300gg-3(b)(1), 18022, 18031(c)(1)(A).

²³⁸ See 42 U.S.C. § 18116(a).

²³⁹ See, e.g., Rumble v. Fairview Health Servs., No. 14-cv-2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (finding that Section 1557 creates a private right of action).

Recognizing this statutory requirement, the 2016 final rule reiterates that Section 1557 prohibits "marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy."²⁴¹ In guidance, HHS provided examples of practices that would contravene Section 1557 and this regulation. Plans that, for example, "cover bariatric surgery in adults but exclude such coverage for adults with particular developmental disabilities place[e] most or all drugs that treat a specific condition on the highest cost tiers or exclude bone marrow transplants regardless of medical necessity would run afoul of Section 1557, HHS explained.²⁴²

HHS' 2016 regulation logically follows the letter and intent of the ACA. Without explicit acknowledgement of, and a resulting prohibition on, discriminatory benefit design, Section 1557's nondiscrimination protections would be rendered illusory. By not reaching the structure of a benefit package, a health insurer could always manipulate their benefit design to elude discrimination law, despite maintaining the same discriminatory effects.

For illustration, consider cancer benefits. Without the ACA reaching benefit designs, a health insurer could not deny an individual with cancer enrollment in a QHP or equal access to the treatments, services, and prescription drugs the plan chooses to cover; however, it could exclude from its coverage all cancer-related surgery, chemotherapy, radiation, and post-treatment drugs. It could also limit beneficiaries to provider networks that fail to include key oncology specialists, thus avoiding coverage of the expensive treatments they may prescribe. For a person with cancer, access to a health plan would be deemed virtually meaningless in the absence of cancer-related coverage. The effect of these exclusions would be the same as an outright denial of enrollment. Elimination of the benefit design regulation perversely encourages this result. It incentivizes insurers to find roundabout ways to deter people with pre-existing conditions from their plans. This is impermissible under Section 1557 of the ACA and Section 504 of the Rehabilitation Act.²⁴³

²⁴³ See 29 U.S.C. § 794; 42 U.S.C. §§ 18116(a), 18031(c)(1)(A); 45 C.F.R. § 92.207(b)(2).



²⁴¹ 45 C.F.R. § 92.207.

²⁴² HHS Nondiscrimination in Health Programs and Activities; Final Rule, 81 Fed. Reg. 31,376, 31,429 (May 18, 2016); *HHS Notice of Benefit and Payment Parameters for 2016*, 80 Fed. Reg. 10,750, 10,822 (Feb. 17, 2015); CMS CCIIO, QHP Master Review Tools for 2015, Non-Discrimination in Benefit Design (2015),

http://insurance.ohio.gov/Company/Documents/2015 Non-Discriminatory Benefit Design QHP Standards.pdf.

The proposed rule removes the current prohibition on discriminatory plan benefit design and marketing in the Section 1557 regulations at 45 C.F.R. § 92.207. These protections are especially important for people with disabilities and those with serious or chronic conditions. This could result in health insurers excluding important benefits, designing their prescription drug formularies in a way that limits access to medically necessary care, or cherry-picking healthier enrollees through marketing practices. Eliminating these regulatory provisions may make it harder for people who experience discrimination to enforce their rights through administrative and judicial complaints.

However, HHS fails to provide any explanation regarding the elimination of these regulatory protections. Therefore, we are unable to adequately comment and strongly oppose HHS' proposed action.

§ 92.208 Employer liability for discrimination in employee health benefit programs

We oppose the repeal of this provision. HHS has not provided any reason or explanation as to why it seeks to repeal this provision. To justify proposed changes in existing regulations, HHS must provide its own explanation and rationale for the changes, documenting a need for these changes based not on an opposition to the policy undergirding a particular regulation but based on reason and data. Given that the public must be provided an opportunity to comment on HHS' alleged justifications for these proposed changes, HHS' attempt to repeal this provision is legally insufficient and violates requirements of public notice and comment as required by the Administrative Procedures Act.

§ 92.209 Nondiscrimination on the basis of association

Current regulations expressly prohibit discrimination on the basis of association with a protected class.²⁴⁴ Without explanation, the proposed rule eliminates this provision. Congress intended Section 1557 to protect against discrimination by association, and these provisions should be retained.

In the 2016 Final Rule, HHS explains that the statute does not restrict "the prohibition to discrimination based on the individual's own race, color, national origin, age, disability or sex. Further, we noted that a prohibition on associational discrimination is consistent with longstanding interpretations of existing antidiscrimination laws, whether the basis of

²⁴⁴ 45 C.F.R. § 92.209.



discrimination is a characteristic of the harmed individual or an individual who is associated with the harmed individual.²⁴⁵

The current regulation's language mirrors that of Title I and Title III of the ADA, which protect against discrimination based on association or relationship with a person with a disability.²⁴⁶ Congress intended that Section 1557 provide at least the same protections for patients and provider entities. In accord with the ADA, the current regulation recognizes this protection extends to providers and caregivers, who are at risk of associational discrimination due to their professional relationships with patients, including those patient classes protected under Section 1557.²⁴⁷

For example, an individual in an interracial marriage who experiences discrimination would be protected under Section 1557 because of the individual's association with a protected class. Similarly, a HIV-negative person in a sero-discordant relationship could not be denied access to pre-exposure prophylaxis (PrEP) to prevent HIV infection. Denying access to this treatment or other health care services would be prohibited associational discrimination, and would adversely affect vulnerable, highest risk populations including gay and bisexual men.

By eliminating regulatory provisions expressly prohibiting discrimination on the basis of association, HHS will create uncertainty and confusion regarding the responsibilities of

https://www.projectinform.org/hiv-news/the-fda-has-approved-generic-prep-but-access-may-remain-difficult/.



²⁴⁵ 81 Fed. Reg. 31439.

²⁴⁶ 42 U.S.C. §§ 12112, 12182 (2012).

²⁴⁷ 28 C.F.R. pt. 35, app. B (2015) (interpreting Title I and Title III of the ADA to protect "health care providers, employees of social service agencies, and others who provide professional services to persons with disabilities").

²⁴⁸ *Id.*, citing *Parr v. Woodmen of the World Life Ins.*, 791 F.2d 888, 892 (11th Cir. 1986).

²⁴⁹ Press Release, FDA Approves First Drug for Reducing the Risk of Sexually Acquired HIV Infection, FOOD & DRUG ADMIN. (July 16, 2012), https://wayback.archive-

it.org/7993/20170112032741/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm. Pre-exposure Prophylaxis (PrEP) for HIV Prevention, CTRS. FOR DISEASE CONTROL AND PREVENTION 1 (May 2014),

https://www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf; PrEP, CTRS. FOR DISEASE CONTROL AND PREVENTION (March 23, 2018), https://www.cdc.gov/hiv/basics/prep.html. While a generic version of Truvada was approved by the FDA in 2017, it appears likely that it will not become commercially available until 2021, when Gilead's patent on emtricitabine (one of the two HIV antiretroviral drugs Truvada is composed of) expires. See *The FDA Has Approved Generic PrEP – but Access May Remain Difficult*, PROJECT INFORM (June 16, 2017),

providers and the rights of persons who experience discrimination. However, because HHS provides no explanation of its reasons for removing 45 C.F.R. § 92.209, we cannot adequately comment, and urge HHS to retain the current regulatory protections.

§ 92.302 Procedures for health programs and activities conducted by recipients and State-based marketplaces &

§ 92.303 Procedures for health programs and activities administered by the Department

We oppose the repeal of these provisions as discussed above in section II.A.2.

IV. Need for Conforming Amendments

NHeLP opposes the proposed amendments to:

- 45 C.F.R. §§ 155.120(c)(1)(ii), 155.220(j)(2) (nondiscrimination provisions concerning how States and Exchanges carry out PPACA requirements and how agents or brokers market to individuals they assist with Exchange enrollment or related applications);
- § 147.104(e) (nondiscrimination provision concerning marketing or benefit design practices of health insurance issuers under the PPACA);
- §§ 156.200(e), 156.1230(b)(3) (nondiscrimination provision concerning the administration of QHPs by issuers and concerning marketing and other conduct by QHP issuers engaged in direct enrollment);
- 42 C.F.R. §§ 460.98(b)(3), 460.112(a) (nondiscrimination provisions for organizations operating Programs for All-inclusive Care of the Elderly (PACE) programs and participants receiving PACE services under Medicare); and
- §§ 438.3(d)(4), 438.206(c)(2), 440.262 (nondiscrimination provisions concerning Medicaid beneficiary enrollment, and promotion and delivery of access and services).

These amendments would remove sexual orientation and gender identity as enumerated prohibited bases of discrimination. HHS's attempt to stylize these amendments as necessary to conform these provisions to HHS' new interpretation of Section 1557 and the civil rights laws referenced in it is incorrect. As a preliminary matter, the scope of sex discrimination in Title VII is currently pending before the



Supreme Court.²⁵⁰ It is premature to change the regulations now before the Supreme Court has spoken to this precise interpretive issue.

For several of the proposed provisions, the regulations listed above were promulgated under a statutory basis other than, or in addition to, Section 1557, as requiring protection against discrimination on the basis of gender identity and sexual orientation.²⁵¹ HHS completely fails to address the statutory grounds or these provisions outside of Section 1557. In fact, those statutes independently provide for prohibitions against discrimination on the basis of gender identity and sexual orientation. HHS may not finalize the proposed revisions to these regulations.

As discussed in more detail above (*supra* Section III.B), the plain language of Section 1557 provides for protection from discrimination based on gender identity. The majority of courts to consider the question have found that the statutory language of Section 1557 prohibits discrimination based on gender identity. As one court has explained: "discriminating on the basis that an individual was going to, had, or was in the process of changing their sex — or the most pronounced physical characteristics of their sex — is still discrimination based on sex." Discrimination on the basis of gender identity is prohibited by 1557. Removing the words "gender identity" from the various regulations listed will not change that fact, but will serve to confuse the entities covered by those regulations, and the stakeholders entitled to protection under them, as to the scope of their legal obligations and rights. This confusion will likely lead to more complaints and litigation over gender identity-based discrimination. HHS should not adopt the proposed changes to these sections.

²⁵³ Flack v. Wis. Dept. of Health Servs., 328 F. Supp. 3d 931, 949 (W.D. Wis. 2018).



²⁵⁰ See Altitude Exp., Inc. v. Zarda, 139 S. Ct. 1599 (2019); R.G. & G.R. Harris Funeral Homes, Inc. v. E.E.O.C., 139 S. Ct. 1599 (2019).

²⁵¹ Specifically, 45 C.F.R. § 155.120(c)(1)(ii) was promulgated pursuant to ACA section 1321(a)(1)(A). See Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, 76 Fed. Reg. 41865, 41897 (2011). 45 § 156.200(e) was promulgated pursuant to ACA section 1321(a)(1)(B). See Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, 76 Fed. Reg. 41865, 41897 (2011). The protections at 42 C.F.R §§ 438.3(d)(4), 438.206(c)(2), 440.262 are based on Social Security Act §§ 1902(a)(19) and 1902(a)(4). Medicaid and Children's Health Insurance Program (CHIP) Programs, 81 Fed. Reg. 27498, 27538 (2016).

²⁵² See, e.g., Tovar v. Essentia Health, 342 F. Supp. 3d 947, 953 (D. Minn. 2018); Boyden v. Conlin, 341 F. Supp. 3d 979, 997 (W.D. Wis. 2018); Flack v. Wis. Dep't of Health Servs., 328 F. Supp. 3d 931, 951 (W.D. Wis. 2018); Prescott v. Rady Children's Hosp.-San Diego, 265 F.Supp.3d 1090, 1098-1100 (S.D. Cal. 2017); Rumble v. Fairview Health Servs., No. 14-CV-2037 SRN/FLN, 2015 WL 1197415, at *18 (D. Minn. Mar. 16, 2015).

In addition, as discussed above (*supra* Section III.B), section 1557 prohibits discrimination based on sexual orientation. To date, no court has specifically addressed whether sexual orientation discrimination is encompassed under section 1557's prohibition against discrimination on the basis of sex. Numerous courts, however, have held that sexual orientation discrimination is a type of sex discrimination, both because it is based on the sex of the individuals to whom a person is attracted, and because it relies on sex stereotypes about romantic pairings and attraction. ²⁵⁴ For the same reason, Section 1557 prohibits discrimination on the basis of sexual orientation. Removing the words "sexual orientation" from the listed regulations will not change the statutory text of Section 1557 or other statutory non-discrimination provisions such that sexual orientation discrimination is allowed, but, as described above, it will serve to confuse the entities covered by those regulations, and the stakeholders entitled to protection under them, as to the scope of their legal obligations and rights. This confusion will likely lead to more complaints and litigation over sexual orientation-based discrimination. HHS should not adopt the proposed changes to these sections.

V. Interim Treatment of Subregulatory Guidance

We oppose HHS' suspension of all subregulatory guidance related to Section 1557 while the rulemaking is in process, and in particular the preamble to the current Section 1557 regulation. HHS is bound by the Administrative Procedures Act to provide justification for its proposed changes and cannot change current regulations without going through the notice and comment period, considering those comments, and then providing justification for its changes in a new final regulation. Particularly with respect to the preamble to the current regulations, the information provided helps covered entities understand the parameters of the regulations, how to comply, and what HHS considered in evaluating comments. Rescinding the subregulatory guidance while the current regulations remain will only sow confusion for covered entities as well as

²⁵⁴ See, e.g., Zarda v. Altitude Express, Inc., 883 F.3d 100, 119 (2d Cir. 2018), cert. granted sub nom. Altitude Exp., Inc. v. Zarda, 139 S. Ct. 1599, 203 L. Ed. 2d 754 (2019); Christiansen v. Omnicom Grp., Inc., 852 F.3d 195, 201 (2d Cir. 2017); Hively v. Ivy Tech Cmty. Coll. of Indiana, 853 F.3d 339, 345 (7th Cir. 2017); Spencer v. Town of Bedford, No. 6:18-CV-31, 2018 WL 5983572, at *5 (W.D. Va. Nov. 2, 2018); Boutillier v. Hartford Pub. Sch., 221 F.Supp.3d 255, 269 (D. Conn. 2016); Videckis v. Pepperdine Univ., 150 F.Supp.3d 1151, 1160 (C.D. Cal. 2015); Terveer v. Billington, 34 F.Supp.3d 100, 116 (D.D.C. 2014); Centola v. Potter, 183 F.Supp.2d 403, 410 (D. Mass. 2002); Heller v. Columbia Edgewater Country Club, 195 F.Supp.2d 1212, 1224 (D. Or. 2002).



individuals protected by Section 1557. The harm of suspending the guidance and the preamble greatly outweighs any benefit.

HHS cites to the Attorney General's memorandums of November 16, 2017 and January 25, 2018 as justification for the suspension. While HHS states that Department of Justice litigators cannot use *noncompliance* with guidance documents as the basis for proving violations, the guidance can certainly be used by covered entities to help ensure *compliance* with Section 1557. It can also be used by the courts to understand HHS' intent in promulgating the current regulations. Suspending this guidance, especially while the current regulations remain in effect, will cause confusion amongst covered entities who have been relying on this guidance and the preamble for a number of years.

Given the time it will take for HHS to proceed through the required steps to finalize revisions, and that the current Section 1557 regulation remains in effect until that process is completed, HHS should not suspend any existing guidance that offers information on interpreting and applying Section 1557.

VI. Regulatory Impact Analysis

a. The Regulatory Impact Analysis (RIA) is insufficient and fails to justify the proposed changes

The NPRM provides a RIA that is wholly insufficient to justify the extensive scope of the proposed changes to language access and entirely fails to identify and to quantify costs to protected individuals. As we discussed above, we believe the cost estimates considered by HHS as justification for the proposed changes are outdated, overestimated and fail to consider the cost and harm to individuals covered by Section 1557. In general, HHS fails to provide the underlying data or methodology that would support its claims.

HHS's estimate of the burden to covered entities for compliance with the nondiscrimination notice and tagline requirements is based on voluntary actions by covered entities. HHS based the elimination of the notice and taglines on these estimates, but did not consider whether alternatives, such as further clarification about the requirements, was warranted in the form of FAQs or other guidance. That is, HHS failed to consider alternatives to a complete repeal of notices and taglines that could have appropriately balanced the need to inform individuals of their rights while recognizing the 2016 Final Rule may not have been clear in its expectations.



Similarly, the majority of the costs are associated with the provision of a single type of document -- the Explanation of Benefits (EOB). HHS did not consider alternatives as to how it would consider enforcement and interpretation of the "significant document" standard with respect to the provision of multiple EOBs sent during a coverage year.

HHS states it has received little evidence that more beneficiaries are seeking language assistance and uses this claim as a justification to remove the notice and taglines. This claim, which relies on reports from health plans, is insufficient to justify the repeal of these important requirements. The regulation has been in effect for three years in which HHS, by its own admission, has had limited resources to conduct public outreach. Second, the protections guaranteed by Section 1557 are both continuing and expanded, warranting a public effort to conduct outreach. Third, the notices and taglines were specifically selected as to balance the needs of LEP individuals against requiring covered entities to translate large numbers of documents. Fourth, LEP persons are uniquely at risk of facing barriers to knowing and asserting their rights. Lack of uptake of services raises questions about the extent to which the public knows its rights and what covered entities are doing to communicate those rights, as opposed to justifying elimination of notices and taglines.

More broadly, however, we take issue with HHS' evaluation of costs to covered entities. The question should not be "whether the benefits of these provisions exceeds the burdens imposed by them." Such a balancing exercise is not called for by the statute, and inserts an inappropriate regulatory finesse on a remedial scheme created by Congress and intended to be interpreted broadly and to correct decades of harm. The task of the agency is to interpret and implement the statute. The proposed balancing of interests may be an appropriate role for Congress, but not for the administrative branch.

b. Language Access Requirements in the 2016 final rule are justified by need

HHS has provided no tangible analysis of the costs and burdens of repealing the notice and tagline requirement. Instead, HHS provides only acknowledgment that repeal "may impose costs, such as decreasing access to, and utilization of, health care for non-English speakers by reducing their awareness of available translation services." ²⁵⁶ HHS perfunctorily labels the impact as "negligible" while providing no evidentiary basis. ²⁵⁷

²⁵⁷ *Id*.



²⁵⁵ See, e.g. 42 U.S.C. § 12101 (ADA findings and purposes). The ADA builds upon Section 504, and Section 1557 follows in their footsteps.

²⁵⁶ 84 Fed. Reg. 27882.

The costs are not only reduced awareness of language services by individuals with LEP, but also reduced awareness by the general public about their rights as protected by 1557, especially regarding the notices which include information about the broader nondiscrimination requirements of Section 1557. HHS's only acknowledgement of this impact is one statement about the "unknown number of persons are likely not aware of their right to file complaints."²⁵⁸

Discrimination of all kinds creates unequal access to health care. HHS' proposed changes fly in the face of the letter and spirit of Section 1557 and its RIA fails to provide any legal justification for these changes.

See also our discussion above regarding § 92.8 about the repeal of provisions related to notices and taglines.

IX. Request For Comment

HHS provides an extensive list of issues on which it solicits comments, in addition to seeking comment on all issues raised by the proposed regulation. The list of issues in Section IX, however, provides insufficient clarity in both the questions and the context such that we do not think we can provide meaningful comment outside of the comments we are providing elsewhere.

To justify proposed changes in existing regulations, HHS must provide its own explanation and rationale for the changes, documenting a need for these changes based not on an opposition to the policy undergirding a particular regulation but based on reason and data. Given that the public must be provided an opportunity to comment on HHS' alleged justifications for these proposed changes, HHS' attempt to solicit feedback on a list of additional issues that it may then use to promulgate unanticipated changes in a final rule violates requirements of public notice and comment as required by the Administrative Procedures Act. These issues would be more appropriate to inform agency decisions prior to issuing an NPRM, such as through a Request for Information, than in response to an NPRM. We thus decline to provide feedback on these issues in Section IX but have provided our explanations, justifications and evidence supporting our comments in the sections above.

²⁵⁸ 84 Fed. Reg. 27883.



Conclusion

We appreciate the opportunity to provide comments on the NPRM. We oppose all the proposed changes and instead urge HHS not to finalize its proposals but instead to leave the current regulations, as well as subregulatory guidance, in place. If you have any questions, please contact us at (202) 289-7661 or via email -- Mara Youdelman (youdelman@healthlaw.org), Wayne Turner (turner@healthlaw.org) or Jennifer Lav (lav@healthlaw.org).

Sincerely,

Elizabeth G. Taylor

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Executive Director

